MaineHealth Institute for Research
Research Compliance Office
Standard Operating Procedures (SOPs)
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HRP-001 SOP: Definitions

1 PURPOSE

1.1 This policy establishes the definitions followed by the human research protection program. This is a non-exhaustive list and regulatory agencies should be referenced for complete definitions where applicable.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Adverse Event (DHHS): Any untoward or unfavorable occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research.

3.2 Adverse Event (FDA): means any untoward medical occurrence associated with the use of a drug product in humans, whether or not it is considered related to the drug product. An adverse event can occur in the course of the use of a drug product; from overdose of a drug product, whether accidental or intentional; from abuse of a drug product; from discontinuation of the drug product (e.g., physiological withdrawal); and it includes any failure of expected pharmacological action

3.3 Agent: See "Employee."

3.4 Allegation of Non-Compliance: An unproved assertion of Non-Compliance.

3.5 Amendment: See "Modification."

3.6 Approved: The determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements. [i]

3.7 Artificial Intelligence: A machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments.[ii]

3.8 Assent: A child's affirmative agreement to participate in research.

3.9 Assurance of Compliance (Human Subjects) or Federalwide Assurance: An assurance is a written commitment to protect human research subjects and comply with the requirements of the Common Rule.

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3.10 Authorization Agreement: Also called a Reliance Agreement, is the agreement that documents respective authorities, roles, responsibilities, and communication between an institution/organization providing the ethical review and a participating institution relying on the ethical review.

3.11 Biologic: Products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources — human, animal, or microorganism — and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available.

3.12 Certificate of Confidentiality: A Certificate of Confidentiality is a document issued by a component of HHS pursuant to The Public Health Service Act Section 301(d), 42 U.S.C. 241(d) amended by Section 2012 of the 21st Century Cures Act, Public Law 114-255, to protect the privacy of individuals who are subjects of certain specified research activities by authorizing investigators to withhold from all persons not connected with the conduct of such research the names or other identifying characteristics of such subjects. Persons so authorized to protect the privacy of such individuals may not disclose information in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

3.13 Certification: The official notification by the institution to the supporting Federal department or agency component that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

3.14 Children: persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

3.14.1 See HRP-013 - SOP - LARs, Children, and Guardians for applicable law at this institution.

3.15 Clinical Investigation: As defined by FDA regulations, means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), or need not meet the requirements for prior submission to the FDA under these sections of the

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FD&C Act, but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations.[iii]

3.16 Clinical Trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

3.17 Coded: Regarding data, that which: 1) contains identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain that has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and 2) has an existing key to decipher the code, enabling linkage of the identifying information to the private information or specimens.[iv]

3.18 Collaborating Individual Investigator: The Office for Human Research Protections notes that some human subjects research conducted by an assured institution may involve the following two types of collaborating individual investigators:

- 3.18.1 Collaborating independent investigator: not otherwise an employee or agent of the assured institution; conducting collaborative research activities outside the facilities of the assured institution; and not acting as an employee of any institution with respect to his or her involvement in the research being conducted by the assured institution.
- 3.18.2 Collaborating institutional investigator: not otherwise an employee or agent of the assured institution; conducting collaborative research activities outside the facilities of the assured institution; acting as an employee or agent of a non-assured institution with respect to his or her involvement in the research being conducted by the assured institution; and employed by, or acting as an agent of, a non-assured institution that does not routinely conduct human subjects research.

3.19 Collaborative Study: A study in which two or more institutions coordinate, with each institution completing a portion of the research activities outlined in a specific protocol.

3.20 Common Rule: A shorthand name for the "Federal Policy for the Protection of Human Subjects" adopted by a number of federal agencies. Although the Common Rule is codified by each agency separately, the text is identical to

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Department of Health and Human Services (DHHS) regulations in 45 CFR 46 Subpart A. [v]

3.21 Compassionate Use: See "Expanded Access."[vi]

3.22 Conflicting Interest: An individual involved in research review is automatically considered to have a conflicting interest when the individual or the individual's spouse, domestic partner, children, and/or dependents have any of the following interests in the sponsor, product or service being tested, or competitor of the sponsor held by the individual or the individual's immediate family:

3.22.1 Involvement in the design, conduct, or reporting of the research.

3.22.2 Ownership interest, stock options, or other ownership interest of any value exclusive of interests in publicly-traded, diversified mutual funds.

3.22.3 Compensation of any amount in the past year or of any amount expected in the next year, excluding compensation for costs directly related to conducting research.

3.22.4 Proprietary interest including, but not limited to, a patent, trademark, copyright or licensing agreement.

3.22.5 Board or executive relationship, regardless of compensation.

3.22.6 Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center.

3.22.7 Any other reason for which the individual believes that he or she cannot be independent.

3.23 Continuing Non-Compliance: A pattern of Non-Compliance that suggests the likelihood that, without intervention, instances of Non-Compliance will recur, a repeated unwillingness to comply, or a persistent lack of knowledge of how to comply.

3.24 Cooperative Research: Cooperative research projects are non-exempt/clinical investigations that involve more than one institution. See Collaborative Study and Multi-Site Study.

3.25 Data and Safety Monitoring (DSM): Includes but is not limited to provisions for checking data to ensure the safety of subjects and address problems that may arise over the course of a study, reporting of unanticipated problems involving risks to subjects or others, descriptions of interim safety reviews and the procedures planned for providing DSM findings to the IRB. May be performed by a researcher, medical monitor, safety monitoring committee, or other means.

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3.26 Data Repository: A data repository is a tool used to compile a set of individual subject/patient data that will be used for analysis purposes. A data repository generally has data added to it in an on-going manner that is stored long-term. Data in the repository are intended to be distributed to multiple users and subsequently used for ongoing analysis purposes. The IRBs prefer use of the term 'data repository' over terms such as 'databases' and 'registries.' If the primary intent of the repository is for use in future research projects, IRB review and approval is required, and may be required for the subsequent use of the data from the repository.

3.27 Data Safety Monitoring Board/Plan (DSMB/DSMP): See "Data and Safety Monitoring."

3.28 Data Use Agreement: An agreement into which the covered entity enters with the intended recipient of a limited data set that establishes the ways in which the information in the limited data set may be used and disclosed and how it will be protected.

3.29 Deferred: An IRB action taken when the convened IRB cannot fully evaluate the research under review and make the determinations required for approval (45 CFR 46.111) without modifications to the protocol and/or informed consent document, or submission of clarifications or additional materials prior to reconsideration of the research.

3.30 De-identified: Under HIPAA, data which do not identify an individual, and there is no reasonable basis to believe that the data can be used to identify an individual. The MaineHealth IRB only permits the Safe Harbor method of de-identification defined by the Privacy Rule, in which PHI is stripped of all 18 HIPAA-defined identifying elements and the covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

3.31 Designated Reviewer: The IRB chair or an Experienced IRB Member designated by the IRB chair to conduct Non-Committee Reviews.

3.32 Disapproved: An IRB action taken when the determinations required for approval of research cannot be made, even with substantive clarifications or modifications to the protocol and/or informed consent process/document.

3.33 Emergency Use: FDA defines emergency use as the use of a test article in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval. If all conditions described in 21 CFR 56.102(d) exist, then the emergency exemption from prospective IRB approval found at 21 CFR 56.104(c) may be used.[vii]

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3.34 Employee: Individuals who: (1) act on behalf of the organization; (2) exercise organizational authority or responsibility; or (3) perform organizationally designated activities. “Employees and agents” can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

3.35 Enrollment: The process of including an individual in a study after their identification and verification that all study-specific eligibility criteria are met. For studies requiring informed consent, a subject is generally considered enrolled upon completion of the informed consent process.

3.36 Exempt Research: Notwithstanding any other limitations or restrictions due to applicable law, regulation, or agency policy, research activities not regulated by the FDA in which the only involvement of human subjects is determined to be in one or more of the categories listed in 45 CFR 46.104(d) and is thereby exempt from review by a convened IRB.[viii]

3.37 Expanded Access (EA): Use of an investigational medical product (drug, biologic, or medical device) to treat a patient with a serious disease or condition who does not have comparable or satisfactory alternative therapies to treat the disease or condition. Note that the intent is clearly treatment, as opposed to an investigational drug in a clinical trial where the primary intent is research (e.g. involves systematic data collection and analysis for purposes of learning about the drug).

3.38 Expedited Research: Notwithstanding any other limitations or restrictions due to applicable law, regulation, or agency policy, research activities not regulated by the FDA in which the only involvement of human subjects is determined to be no more than minimal risk, and for minor changes in approved research, which falls into one or more of the categories listed in 45 CFR 46.110.

3.39 Experienced IRB Member: An IRB member is considered experienced if the IRB chair considers the IRB member to have sufficient experience in and knowledge of conducting IRB reviews.

3.40 Experimental Subject: For Department of Defense (DOD) research, research involving an “experimental subject” is an activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving “experimental subjects” is a subset of research involving human participants.

3.41 Expiration Date: The first date that the protocol is no longer approved. The date after the end date of the approval period.

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3.42 Federal Department or Agency: A federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (e.g., the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency).[ix]

3.43 Financial Conflict of Interest (FCOI): See "Conflicting Interest."

3.44 Finding of Non-Compliance: Non-Compliance in fact.

3.45 Generalizable Knowledge: Knowledge that may be applied to *populations outside of the specific study population* (populations outside of MaineHealth).

3.46 Genomic Data: Information derived from study of an organism's genome, i.e., the set of DNA (including all the genes within) in every cell that provides all of the information needed to build and maintain that organism.

3.47 Genomic Data Sharing (GDS): The practice of broad and responsible sharing of genomic research data.

3.48 Greater than Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research *are* greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

3.49 Guardian: an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

3.49.1 See HRP-013 - SOP - LARs, Children, and Guardians for applicable law at this institution.

3.50 Health Information: Under HIPAA, health Information means any information, including genetic information, whether oral or recorded in any form or medium, that (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

3.51 Health Insurance Portability and Accountability Act of 1996 (HIPAA): U.S. law requiring the creation of a Privacy Rule for identifiable health information. While the primary impact of the Privacy Rule is on the routine provision of and billing for health care, the Rule also affects the conduct and oversight of research. The Privacy Rule defines individually identifiable health information transmitted or maintained by a covered entity in any form (electronic, written or oral) as "protected health information" (PHI) and establishes the conditions under which investigators may access and use this information in the conduct of research.

3.52 HIPAA Authorization: An individual's written permission to allow a covered entity to use or disclose specified PHI for a particular purpose. Except as otherwise

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permitted by the Privacy Rule, a covered entity may not use or disclose PHI for research purposes without a valid Authorization that includes all of the required elements under the Privacy Rule.

3.53 HIPAA Waiver or Alteration of Authorization: The documentation that the covered entity obtains from a researcher or an IRB or a Privacy Board that states that the IRB or Privacy Board has waived or altered the Privacy Rule's requirement that an individual must authorize a covered entity to use or disclose the individual's PHI for research purposes.

3.54 Honest Broker: An individual or system who collects and provides de-identified information/samples to a recipient secondary researcher. The honest broker should not be involved with the recipient's study. For Protected Health Information, the honest broker should de-identify data or samples according to HIPAA Safe Harbor standards before sending it to the researcher.

3.55 Human Research: Any activity that either:[x]

3.55.1 Is Research as Defined by DHHS and involves Human Subjects as Defined by DHHS;

3.55.2 or

3.55.3 Is Research as Defined by FDA and involves Human Subjects as Defined by FDA.

3.56 Human Subject as Defined by DHHS: A living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through Intervention or Interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. For the purpose of this definition:

3.56.1 Intervention: Physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

3.56.2 Interaction: Communication or interpersonal contact between investigator and subject.

3.56.3 Private Information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).

3.56.4 Identifiable Private Information[xi]: Private Information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

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3.56.5 Identifiable Biospecimen[xi]: A biospecimen for which the identity or the subject is or may be readily ascertained by the investigator or associated with the biospecimen.

3.57 Human Subject as Defined by FDA: An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen a medical device is used.

3.58 Humanitarian Use Device (HUD): A Humanitarian Use Device is a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year.

3.59 ICH-GCP E6 (R3): A document constructed by a multi-national board (International Conference on Harmonization-Good Clinical Practice [ICH-GCP]) for purposes of establishing an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects.

3.60 Immediate Family: Spouse, domestic partner; and dependent children.

3.61 Individual Investigator Agreement: a permissible mechanism under which an institution holding an DHHS-approved Federalwide Assurance (FWA) may extend – for one or more research protocols – the applicability of its FWA to cover two types of collaborating individual investigators: collaborating independent investigators and collaborating institutional investigators employed by a non-assured institution.

3.62 Individually Identifiable Health Information: Under HIPAA, information that is a subset of health information, including demographic information collected from an individual, and (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (a) that identifies the individual; or (b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

3.63 Individuals with Impaired Decision-Making Capacity: Individuals having a condition, situation, or circumstance that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. These may include individuals having severe psychiatric disorders, organic impairments (e.g., dementia) or developmental disorders. Others, including persons under the influence of or dependent on mind-altering substances or alcohol, those suffering from degenerative diseases affecting the

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brain, and terminally ill patients may also be compromised in the ability to make decisions in their best interest.

3.64 Informed Consent: Permission granted in the knowledge of the possible consequences, typically that which is given as written certification of the following three elements: 1) disclosure to the prospective human participant information needed to make an informed decision; 2) facilitating the understanding of what has been disclosed; and 3) promoting the voluntariness of the decision about whether or not to participate in the research.

3.65 Institutional Official/ Organizational Official (IO/OO):

3.65.1 Institutional Official (IO): Term utilized by DHHS. The Institutional Official (IO) is the individual who is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Assurance. The IO is responsible for ensuring that the Human Research Protection Program (HRPP) functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. The IO represents the institution named in the Federalwide Assurance (FWA)[xii]. The IO is the Chief Academic Officer .

3.65.2 Organizational Official (OO): Term utilized by AAHRPP.

3.65.2.1 An identified, knowledgeable leader of the HRPP who is responsible for the program and has the authority to implement the program. This individual may rely on others for the interpretation of laws, regulations, codes, and guidance and the day-to-day operations of the HRPP, and should have a basic understanding of the relevant laws, codes, regulations and guidance that govern research involving human participants, the responsibilities of an organizational official, and the responsibilities of the IRB or EC and researchers and research staff in protecting research participants. This individual should be directly involved in the allocation of resources to the HRPP. In some circumstances, more than one individual serves in this capacity[xiii].

3.66 Institutional Profile: A record of information an institution keeps about another collaborating institution/organization for one or more Collaborative Studies or Multi-Site Studies.

3.67 Institutional Review Board (IRB): An institutional review board established in accord with and for the purposes expressed in policies surrounding the protection of human subjects in research. OBJ

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3.68 Investigational Device: A device (including a transitional device) that is the object of an investigation. Investigation, as it pertains to devices, means a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device.

3.69 Investigational Drug: New drugs that have not yet been approved by the FDA or approved drugs that are being studied in a clinical investigation.

3.70 Legally Authorized Representative (LAR): An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedures(s) involved in the research.

3.70.1 If there is no applicable law addressing this issue, then this individual is recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

3.70.2 See HRP-013 - SOP - LARs, Children, and Guardians for who may serve as a Legally Authorized Representative at this institution.

3.71 Life-Threatening: In reference to a disease or condition, means diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. The criteria for life-threatening do not require the condition to be immediately life-threatening or to immediately result in death. Rather, the subjects must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible. Life-threatening, for the purposes of 21 CFR 56.102(d), includes both life-threatening and severely debilitating.

3.72 Limited Data Set: Data sets that exclude the 16 categories of direct identifiers specified in the Privacy Rule. Limited Data Sets may be used or disclosed, for purposes of research, public health, or health care operations, without obtaining either an individual's Authorization or a waiver or an alteration of Authorization for its use and disclosure, only if the covered entity obtains satisfactory assurances in the form of a Data Use Agreement. Limited Data Sets are not de-identified information under the Privacy Rule.

3.73 Local Context: Generally referring to local circumstances, preferences, and variability, and could include such factors as culture and language, geography, socioeconomic factors, the professionals conducting the research, the institutions where the research will be conducted, or local standards of care.

3.74 MaineHealth Policy: Policies included in the SharePoint policy manager.

3.75 Medical Device: An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; intended for use in the diagnosis of disease or other conditions, or in the cure,

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mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

3.76 Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.[xiv]

3.76.1 When following Department of Defense regulations, the definition of minimal risk in 32 CFR 219 does not include the inherent occupational risks that certain participants face in their everyday life, such as those:

3.76.1.1 Encountered by Service members, law enforcement, or first responders while on duty.

3.76.1.2 Resulting from or associated with high-risk behaviors or pursuits.

3.76.1.3 Experienced by individuals whose medical conditions involve frequent tests or constant pain.

3.77 Modification: Any change to any aspect of approved research. Requires IRB approval except in cases where the change is being made to eliminate an apparent immediate hazard to the subject (in which case the IRB must then be notified at once). When research is fundamentally changed (e.g. changes which alter the original scope, purpose, or intent of the research), the IRB may require a new study application rather than allow such changes to be made through a modification to the existing research plan.

3.78 Multi-Site Study: A study in which two or more institutions coordinate, with each institution completing all research activities outlined in a specific protocol.

3.79 Non-Committee Review: Any of the following:

3.79.1 Determination of whether an activity is Human Research.

3.79.2 Determination of whether Human Research is exempt from regulation.

3.79.3 Reviews of non-exempt research using the expedited procedure.

3.79.4 Determinations of which subjects can continue in expired research.

3.79.5 Concurrence of IRB Chair or designee for non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use) or non-emergency individual patient expanded access IND with request for authorization to use alternative IRB review procedures.

3.80 Non-Compliance: Failure to follow the regulations, or the requirements or determinations of the IRB.

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3.81 Non-Significant Risk (NSR) Device: A non-significant risk device is an investigational device that does not meet the definition of a significant risk device.

3.82 Parental Permission: Consent given by a parent or legal guardian for their child to participate in research.

3.83 Participant: See "Human Subject."

3.84 Participating Site (pSite): An institution that participates in a Single IRB (sIRB) Study.

3.84.1 For Department of Defense (DOD) research the term includes military personnel in either civilian or military custody.

3.85 Patient: See "Human Subject."

3.86 Planned Emergency Research: Research that involves participants who are in a life-threatening situation for which available therapies or diagnostics are unproven or unsatisfactory, and because of the participants' medical condition and the unavailability of legally authorized representatives of the participants, it is generally not possible to obtain legally effective informed consent.

3.87 Preparatory to Research: As mentioned in Privacy Rule, any activity which may access, obtain, or use Protected Health Information in order to identify potential study participants, assess the feasibility of conducting a research project, or developing a grant application or protocol.

3.88 Principal Investigator: The lead researcher on a project, with ultimate responsibility for the preparation, conduct, and administration of study activities and for management and oversight of all research study staff in compliance with applicable laws, regulations, and institutional policy governing the conduct of research.

3.89 Prisoner: Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.[xv]

3.90 Privacy Board: A board that is established to review and approve requests for waivers or alterations of Authorization in connection with a use or disclosure of PHI as an alternative to obtaining such waivers or alterations from an IRB. A Privacy Board consists of members with varying backgrounds and appropriate professional competencies as necessary to review the effect of the research protocol on an individual's privacy rights and related interests. The board must include at least one member who is not affiliated with the covered entity, is not affiliated with any entity conducting or sponsoring the research, and is not related to any person who is affiliated with any such entities. A Privacy Board

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cannot have any member participating in a review of any project in which the member has a conflict of interest.

3.91 Privacy: Having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. It is the state or condition of being free from unauthorized intrusion, being observed or disturbed by other people.

3.92 Protected Health Information (PHI): Under the Privacy Rule, individually identifiable health information, held or maintained by a covered entity or its business associates acting for the covered entity, that is transmitted or maintained in any form or medium (including the individually identifiable health information of non-U.S. citizens). This includes identifiable demographic and other information relating to the past, present, or future physical or mental health or condition of an individual, or the provision or payment of health care to an individual that is created or received by a health care provider, health plan, employer, or health care clearinghouse. For purposes of the Privacy Rule, genetic information is considered to be health information.[xvi]

3.93 Protocol Exception: a one-time, intentional action or process that departs from the approved protocol. Protocol Exceptions are generally for a single subject (e.g., the subject does not meet eligibility criteria or is allergic to one of the medications provided as supportive care). IRB approval of the Protocol Exception is required prior to implementation by the study team.

3.94 Public Health Authority: An agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an indigenous tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate. OBJ

3.95 Related to the Research: A financial interest is Related to the Research when the interest is in:

- 3.95.1 A sponsor of the research;
- 3.95.2 A competitor of the sponsor of the research;
- 3.95.3 A product or service being tested; or
- 3.95.4 A competitor of the product or service being tested.

3.96 Reportable New Information (RNI): Any information, including unanticipated problems, noncompliance, complaints, and any change to the research implemented without IRB approval which may impact or may have impacted the rights, safety, or welfare of subjects or inform the IRB's oversight of the research.

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3.97 Research as Defined by DHHS: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

3.97.1 The following activities are not considered Research as Defined by DHHS:

3.97.1.1 Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

3.97.1.2 Public health surveillance activities conducted by a public health authority, limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance.

3.97.1.2.1 Including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.

3.97.1.2.2 Including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products.

3.97.1.2.3 Including those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

3.97.1.3 Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

3.97.1.4 Authorized operational activities (as determined by the relevant federal agency) in support of intelligence, homeland security, defense, or other national security missions.

3.97.1.5 Secondary research involving non-identifiable newborn screening blood spots.

3.98 Research as Defined by FDA: Any experiment that involves a test article and one or more Human Subjects, and that meets any one of the following:

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3.98.1 Must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;

3.98.2 Must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR

3.98.3 Any activity the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

3.99 Restricted: Applies to investigators who are delinquent in meeting IRB requirements.

3.100 Scientific Review: Examination of a study for scientific merit, feasibility, integrity, and utilization of resources.

3.101 Screening: Accessing, examining, reviewing, using, or collecting information about potential human subjects in order to determine whether an individual is eligible for participation based on established inclusion and exclusion criteria.

3.102 Serious Adverse Event: An adverse event is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: Death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

3.103 Serious Non-Compliance: Non-Compliance such that the failure to comply could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data.

3.104 Significant New Findings: Information or discoveries about the research, test article, and/or the condition under study which are identified during the course of research and may impact or may have impacted subjects' rights and welfare.

3.105 Significant Risk (SR) Device: An investigational device that: (1) Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare

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of a subject; or (2) Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject; or (3) Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or (4) Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject. OBJ

3.106 Single IRB (sIRB) Study: A study in which two or more institutions (participating sites, or pSites) coordinate to complete the research activities, but all institutions rely on a single institution's/organization's IRB for ethical review. The reviewing IRB may or may not be affiliated with any of the pSites.

3.107 Smart Form: The structured, online application within the hIRB system that guides study teams through the submission, modification, and review processes. It uses conditional logic to present only the questions and sections relevant to a given study based on the information entered.

3.108 Sponsor: The company, institution, individual donor, or organization responsible for the initiation, management or financing of a research study.

3.109 Sponsored Research: Research funded by external entities (public, industry, or private) through a grant or contract that involves a specified statement of work (e.g., the research proposal), including clinical trials involving investigational drugs, devices or biologics.

3.110 Staff Reviewer: IRB staff that are not identified as a Designated Reviewer on the IRB Roster but, in the opinion of the IRB manager, can conduct Non-Committee Reviews limited only to the following:

3.110.1 Determination of whether an activity is Human Research.

3.110.2 Determination of whether the organization is engaged in Human Research.

3.110.3 Determination of whether Human Research is exempt from regulation, when limited IRB review is not required.

3.111 Study Team: Individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they are affiliated with MaineHealth or its affiliates. MaineHealth also considers the following individuals to be study team: research personnel who directly interact with study participants or have access to participants' Personally Identifiable Information (PII) and faculty mentors/advisors.

3.112 Suspension of IRB Approval: An action of the IRB, IRB designee, Institutional Official/Organizational Official, or designee of the Institutional Official/Organizational Official to temporarily or permanently withdraw IRB approval of some or all research procedures short of a Termination of IRB Approval. Suspended studies remain open and are subject to continuing review.

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3.113 Systematic: Having or involving a system, method, or plan.

3.114 Termination of IRB Approval: An action of the IRB, IRB designee, Institutional Official/Organizational Official, or designee of the Institutional Official/Organizational Official to permanently withdraw IRB approval of all research procedures. Terminated studies are permanently closed and no longer require continuing review.

3.115 Test Article: The FDA defines "Test article" as meaning any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act [42 U.S.C. 262 and 263b-263n]. [21 CFR 50.3(j)] These include, but are not limited to: human drugs, medical devices, biological products, dietary supplements, medical foods, mobile medical apps, radioactive drugs, and radiation-emitting electronic products.

3.116 Unanticipated Problem Involving Risks to Subjects or Others: Any information that is (1) unanticipated, (2) related to the research, and (3) indicates that subjects or others are at increased risk of harm.[xvii]

3.116.1 For Department of Defense (DOD) research the term Unanticipated Problem Involving Risks to Subjects or Others includes any incident, experience, or outcome that meets ALL three of the following conditions:

3.116.1.1 Is unexpected (in terms of nature, severity, or frequency) given the procedures described in the research protocol documents (e.g., the IRB-approved research protocol and informed consent document) and the characteristics of the human subject population being studied.

3.116.1.2 Is related or possibly related to participation in the research (in this Instruction, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).

3.116.1.3 Suggests that the research places human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred.

3.117 Unapproved/Uncleared Medical Device: In expanded access, a medical device which has not received FDA approval or clearance.

3.118 Undue Influence: Attempting to interfere with the normal functioning and decision-making of the IRB, or to attempt to influence an IRB member or staff member or any other member of the research team, outside of the established

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processes or normal and accepted methods in order to obtain a particular result, decision, or action by the IRB or one of its members or staff.

3.119 Unexpected: The incident, experience or outcome is not expected (in terms of nature, severity, or frequency) given the research procedures that are described in the study-related documents, such as the IRB-approved research protocol/research plan and informed consent documents; and the characteristics of the subject population being studied.

3.120 Vulnerable Populations: Under the Common Rule, categories of subjects who may be more likely to experience coercion and undue influence, or who have otherwise been determined to require additional protections. Examples include (but are not limited to) children, prisoners, individuals with impaired decision-making capacity, and economically or educationally disadvantaged persons.

3.121 Waiver of Written Documentation of Consent: As permitted by applicable regulations, IRB forbearance of the Common Rule requirement for the investigator to obtain a signed consent form for some or all participants. *Please note: An appropriate consent process is still required.

3.122 Waiver or Alteration of Consent Process: As permitted by applicable regulations, IRB forbearance of the Common Rule requirement for the investigator to complete the informed consent process with some or all participants. Generally restricted to Planned Emergency Research.

3.123 Ward: In Maine, an individual for whom a guardian has been appointed. OBJ

4 RESPONSIBILITIES

4.1 Individuals writing policies and procedures are to indicate terms defined in this policy with a double underline.

4.2 Individuals using policies and procedures are to consult this policy for the definitions of double underlined terms.

5 PROCEDURE

5.1 None

6 MATERIALS

6.1 HRP-013 - SOP - LARs, Children, and Guardians

7 REFERENCES

7.1 45 CFR §46.102

7.2 21 CFR §50.3, 21 CFR §56.102, 21 CFR §312.3, 21 CFR §812.2(a), 21 CFR §812.3(p)

7.3 AAHRPP elements I.1.A, I.1.E, I.5.D, I.6.B, I.7.C, I-9, II.1.D, II.2.A, II.2.B, II.2.G, II.2.H, II.2.E-II.2.E.2, II.2.F-II.2.F.3, II.2.I, II.3.A, II.4.A, III.1.B, III.2.D

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HRP-012 SOP: Observation of Consent Process

1 PURPOSE

1.1 This procedure establishes the process to observe the consent process.

1.2 The process begins when the IRB determines that the consent process should be observed.

1.3 The process ends when the consent observation is complete.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The IRB may consider requiring observation of the consent process when:

3.1.1 The IRB wants verification from sources other than the investigator that consent processes adhere to the current version of the IRB-approved study protocol and applicable regulatory requirements.

3.1.2 There are Allegations or Findings of Non-Compliance.

3.1.3 The nature of the research or reportable new information indicates that the consent process can be improved through observation.

3.2 The IRB, Institutional Official/ Organizational Official (IO/OO), or designee determines who conducts the observation. The individual conducting the observation should have sufficient experience to appropriately evaluate the consent process. This may include, but is not limited to:

3.2.1 IRB staff.

3.2.2 IRB members.

3.2.3 A person recommended by the investigator.

3.2.4 An independent person hired by the IRB, but paid for by the investigator's funds.

4 RESPONSIBILITIES

4.1 The person designated to conduct the observation of the consent process carries out these procedures.

5 PROCEDURE

5.1 Notify the subject or the subject's Legally Authorized Representative (LAR) of the intent to observe the consent process, including the purpose of the observation, and obtain their agreement to observe the process.

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5.1.1 If the subject objects to the observation, document that the observation could not take place and work with the study team to re-schedule the observation.

5.2 Observe the consent process and determine whether consent was obtained in a manner consistent with:

5.2.1 Section 1 (“Consent Process”) of HRP-314a - WORKSHEET - Criteria for Consent; and

5.2.2 The current version of the IRB-approved study protocol.

5.3 If these requirements are not met, indicate that consent is not legally effective and the prospective subject may not be entered into the research.

5.4 If these requirements are met, when applicable, verify consent was documented in a manner consistent with Section 2 (“Long Form of Consent Documentation”), of HRP-314a - WORKSHEET - Criteria for Consent and the current version of the IRB-approved study protocol.

5.5 Document in writing that the consent process was observed, including whether informed consent was freely given by the subject or LAR and the requirements identified above were met. Report this information back to the IRB, submitting the information as Reportable New Information (RNI), when necessary.

6 MATERIALS

6.1 HRP-314a - WORKSHEET - Criteria for Consent

7 REFERENCES

7.1 45 CFR §46.109

7.2 21 CFR §56.109

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HRP-013 SOP: LARs, Children, and Guardians

1 PURPOSE

1.1 This policy establishes how to determine which individuals meet the following DHHS and FDA definitions:

1.1.1 Legally Authorized Representative (LAR)

1.1.2 Children

1.1.3 Guardian

2 REVISIONS FROM PREVIOUS VERSION

2.1 Policy harmonized with the MaineHealth Consent to Treat for Procedures, Interventions, and Treatments Policy ("MH Consent to Treat") to ensure consistent identification and documentation of individuals legally permitted to provide consent or permission for research participation.

3 POLICY

3.1 Unless the IRB has waived the requirement to obtain consent, when research involves adults unable to consent, permission must be obtained from a LAR.

3.1.1 When research is conducted in MAINE the following individuals meet this definition:

3.1.1.1 Maine law does not specifically address informed consent by LARs of incapacitated persons or minors for participation in clinical research. Thus, the applicable guidelines for determining the most appropriate LAR for research are based upon the guidelines that apply in the clinical setting. Reference MH Consent to Treat.

3.1.2 For research outside MAINE, a determination of who is a LAR is to be made with consultation from legal counsel.

3.2 DHHS and FDA's Subpart D applies to all research involving children.

3.2.1 Since Maine laws do not specifically address consent for research, the MaineHealth IRB will consider the regulatory definition of "minor" when determining the applicable legal age of consent to research. Pursuant to Title 22 MRSA §1501(3), minors are defined as persons under the age of eighteen. Under Maine law, the general rule is that those who have attained the age of eighteen may sign legally binding agreements and consent for medical care. Therefore, the MaineHealth IRB defines children as persons who are under eighteen years of age.

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3.2.2 When research is conducted in MAINE all individuals under the age of 18 years are children. Exceptions exist for obtaining parental consent for treatment found under Title 22 M.R.S.A. §1503, which provides that a minor may give consent to all medical, mental, dental and other health counseling and services if the minor is:

1. Living separately; independent of parental support. Is living separately from parents or a legal guardian and is independent of parental support. A minor may prove that the minor meets the requirements of this subsection with documentation including, but not limited to:

A. A written statement affirming that the minor is living separately from parents or a legal guardian and is independent of parental support signed by:

(1) A director or designee of a governmental or nonprofit agency that receives public or private funding to provide services to homeless persons;

(2) A local education agency liaison for homeless children and youth designated pursuant to 42 United States Code, Section 11432(g)(1)(J)(ii) or a school social worker or counselor; or

(3) An attorney representing the minor in any legal matter;

B. A copy of a protection from abuse complaint or a temporary order or final order of protection against the minor's parent or legal guardian; or

C. Proof of filing a petition for emancipation pursuant to Title 15, section 3506 A;

2. Married. Is or was legally married;

3. Armed Forces. Is or was a member of the Armed Forces of the United States; or

4. Emancipated. Has been emancipated by the court pursuant to Title 15, section 3506 A.

In addition, Maine law permits minors not meeting the criteria under Title 22 M.R.S.A. §1503 to seek care for drug addiction, sexually transmitted diseases, emotional disorders, abortion or mental health treatment without parental or guardian permission as noted in Title 22 M.R.S.A. §§1502, 1802 and 1908 and Title 32, §§2595,3292,3817, 6221 and 7004 and gender affirming care if certain criteria are met as noted in Title 22

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M.R.S.A §1508. However, if hospitalization of greater than 16 hours is required for treatment, consent is required (Title 22 M.R.S.A §1823). If research involves treatments or procedures for which minors can give consent outside the research context, such individuals may not meet the definition of children as defined at 45 CFR 46.402(a). However, because Maine statutes do not specifically address consent for research, the MaineHealth IRB will review issues of actual consent (as opposed to assent) related to the enrollment of minors (as defined under 22 M.R.S.A §1501(3)) in research on a case-by-case basis.

Reference MH Consent to Treat and contact legal counsel for more information.

3.2.3 For research outside MAINE, a determination of who is a child is to be made with consultation from legal counsel.

3.3 Unless the IRB has waived the requirement to obtain consent, when research involves children consent may only be obtained from biologic or adoptive parents or guardian.

3.3.1 Before obtaining permission from an individual who is not a parent, reference MH Consent to Treat and contact legal counsel.

4 RESPONSIBILITIES

4.1 Investigators are to follow this policy when obtaining permission for adults unable to consent or children to take part in research.

5 PROCEDURE

5.1 None

6 MATERIALS

6.1 None

7 REFERENCES

7.1 45 CFR §46.102, 45 CFR §46.402

7.2 21 CFR §50.3

7.3 AAHRPP elements I.1.G, I-9, II.4.B

7.4 MaineHealth Consent to Treat for Procedures, Interventions, and Treatments Policy original adoption date 02/06/23, last revision date 11/6/25

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HRP-020 SOP: Incoming Items

1 PURPOSE

1.1 This procedure establishes the process to triage information submitted to the IRB.

1.2 The process begins when any communication is received by the IRB.

1.3 The process ends when an IRB staff member determines the appropriate action for the received information.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Assign items to IRB staff for pre-review within 5 business day.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 If the item is a request either for this IRB to review for another Participating Site (pSite) or for this institution to rely on an external IRB, follow HRP-021 - SOP - Pre-Review.

5.2 If the item is a request for an approval or determination[xviii] by this institution's IRB that does not include other pSites, follow HRP-021 - SOP - Pre-Review.

5.3 If the item is an update to a study for which an external IRB is the IRB of record, follow HRP-805 - SOP - External IRB Updates.

5.3.1 If there are financial disclosures, follow HRP-055 - SOP - Financial Conflicts of Interests.

5.4 If the item is a notification of an emergency use of a test article in a life-threatening situation assign to IRB staff and then have a Designated Reviewer follow HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access.

5.5 If the item is an investigator's request to continue subjects in expired research assign to IRB staff and then have a Designated Reviewer follow HRP-063 - SOP - Expiration of IRB Approval.

5.6 If the item does not fit into the above categories:

5.6.1 If the item is a question, concern, or complaint involving research or human subjects:

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5.6.1.1 Document the nature of the question, concern, or complaint and the contact information of the person contacting the IRB.

5.6.1.2 Respond to any questions or concerns. When appropriate, tell the person that you will call/email him/her once you have been able to find additional information. If necessary, consult with your supervisor.

5.6.2 Follow HRP-024 - SOP - New Information.

6 MATERIALS

6.1 HRP-021 - SOP - Pre-Review

6.2 HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access

6.3 HRP-024 - SOP - New Information

6.4 HRP-055 - SOP - Financial Conflicts of Interests

6.5 HRP-063 - SOP - Expiration of IRB Approval

6.6 HRP-805 - SOP - External IRB Updates

7 REFERENCES

7.1 AAHRPP elements I.1.A, I.4.A, I.5.D, I.7.C, I-9, II.2.A, II.2.B, II.2.E-II.2.E.2, II.2.F-II.2.F.3

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HRP-021 SOP: Pre-Review

1 PURPOSE

1.1 This procedure establishes the process to pre-review a request for approval (approval of new research, approval to rely on an external IRB, humanitarian use device (HUD), continuing review of research, or modification to previously approved research) or a determination whether an activity is exempt Human Research or is not Human Research.

1.2 The process begins when the IRB receives a request for local IRB approval, including requests from other institutions when this institution is the IRB of record, e.g., for a Collaborative Study or Multi-Site Study, or a request to rely on an external IRB.

1.3 The process ends when the information has been placed on the agenda for an IRB meeting or will be handled by Non-Committee Review, or the information is sent to the Reliance Coordinator or IRB staff to review the request to rely on an external IRB.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The addition of a participating site to a previously approved protocol for which the IRB will serve as the IRB of record for that participating site is considered a modification to previously approved research.

3.2 Single subject protocol exceptions are reviewed as modifications to previously approved research.[xix]

3.3 A new HUD protocol submission must be reviewed at a convened IRB meeting. Continuing review of a HUD can be handled by Non-Committee Review.

3.4 Pre-Review is conducted by IRB staff within 5 business days.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 If the submission is a response to modifications required to secure approval received within 30 days of the IRB review date:

5.1.1 Evaluate whether the investigator made the required modifications.

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5.1.2 Execute the "Review Required Modifications" activity and indicate whether the modifications were completed as required.

5.1.2.1 If the investigator made the required modifications, follow HRP-052 - SOP - Post-Review.

5.1.2.2 If the investigator did not make the required modifications add additional direction in "Notes", if needed, and indicate that the required modifications were not completed. The submission will be returned to the investigator.

5.1.3 If the investigator refuses to make the changes required for approval, schedule the submission for convened IRB review.

5.2 If the request is for this institution to rely on an external IRB:

5.2.1 Refer to HRP-806 - SOP - Review Request to Rely on External IRB

5.3 If the request includes review of a pSite submission:

5.3.1 Determine if the pSite is engaged in the non-exempt human subjects research using HRP-311- WORKSHEET - Engagement Determination.

5.3.1.1 If the pSite is not engaged in the non-exempt human subjects research, execute the "Submit Invitation Decision" activity to notify the lead investigator using HRP-850 - LETTER - Decline to Serve that this IRB will not serve as the IRB of Record for the pSite.

5.3.2 If the pSite is engaged, click on the Institutional Profile area in the IRB system and:

5.3.2.1 Confirm that the pSite has an active profile. If not, see 5.3.2.2.1.

5.3.2.2 Determine whether an existing Authorization Agreement covers the study activities for the pSite.

5.3.2.2.1 If not, follow HRP-801 - SOP - Establishing Reliance Agreements to collect the information needed to confirm reliance and create a new or updated Institutional Profile in the IRB system.

5.3.3 Execute the "Submit Invitation Decision" activity to notify the pSite using HRP-851 - LETTER - Invitation Decision or HRP-850 - LETTER - Decline to Serve that this IRB will or will not serve as the IRB of Record for their participation in the study.

5.3.4 If the IRB will serve as the sIRB for the pSite, after all site materials are submitted, proceed to Section 5.5.

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5.4 If the request includes review of a Collaborating Independent Investigator or Collaborating Institutional Investigator:

5.4.1 Determine if the Collaborating Independent Investigator or Collaborating Institutional Investigator is engaged in the non-exempt human subjects research using HRP-311 - WORKSHEET - Engagement Determination.

5.4.1.1 If the Collaborating Independent Investigator or Collaborating Institutional Investigator is not engaged in the non-exempt human subjects research, notify the PI that the activities of the Collaborating Independent Investigator or Collaborating Institutional Investigator do not engage them in human subjects research.

5.4.2 If the Collaborating Independent Investigator or Collaborating Institutional Investigator is engaged in the non-exempt human subjects research, follow HRP-801 - SOP - Establishing Reliance Agreements to consider whether to establish an Individual Investigator Agreement.

5.5 For all other submissions, complete Pre-Review Activity or review the previously completed Pre-Review Activity and revise as needed, considering the items on HRP-308 - WORKSHEET - Pre-Review and note all remaining contingencies in the "Notes" section.

5.6 If the information is not complete, contact the investigator by selecting the "Request Pre-Review Clarifications" Activity. Offer the investigator the opportunity to provide additional information.

5.6.1 Continue processing once the investigator responds to the request for additional information.

5.7 If the request is for an initial approval and principal investigator is Restricted, contact the investigator. Explain that the investigator is Restricted, give the reasons, and indicate that if a new protocol goes to the IRB, the IRB policy is to disapprove the research. Offer the investigator the opportunity to withdraw the submission pending removal of the Restricted status.

5.7.1 If the investigator withdraws the submission, stop processing the current submission.

5.7.2 If the investigator will not withdraw the submission, discuss whether you may continue to process the submission with the IRB Manager.

5.8 Evaluate the most likely level of review using HRP-310 - WORKSHEET - Human Research Determination, HRP-311 - WORKSHEET - Engagement Determination, HRP-312 - WORKSHEET - Exemption Determination, HRP-313 - WORKSHEET -

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Expedited Review, and/or HRP-323 - WORKSHEET - Criteria for Approval HUD as references:

5.8.1 If the request can be handled as a Non-Committee Review and the principal investigator is not Restricted, Follow HRP-031 - SOP - Non-Committee Review Preparation.

5.8.2 If the request cannot be handled as a Non-Committee Review, place the protocol on the agenda for a convened IRB meeting in an IRB with appropriate scope using the "Assign Meeting" activity. Follow HRP-040 - SOP - IRB Meeting Preparation. (Do not assign a Veterans Administration (VA) protocol to a commercial IRB unless it has been specifically designated by the VA Office of Research and Development to serve as an IRB for cooperative research.[xx])If the request is a non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested or device compassionate use, follow HRP-031 - SOP - Non-Committee Review Preparation and HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access.

6 MATERIALS

6.1 HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access

6.2 HRP-024 - SOP - New Information

6.3 HRP-031 - SOP - Non-Committee Review Preparation

6.4 HRP-040 - SOP - IRB Meeting Preparation

6.5 HRP-052 - SOP - Post-Review

6.6 HRP-308 - WORKSHEET - Pre-Review

6.7 HRP-310 - WORKSHEET - Human Research Determination

6.8 HRP-311 - WORKSHEET - Engagement Determination

6.9 HRP-312 - WORKSHEET - Exemption Determination

6.10 HRP-313 - WORKSHEET - Expedited Review

6.11 HRP-323 - WORKSHEET - Criteria for Approval HUD

6.12 HRP-801 - SOP - Establishing Reliance Agreements

6.13 HRP-806 - SOP - Review Request to Rely on External IRB

6.14 HRP-850 - LETTER - Decline to Serve

6.15 HRP-851 - LETTER - Invitation Decision

7 REFERENCES

7.1 AAHRPP elements I.1.A, I-2, I.6.B, I.7.A, I-9, II.2.A-D, II.2.E-II.2.E.2, II.2.F-II.2.F.3

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HRP-023 SOP: All Emergency Use, Compassionate Use (Device Only) and IRB Waiver for Individual Patient Expanded Access (Drug Only) Review

1 PURPOSE

1.1 This procedure establishes the process to review notifications of:

1.1.1 Emergency use of a drug, biologic, or device in a life-threatening situation.

1.1.2 Non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use).

1.1.3 Non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested.

1.2 The process begins when the Designated Reviewer receives a notification of a proposed or actual use.

1.3 The process ends when a Designated Reviewer has:

1.3.1 Determined whether the proposed or actual use will follow or has followed FDA-regulation and guidance; and

1.3.2 Notified the physician and IRB staff of the determination.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Whenever possible physicians are to notify the IRB of a proposed emergency use of a drug, biologic, or device in a life-threatening situation in advance of the use.

3.2 Physicians are to notify the IRB of a proposed compassionate use of an unapproved device, for the purpose of obtaining concurrence from an IRB Chair.

3.3 Emergency uses and device compassionate uses cannot be claimed as research.

3.4 Investigators are to notify the IRB of a non-emergency individual patient expanded access use of an investigational drug "Request for Authorization to Use Alternative IRB Review Procedures" identified on FDA Form 3926 (field 10.b.) or a separate waiver request included with FDA Form 1571 for the purpose of obtaining concurrence from an IRB Chair or designee.

4 RESPONSIBILITIES

4.1 A Designated Reviewer carries out these procedures.

5 PROCEDURE

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5.1 Determine if the notification/request is one of the following:

5.1.1 Emergency use of a drug, biologic, or device in a life-threatening situation. If so, use the HRP-322 - WORKSHEET - Emergency Use to determine whether the circumstances will meet, or if the use described in the 5-day report have met, the regulatory and guidance criteria for emergency use, and indicate the results of this determination to the IRB staff (or directly to the physician if time sensitive).

5.1.1.1 If the notice is in advance of the use, inform the IRB staff (or physician if time sensitive) that the physician can proceed with the use or work with the physician to identify what additional information/procedures the physician needs to follow. If the information provided is sufficient to confirm the circumstance meets the criteria for emergency use, no further reporting is required.[xxi] If further reporting is necessary, inform the IRB staff to request the 5-day report.

5.1.1.2 If the actual emergency use described in the 5-day report did not follow FDA requirements, manage as Non-Compliance using the Submit RNI activity.

5.1.2 Compassionate use of a device. If so, use HRP-325 - WORKSHEET - Device. Compassionate Use to determine whether the circumstances will meet the regulatory and guidance criteria and indicate the results of this determination to the physician.

5.1.2.1 Execute the "Submit Designated Review" activity. For the Review Level, choose Expedited Review and choose "IRB Chair concurrence" and "Non-emergency individual/small group compassionate use of a device" for the category. Choose that continuing review is not required.

5.1.3 Non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested. If so, use HRP-314 - WORKSHEET - Criteria for Approval to determine whether the proposed use meets the requirements under 21 CFR 50 and 56.111[xxii] and indicate the results of this determination to the IRB staff.

5.1.3.1 Execute the "Submit Designated Review" activity. For the Review Level, choose Expedited Review and choose "IRB Chair concurrence" and "Non-emergency individual patient drug expanded access" for the category. Choose that continuing review is required.

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5.1.3.2 In the "Notes" section document that the decision to concur (or not) is in lieu of review and approval at a convened IRB meeting at which a majority of the members are present per the request for a waiver under 21 CFR § 56.105 of the requirements in § 56.108(c).

5.1.4 If none of the above, stop processing the request and inform the physician or submitter.

5.2 Inform IRB staff of the results of the evaluation.

6 MATERIALS

6.1 HRP-024 - SOP - New Information

6.2 HRP-314 - WORKSHEET - Criteria for Approval

6.3 HRP-322 - WORKSHEET - Emergency Use

6.4 HRP-325 - WORKSHEET - Device Compassionate Use

7 REFERENCES

7.1 21 CFR § 50.23; 21 CFR § 50.24; 21 CFR § 56.102(d); 21 CFR § 56.104(c)

7.2 21 CFR § 312.305

7.3 21 CFR § 812.36; 21 CFR § 812.47

7.4 21 CFR § 56.105; 21 CFR § 56.108(c)

7.5 FDA Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors Frequently Asked Questions About Medical Devices: http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf.

7.6 Individual Patient Expanded Access Applications: Form FDA 3926 Guidance for Industry: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/individual-patient-expanded-access-applications-form-fda-3926

7.7 AAHRPP element 1.7.C

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HRP-024 SOP: New Information

1 PURPOSE

1.1 This procedure establishes the process to manage information reported to the IRB to ensure that information that represents Non-Compliance, Unanticipated Problems Involving Risks to Subjects or Others, Suspensions of IRB Approval, and Terminations of IRB Approval are managed to protect the rights and welfare of subjects.

1.2 The process begins when the IRB receives an information item.

1.3 The process ends when the information item is determined not to represent a problem that requires management, is managed administratively, or referred to the convened IRB for review.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Allegations of Serious or Continuing Non-Compliance on the part of IRB staff or IRB members will be referred to the Institutional Official (IO)/Organizational Official (OO) for further action.

3.2 The organization will promptly notify the federal department or agency funding the research of any for cause investigation of that research by another federal department or agency.

3.2.1 For Department of Defense (DOD) research the report is sent to the DOD human research protection officer.

3.3 The organization will promptly notify the Department of Defense (DOD) if the IRB of record changes.

3.4 Substantiated allegations related to classified Department of Defense (DOD) Human Subjects Research must be reported immediately.

3.5 For Veterans Administration (VA) research:

3.5.1 The following events involving exempt or nonexempt VA human subjects research must be reported to the local VA medical facility per the facility's required reporting timelines:

3.5.1.1 Deaths of a human subject participating in VA human subjects research that is believed to be both unexpected and related or possibly related to participation in a VA human subjects research study (applies to the death of a human subject

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enrolled in the study under the auspices of the VA medical facility).

3.5.1.1.1 The VA medical facility Director must notify ORO within 1 business day after VA medical facility personnel first become aware of the death of a human subject enrolled in a study approved by the VA medical facility.

3.5.1.2 Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO) in VA human subjects research.

3.5.1.2.1 The VA medical facility Director must notify ORO promptly, but no later than 60 calendar days after VA medical facility personnel first become aware of the occurrence of an unanticipated problem involving risks to subjects or others (UPIRTSO).

3.5.1.3 Occurrence of serious or continuing noncompliance with applicable laws, regulations, policies, and agreements pertaining to VA human subjects research.

3.5.1.3.1 The VA medical facility Director must notify ORO promptly, but no later than 60 calendar days after VA medical facility personnel first become aware of the serious or continuing noncompliance.

3.5.1.4 The suspension or early termination of a VA human research study by the IRB, R&DC, or IO due to the study not being conducted in accordance with applicable regulations, policies, agreements, or IRB requirements or due to concerns about the safety, rights, or welfare of human subjects or others.

3.5.1.5 A change in the status (e.g., expiration, restriction, suspension, or termination) of the VA medical facility's human subjects research FWA.

3.5.1.6 The termination or non-renewal of the HHS-OHRP registration of any IRB relied upon by the VA medical facility for review and oversight of VA research.

3.5.1.7 A failure of the VA medical facility to achieve or maintain full accreditation of its HRPP if such accreditation is sought by the VA medical facility.

3.5.1.8 The issuance of a research-related citation or determination of noncompliance by a state or Federal entity (including the VA Office of Inspector General) or an accrediting organization, pertaining to the VA medical facility's HRPP and human subjects research portfolio.

3.5.1.8.1 The VA medical facility Director must notify ORO promptly, but no later than 5 business days after VA

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medical facility personnel first become aware of any of the items above from suspension or early termination through issuance of a research-related citation.

3.6 A modification is required in order to lift a suspension of IRB approval and must be reviewed by the convened IRB to determine whether all corrective actions are met.

3.7 If IRB staff become aware of an information item that has not been submitted in the IRB system, they will enter the new information using the "Report New Information" activity and associate the information item with the appropriate study as applicable.

3.8 Information items are reviewed within 5 business days of submission.

4 RESPONSIBILITIES

4.1 The IRB staff members carry out this procedure.

5 PROCEDURE

5.1 Answer the following questions and complete the Submit RNI Pre-Review Activity: (See attached flowchart for a diagram of the flow of this procedure.)

5.1.1 Is this an Allegation of Non-Compliance?

5.1.2 Is this a Finding of Non-Compliance?

5.1.3 Is this an Unanticipated Problem Involving Risks to Subjects or Others?

5.1.4 Is this a Suspension of IRB Approval or Termination of IRB Approval?

5.2 If you are unable to answer a question, execute "Request Pre-Review Clarifications" or complete "Submit RNI Pre-Review" and indicate "Additional review required".

5.2.1 If assigning to a Designated Reviewer, follow HRP-031 - SOP - Non-Committee Review Preparation.

5.2.2 If assigning to an IRB meeting, follow HRP-040 - SOP - IRB Meeting Preparation.

5.3 If the IRB is unable to answer a question, follow HRP-025 - SOP - Investigations.

5.4 If the answer is "yes" to one or more questions, then follow the corresponding sections below.

5.4.1 Allegations of Non-Compliance: Determine whether each Allegation of Non-Compliance has any basis in fact.

5.4.1.1 If yes, follow the procedures under Findings of Non-Compliance.

5.4.1.2 If no, follow any other corresponding sections.

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5.4.2 Findings of Non-Compliance: Determine whether each Finding of Non-Compliance is Serious Non-Compliance or Continuing Non-Compliance.

5.4.2.1 If no, follow the procedures under Non-Serious/Non-Continuing Non-Compliance.

5.4.2.2 If yes, follow the procedures under Serious or Continuing Non-Compliance.

5.4.3 Non-Serious/Non-Continuing Non-Compliance

5.4.3.1 Determine whether the individual or group responsible for the Non-Compliance has developed and implemented a suitable corrective action plan.

5.4.3.2 If the individual or group responsible for the Non-Compliance is unwilling or unable to develop and implement a suitable corrective action plan, consider the Non-Compliance to be Continuing Non-Compliance and follow the procedures for Serious or Continuing Non-Compliance.

5.4.4 Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others

5.4.4.1 If the notification involves enrollment of a Prisoner in a study not approved to enroll Prisoners, please see below for additional considerations to aid in decision-making.

5.4.4.2 Confirm your decision with the IRB chair or IRB manager, if needed.

5.4.4.3 Place on the agenda for the next available convened IRB meeting in an IRB with appropriate scope as an item of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others.

5.5 If in your opinion the rights and welfare of subjects might be adversely affected before the convened IRB can review the information, contact the IRB chair or IRB manager to consider a Suspension of IRB Approval following the HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB.

5.6 If the notification involves a subject becoming a Prisoner in a study not approved by the IRB to involve Prisoners:

5.6.1 Confirm that the subject is currently a Prisoner.

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5.6.1.1 If the subject is currently not a Prisoner no other action is required.

5.6.2 Consider whether stopping all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated subject until the regulatory requirements for research involving Prisoners are met or until the subject is no longer a Prisoner would present risks to the subject.

5.6.2.1 If the subject's involvement in the research cannot be stopped for health or safety reasons, do one of the following:

5.6.2.1.1 Keep the subject enrolled in the study and review the research for involvement of Prisoners. If the research is subject to DHHS oversight, notify OHRP.

5.6.2.1.2 Remove the subject from the study and provide the study intervention as clinical care or compassionate use.

5.6.2.2 If the subject's involvement in the research can be stopped, inform the investigator that all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated subject must be stopped immediately until the regulatory requirements for research involving Prisoners are met or until the subject is no longer a Prisoner.

5.6.3 For Department of Defense (DOD) research, have the convened IRB promptly (within 30 days) re-review the research protocol to ensure that the rights and well-being of the human subject, now a prisoner, are not in jeopardy.

5.6.3.1 Promptly report all decisions to the Department of Defense (DOD).

5.6.3.2 The Department of Defense (DOD) must concur with the IRB before the subject can continue to participate while a Prisoner.

5.7 If the information involves any of the following, complete and send HRP-529 - LETTER - AAHRPP Notice of Information Item to AAHRPP as soon as possible but generally within two days of the receipt of the information, in addition to other applicable procedures listed in this SOP:

5.7.1 Negative actions by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483

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Inspection Reports with official action indicated, FDA Restrictions Placed on IRBs or Investigators, and corresponding compliance actions taken under non-US authorities related to human research protections.

5.7.2 Litigation, arbitration, or settlements initiated related to human research protections.

5.7.3 Press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the Organization's HRPP.

5.8 Take any additional actions required to resolve any concerns or complaints associated with the information.

5.9 If the information does not involve a Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others complete the "Submit RNI Pre-Review" activity.

5.9.1 As applicable, select "Non-compliance that is neither serious nor continuing", "Allegation of non-compliance with no basis in fact", or "None of the above" as the determination(s). The RNI state will move to "Acknowledged" and an automated e-mail notification will be sent.

6 MATERIALS

6.1 HRP-025 - SOP - Investigations

6.2 HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB

6.3 HRP-031 - SOP - Non - Committee Review Preparation

6.4 HRP-040 - SOP - IRB Member

6.5

6.6 HRP-529 - LETTER - AAHRPP Notice of Information Item

7 REFERENCES

7.1 21 CFR §56.108(b)

7.2 45 CFR §46.103(b)(5), 45 CFR §46.108(a)

7.3 VHA Directive 1200.05(3), Amended July 13, 2023

7.4 VHA Directive 1058, November 8, 2024

7.5 DoDI 3216.02

7.6 AAHRPP elements I.5.A, I.5.D, I-9, II.2.D, II.2.G, II.2.H, II.2.E-II.2.E.2, II.2.F-II.2.F.3, II.4.A, III.2.D

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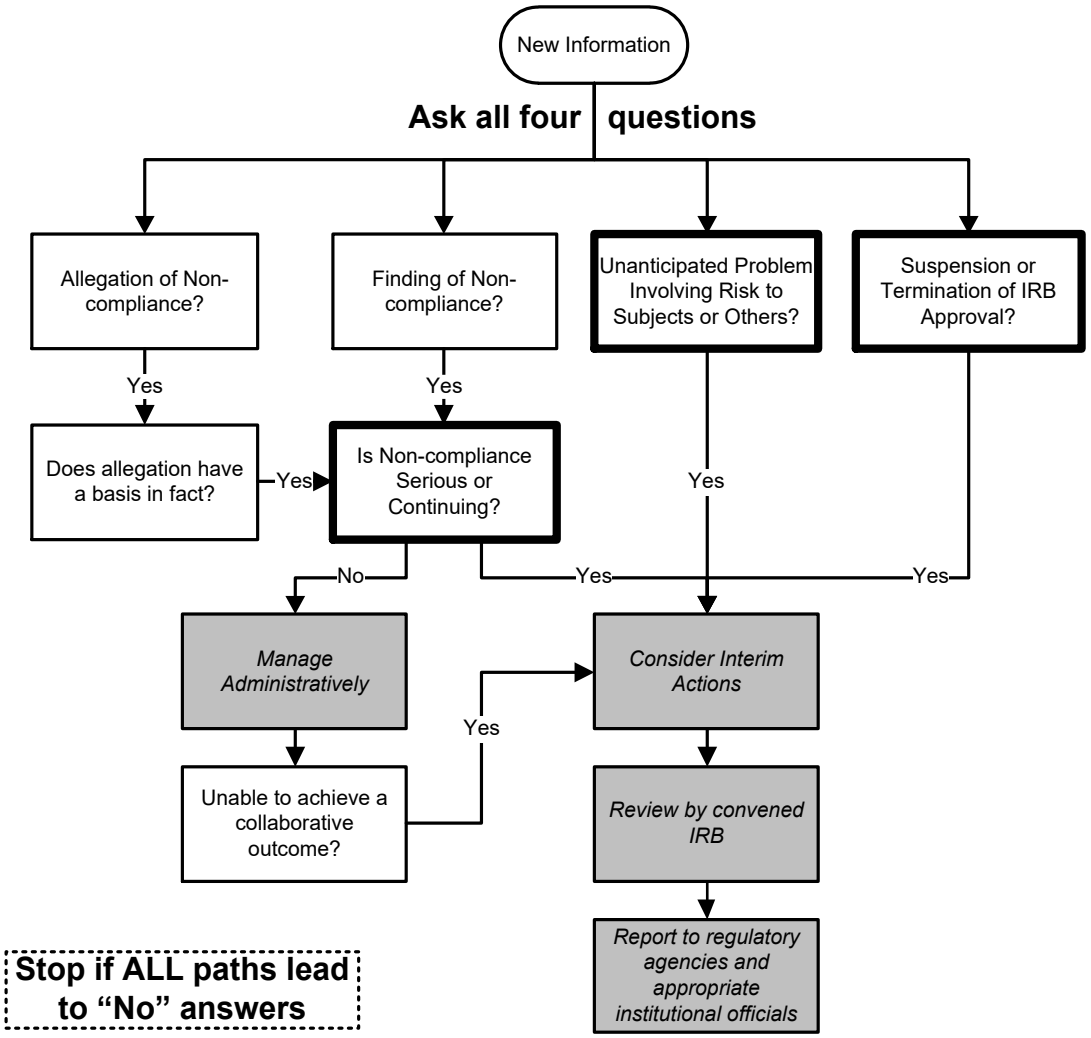
7.7 Flowchart



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HRP-025 SOP: Investigations

1 PURPOSE

1.1 This procedure establishes the process to conduct investigations.

1.2 The process begins when the IRB staff members and chair cannot answer a question required by HRP-024 - SOP - New Information.

1.3 The process ends when the investigation is complete and the answer has been provided to the Institutional Official/Organizational Official (IO/OO) or designee.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 None

4 RESPONSIBILITIES

4.1 The IO/OO or designee:

4.1.1 Appoints the members of the investigative committee based on the expertise and background needed to answer the question.

4.1.2 Appoints a chair of the investigative committee.

4.1.3 Charges the investigative committee with the question to be answered.

4.2 The investigative committee carries out these procedures within 60 days.

4.3 Investigative committee members make their decisions based on a preponderance of the evidence.

4.4 Investigative committee decisions are made by majority vote.

4.5 Individuals being interviewed may have counsel present. However, counsel cannot address the investigative committee. The investigative committee by a vote of the majority may exclude counsel when in the opinion of the investigative committee that person's presence is disruptive.

5 PROCEDURE

5.1 Notify the investigator that an investigation is being conducted, the question to be answered, and the time frame for completion.

5.2 Determine what information to gather and what individuals to interview.

5.3 Gather information and interview individuals.

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5.4 If the investigative committee believes that a transcription of the interviews will be required to make a proper decision, the investigative committee may record the interviews and obtain a transcript.

5.5 Repeat information gathering and interviews until a decision can be made.

5.6 The investigative committee provides a written report of the investigative committee's decision to the IO/OO or designee.

6 MATERIALS

6.1 HRP-024 - SOP - New Information

7 REFERENCES

7.1 AAHRPP elements I.5.D, I-9, II.2.G

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HRP-026 SOP: Suspension or Termination Issued Outside of Convened IRB

1 PURPOSE

1.1 This procedure establishes the process for someone other than the convened IRB to institute a Suspension of IRB Approval or a Termination of IRB Approval.

1.2 The process begins when the IRB chair, Organizational Official / Institutional Official (IO/OO) or designee institutes a Suspension of IRB Approval or a Termination of IRB Approval.

1.3 The process ends when the Suspension of IRB Approval or a Termination of IRB Approval has been placed on the agenda for review by the convened IRB.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The IRB chair may institute a Suspension of IRB Approval when in the opinion of the IRB chair subjects may be at risk of adverse effects on their rights and welfare before action may be considered by the convened IRB.

3.2 The IO/OO or designee may institute a Suspension of IRB Approval or Termination of IRB Approval for any reason.

3.2.1 For Veterans Administration (VA) research, this authority may be delegated by the IO to the Chief of Staff (COS). ORD has authority to suspend or terminate any research activity it is funding.

3.3 Whenever possible the individual following these procedures communicates with investigators orally and in writing.

3.4 Suspension of IRB Approval or Termination of IRB Approval must be reported to the local VA medical facility per the facility's required reporting timelines.

4 RESPONSIBILITIES

4.1 The individual instituting a Suspension of IRB Approval or Termination of IRB Approval follows these procedures.

5 PROCEDURE

5.1 Notify the investigator of the Suspension of IRB Approval or Termination of IRB Approval along with the reasons for the decision.

5.1.1 If the determination was Suspension of IRB Approval:

5.1.1.1 Execute the "Suspend" activity in the study workspace.

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5.1.1.2 Execute the "Prepare Letter" activity in the study workspace and modify the letter as needed.

5.1.1.3 Execute the "Send Letter" activity.

5.1.2 If the determination was Termination of IRB Approval:

5.1.2.1 Execute the "Terminate" activity in the study workspace.

5.1.2.2 Execute the "Prepare Letter" activity in the study workspace and modify the letter as needed.

5.1.2.3 Execute the "Send Letter" activity.

5.2 Ask the investigator to provide for the status of all Human Subjects currently involved in the research (e.g., actively receiving investigational treatment, follow-up only).

5.3 Ask the investigator whether any actions are required to protect those subjects' rights and welfare or to eliminate an apparent immediate hazard.

5.4 Consider whether any of the following additional actions are required to protect those or other subjects' rights and welfare or to eliminate an apparent immediate hazard:

5.4.1 Transferring subjects to another investigator.

5.4.2 Making arrangements for clinical care outside the research.

5.4.3 Allowing continuation of some research activities under the supervision of an independent monitor.

5.4.4 Requiring or permitting follow-up of subjects for safety reasons.

5.4.5 Requiring adverse events or outcomes to be reported to the IRB, the sponsor, and relevant agencies.

5.4.6 Notification to current Human Subjects.

5.4.7 Notification to former Human Subjects.

5.5 For Veterans Administration (VA) research, the VA medical facility Director must report the Suspension of IRB Approval or Termination of IRB Approval to ORO within 5 business days of becoming aware of the determination(s). The notification must include a statement of the reason for the action.

5.6 Refer to the IRB staff to place on the agenda for a convened IRB meeting in an IRB with appropriate scope as an item of Suspension of IRB Approval or Termination of IRB Approval. Follow HRP-041 - SOP - IRB Meeting Conduct for convened IRB review of the item.

5.7 Complete and send to the investigator HRP-515 - LETTER - Suspension or HRP-515b - LETTER - Termination.

6 MATERIALS

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6.1 HRP-041 - SOP - IRB Meeting Conduct

6.2 HRP-515 - LETTER - Suspension

6.3 HRP-515b - LETTER - Termination

7 REFERENCES

7.1 21 CFR §56.108(b)(3), 21 CFR §56.113

7.2 45 CFR §46.103(b)(5)(ii), 45 CFR §46.108(a), 45 CFR §46.113

7.3 VHA Directive 1058, November 8, 2024

7.4 VHA Directive 1200.05(3), January 7, 2019, Amended July 13, 2023

7.5 AAHRPP elements I-9, II.2.D, II.2.G, II.2.H

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HRP-027 SOP: All Emergency Use, Compassionate Use (Device Only) and IRB Waiver for Individual Patient Expanded Access (Drug Only) Post-Review

1 PURPOSE

1.1 This procedure establishes the process to communicate the review of:

1.1.1 Emergency use of a drug, biologic, or device in a life-threatening situation.

1.1.2 Non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use).

1.1.3 Non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested.

1.2 The process begins when the Designated Reviewer has notified IRB staff of whether an actual or proposed use has followed or will follow FDA regulations and guidance.

1.3 The process ends when the IRB staff has communicated the results to the physician and if necessary initiated the non-compliance process.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 None

4 RESPONSIBILITIES

4.1 IRB staff carry out these procedures.

5 PROCEDURE

5.1 For emergency use of a drug, biologic, or device in a life-threatening situation:

5.1.1 If the Designated Reviewer has indicated that the proposed use will follow FDA regulations:

5.1.1.1 Complete HRP-570 - LETTER - Pre-Rev EU - Crit Met and send to the physician.

5.1.1.2 If a 5-day report is required, set a 5-day deadline for receipt of the 5-day report.

5.1.2 If the Designated Reviewer has indicated that the proposed use will NOT follow FDA regulations, complete HRP-571 - LETTER - Pre-Rev EU - Crit Not Met and send to the physician.

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5.1.3 If the Designated Reviewer has indicated that the actual use described in the 5-day report followed FDA regulations, complete HRP-572 - LETTER - Review of EU - Crit Met and send to the physician.

5.1.4 If the Designated Reviewer has indicated that the actual use did NOT follow FDA regulations:

5.1.4.1 Complete HRP-573 - LETTER - Review of EU - Crit Not Met and send to the physician.

5.1.4.2 Manage under HRP-024 - SOP - New Information as Non-Compliance.

5.2 For compassionate use of a device, complete HRP-574 - LETTER - Device Compassionate Use.

5.3 For non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested, complete HRP-575 - LETTER - Rev of IRB Waiver for Indiv Pt Drug Exp Access.

6 MATERIALS

6.1 HRP-024 - SOP - New Information

6.2 HRP-570 - LETTER - Pre-Rev EU - Crit Met

6.3 HRP-571 - LETTER - Pre-Rev EU - Crit Not Met

6.4 HRP-572 - LETTER - Review of EU - Crit Met

6.5 HRP-573 - LETTER - Review of EU - Crit Not Met

6.6 HRP-574 - LETTER - Device Compassionate Use

6.7 HRP-575 - LETTER - Rev of IRB Waiver for Indiv Pt Drug Exp Access

7 REFERENCES

7.1 21 CFR §50.23; 21 CFR §50.24; 21 CFR §56.102(d); 21 CFR §56.104(c)

7.2 21 CFR §312.305

7.3 21 CFR §812.36; 21 CFR §812.47

7.4 FDA Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors Frequently Asked Questions About Medical Devices: http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf..

7.5 AAHRPP element I.7.C

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HRP-030 SOP: Designated & Staff Reviewers

1 PURPOSE

1.1 This procedure establishes the process for documenting who can conduct Non-Committee Reviews.

1.2 The process begins when the IRB chair designates an Experienced IRB Member, or the IRB manager determines an IRB staff member can act as a Staff Reviewer, to conduct Non-Committee Reviews.

1.3 The process ends when the Experienced IRB Member or Staff Reviewer has been noted in the corresponding roster to conduct Non-Committee Reviews.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.

3.2 Staff Reviewer rosters are maintained using HRP-602 - DATABASE - Staff Reviewer Roster.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 Obtain from the IRB chair the name of the IRB member designated to conduct Non-Committee Reviews.

5.1.1 Verify that the IRB member is an Experienced IRB Member.

5.1.2 Update HRP-601 - DATABASE - IRB Roster to indicate that the IRB member is a Designated Reviewer.

5.1.3 Navigate to the Meetings menu. In the “Committees tab”, click on the applicable IRB Committee. Execute the “Update Eligible Designated Reviewers” activity to indicate that the IRB member is a Designated Reviewer.

5.2 Obtain from the IRB manager the name of the IRB staff member eligible to act as a Staff Reviewer to conduct certain Non-Committee Reviews.

5.2.1 Update HRP-602-DATABASE-Staff Reviewer to indicate that the IRB staff member is a Staff Reviewer.

6 MATERIALS

6.1 HRP-601 - DATABASE - IRB Roster

6.2 HRP-602 - DATABASE- Staff Reviewer

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7 REFERENCES

7.1 21 CFR §56.110(b).

7.2 45 CFR §46.110(b).

7.3 AAHRPP elements I.1.A, I-9, II.2.A, II.2.B, II.2.D, II.2.F-II.2.F.3

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HRP-031 SOP: Non-Committee Review Preparation

1 PURPOSE

1.1 This procedure establishes the process to prepare for a Non-Committee Review.

1.2 The process begins when an IRB staff member identifies an application as being possibly eligible for Non-Committee Review.

1.3 The process ends when the IRB staff member provides the materials to a Designated Reviewer or Staff Reviewer for Non-Committee Review.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.

3.2 Staff Reviewer rosters are maintained using HRP-602 - DATABASE - Staff Reviewer Roster.

3.3 For individuals who access materials through an electronic system or are provided all submitted materials, those individuals are expected to review the materials listed in HRP-301 - WORKSHEET - Review Materials according to their role: “Documents Provided to All IRB Members and Alternate IRB Members,” “Additional Items Provided to Primary Reviewer,” and “Additional Items Provided to Scientific/Scholarly Reviewer.”

3.4 Waiver or alterations of HIPAA authorization reviewed via Non-Committee Review must be completed by a Designated Reviewer or Privacy Board designee.

3.5 A reviewer is assigned to a submission within 3 business days of receipt of a complete submission.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 Refer to HRP-601 - DATABASE - IRB Roster and/or HRP-602 - DATABASE - Staff Reviewer Roster to identify an appropriate reviewer, based on the review level and/or required determination.

5.1.1 All Non-Committee Reviews can be performed by Designated Reviewers.

5.1.1.1 If no Designated Reviewer is available, or if available Designated Reviewers are unable to perform a Non-Committee Review in a timely manner such that review by the convened

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IRB would result in a timelier review, schedule the protocol to be reviewed by the convened IRB.

5.1.2 Staff Reviewers are not Designated Reviewers and therefore are limited to making the determinations identified in the definition of Staff Reviewer in HRP-001 - SOP - Definitions.

5.2 Execute the “Assign Designated Reviewer” activity to select a reviewer.

6 MATERIALS

6.1 HRP-001-SOP - Definitions

6.2 HRP-301 - WORKSHEET - Review Materials

6.3 HRP-601 - DATABASE - IRB Roster

6.4 HRP-602 - DATABASE - Staff Reviewer Roster

7 REFERENCES

7.1 21 CFR §56.110(b)

7.2 45 CFR §46.110(b)

7.3 45 CFR §164.512(i)

7.4 AAHRPP elements I.1.A, I.1.F, I.6.B, I.7.A, I-9, II.2.A-C, II.2.F-II.2.F.3

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HRP-032 SOP: Non-Committee Review Conduct

1 PURPOSE

1.1 This procedure establishes the process for conducting a Non-Committee Review.

1.2 The process begins when the Designated Reviewer or Staff Reviewer receives the review materials.

1.3 The process ends when the Designated Reviewer or Staff Reviewer completes the review and returns the completed materials to an IRB staff member.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Designated Reviewer may not disapprove research.

3.2 Designated Reviewer and Staff Reviewer utilize all applicable worksheets in the review of research.

3.3 The documents, worksheets, and checklists described HRP-301 - WORKSHEET - Review Materials are provided to the reviewer to conduct their review and meet regulatory requirements.

3.4 All applicable criteria for approval in HRP-314 - WORKSHEET - Criteria for Approval must be satisfied in order for the research to be approved using the expedited procedure.

3.5 All applicable criteria in HRP-312 - WORKSHEET - Exemption Determination must be satisfied for research to be determined to be exempt (including applicable criteria for Limited IRB Review in HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent when appropriate).

3.6 Reviews are completed and returned to the IRB staff within 5 business days or receipt.

4 RESPONSIBILITIES

4.1 The Designated Reviewer or Staff Reviewer carries out these procedures.

5 PROCEDURE

5.1 Review all materials.

5.2 If the information is not complete, contact the investigator by selecting the “Request Designated Review Clarifications” activity. Offer the investigator the opportunity to provide additional information.

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5.2.1 Continue processing once the investigator responds to the request for additional information.

5.2.2 If the investigator will not correct the submission, have the investigator execute the "Submit Response" activity to resubmit and continue processing.

5.3 Make the appropriate determination:

5.3.1 Not Human Research,

5.3.2 Human Research not Engaged,

5.3.3 Exempt Human Research (including exempt Human Research that requires Limited IRB Review),

5.3.4 Modifications required to secure approval of Human Research using the expedited procedure,

5.3.5 Human Research approved using the expedited procedure, or

5.3.6 Human Research that requires review by a convened IRB.

5.4 Notify IRB staff to re-assign the submission if:

5.4.1 The submission is assigned to a Staff Reviewer and requires review using the expedited procedure.

5.4.2 The submission is assigned to a Designated Reviewer and requires review by a convened IRB.

5.5 If consultation is needed follow HRP-051 - SOP - Consultation.

5.6 If the review is complete, execute the "Submit Designated Review" activity.

5.6.1 The risk level determination should reflect the entirety of the research, not components of individual follow-on submissions. For follow-on submission, update the risk level only when modifications to study procedures prompt a change in risk level of the research.

5.6.2 For follow-on submissions to Minimal Risk research, confirm that the review categories selected are still applicable.

5.6.2.1 Update the review category(ies) only when study procedures are modified and impact the category(ies).

5.6.2.2 For research initially reviewed by the convened IRB and determined to be Minimal Risk (via Category 9), leave the review category identified as Category 9.

5.6.3 For follow-on submission to research involving greater than Minimal Risk:

5.6.3.1 For modifications, select minor modification.

5.6.3.2 For continuing reviews, confirm that greater than Minimal Risk activities have not occurred during the review period and select the applicable expedited review category (8a – long-term follow-up; 8b – no subjects enrolled; 8c – data analysis).

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5.6.4 For non-emergency individual patient expanded access use of a drug and non-emergency individual/small group compassionate use of a device, select 'IRB chair concurrence' and the corresponding sub-category.

5.6.5 For continuing reviews involving Humanitarian Use Devices (HUD), select "Other".

6 MATERIALS

6.1 HRP-051 - SOP – Consultation

6.2 HRP-301 - WORKSHEET - Review Materials

6.3 HRP-312 - WORKSHEET - Exemption Determination

6.4 HRP-314 - WORKSHEET - Criteria for Approval

6.5 HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent

7 REFERENCES

7.1 21 CFR §56.110(b), 21 CFR 56.111.

7.2 45 CFR §46.110(b), 21 CFR §46.111.

7.3 AAHRPP elements I.1.A, I.6.B, I.7.A, I-9, II.2.A-C, II.2.F-II.2.F.3, II.5.A

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HRP-040 SOP: IRB Meeting Preparation

1 PURPOSE

1.1 This procedure establishes the process to prepare for a convened IRB meeting.

1.2 The process begins when the agenda is closed, approximately 10 business days before a meeting date.

1.3 The process ends when IRB meeting agenda materials have been sent or made available to IRB members.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 At least one IRB member or consultant is responsible for scientific/scholarly review of research.

3.2 Protocols are reviewed by IRB members and consultants with sufficient expertise.

3.3 When IRB members review research that involves vulnerable subjects, at least one individual who is knowledgeable about or experienced in working with such subjects will be present at the meeting.

3.4 IRB members are provided sufficient information so that each member can provide an opinion on whether the regulatory criteria for approval are met.

3.5 Alternate IRB members serve the same function as other IRB members, except that if the alternate IRB member and the regular IRB member for whom the alternate member is substituting are both present only one member may vote.

3.6 For individuals who access materials through an electronic system or are provided all submitted materials, those individuals are expected to review the materials listed in HRP-301 - WORKSHEET - Review Materials according to their role: “Documents Provided to All IRB Members and Alternate IRB Members”, “Additional Items Provided to Primary Reviewer”, and “Additional Items Provided to Scientific/Scholarly Reviewer”.

3.7 Review materials are provided to all IRB members at least 7 business days before convened meetings.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

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5.1 Confirm which IRB members (regular, alternate, and chairs) will be present at the meeting.

5.2 Consult HRP-601 - DATABASE - IRB Roster to be aware of the experience, expertise, and representational capacity of the IRB.

5.3 Review all submissions placed on the agenda for a convened IRB meeting.

5.4 Prepare an agenda for the meeting.

5.4.1 Execute the “Assign Reviewers” activity in the meeting workspace to assign a primary reviewer to each agenda item.

5.4.2 Execute the “Assign Reviewers” activity in the meeting workspace to assign a scientific/scholarly reviewer to each agenda item who has scientific/scholarly expertise in the area of research. The primary reviewer and scientific/scholarly reviewer may be the same individual.

5.4.3 If the scientific/scholarly reviewer is not an IRB member, determine whether the scientific/scholarly reviewer has a Conflicting Interest as defined in HRP-001 - SOP - Definitions. If so, assign another scientific/scholarly reviewer.

5.4.4 Execute the “Prepare Agenda” activity in the meeting workspace to generate the agenda and modify as needed.

5.5 Use HRP-305 - WORKSHEET - Quorum and Expertise to ensure that the meeting will be appropriately convened and to ensure the IRB will have the appropriate expertise for each protocol.

5.5.1 If the meeting will not meet the quorum and expertise requirements, take steps to obtain the required attendance of members and consultants or cancel the meeting.

5.5.2 Follow the procedures in HRP-051 - SOP - Consultation to obtain consultants. Note any consultants on the agenda.

5.6 Ensure the report of protocols approved using the expedited procedure is available in the meeting workspace.

5.7 For individuals who are provided materials (IRB members, scientific/scholarly reviewers, consultants):

5.7.1 Execute the “Send Agenda” activity in the meeting workspace to deliver review materials to reviewers.

6 MATERIALS

6.1 HRP-001 - SOP - Definitions

6.2 HRP-051 - SOP - Consultation

6.3 HRP-301 - WORKSHEET - Review Materials

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6.4 HRP-305 - WORKSHEET - Quorum and Expertise

6.5 HRP-601 - DATABASE - IRB Roster

7 REFERENCES

7.1 45 CFR §46.108(b)

7.2 21 CFR §56.108(c)

7.3 AAHRPP elements I.1.F, I.5.D, I.6.B, I.7.A, I-9, II.1.B, II.1.D, II.1.E, II.2.D, II.2.G, II.2.E-II.2.E.2

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HRP-041 SOP: IRB Meeting Conduct

1 PURPOSE

1.1 This procedure establishes the process to conduct convened meetings.

1.2 The process begins when the IRB members gather for a convened meeting.

1.3 The process ends when the meeting is adjourned.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The IRB reviews research in accordance with the applicable regulatory criteria for approval.

3.2 The IRB chair (and vice chair, where applicable), votes as a regular member.

3.3 Meetings are conducted in person or via teleconference.

3.4 IRB attendance is captured by documenting in the IRB meeting minutes the IRB members and alternates in attendance, replacement of a voting member by an alternate, attendance of IRB members who participate through teleconference, and IRB members who are recused due to a conflicting interest. Members are absent when recused and do not count towards quorum while recused.

3.5 If quorum is lost during a meeting, the IRB cannot take votes until the quorum is restored, even if more than half of the members are still present.

3.6 Substantive changes or requirements, requests for more information for IRB consideration, and other issues related to the criteria for approval require review and approval by the convened IRB.

3.7 Minor or prescriptive changes or requirements (modifications required to secure approval) may be reviewed for approval by the IRB chair or a designated individual.

3.8 The documents, worksheets, and checklists described in HRP-301 - WORKSHEET - Review Materials are provided to IRB members in advance of meetings per HRP-040 - SOP - IRB Meeting Preparation to conduct meetings and meet regulatory requirements.

3.9 For Veterans Administration (VA) Research “Substantive Changes” are defined as those ineligible for “Modifications Required to Secure Approval” as defined in this SOP.

4 RESPONSIBILITIES

4.1 The IRB chair carries out these procedures, unless otherwise noted.

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4.2 Primary reviewers lead IRB members through consideration of the regulatory criteria for approval.

5 PROCEDURE

5.1 Call the meeting to order.

5.2 Ask IRB members whether anyone has a Conflicting Interest in any item on the agenda and note the responses.

5.3 Ask IRB members if there are any questions about the report of completed non-committee reviews that was made available to the IRB prior to the meeting.

5.4 For each agenda item:

5.4.1 Table the item when notified by IRB staff that requirements for review of a specific item as defined in HRP-305 - WORKSHEET - Quorum and Expertise are not met.[xxiii]

5.4.2 If there are IRB members with a Conflicting Interest, invite the IRB to ask questions of those members and then ask those members to leave for discussion and voting or if present by teleconference, be placed on hold or disconnect for discussion and voting.

5.4.2.1 For Veterans Administration (VA) research, members with a Conflicting Interest present by teleconference are to disconnect for discussion and voting.

5.5 For each agenda item involving the initial review, modification or continuing review of a protocol:

5.5.1 If there is a consultant present, ask the consultant to present his or her review to the IRB.

5.5.2 If a consultant provided written information to the IRB, ask the primary reviewer to present that information to the IRB.

5.5.3 Ask the scientific or scholarly reviewer or primary reviewer to present the scientific or scholarly review to the IRB.

5.5.4 Ask the primary reviewer to lead the IRB through a discussion of the criteria in HRP-314 - WORKSHEET - Criteria for Approval and all referenced checklists (listed below) to have the convened IRB determine which regulatory criteria are met (or continue to be met), which are not met (or no longer met), and which would be met if the investigator modified the protocol as requested by the IRB.

5.5.5 Restate the IRB's consensus regarding any protocol specific findings justifying a determination when required by a checklist and not previously determined and documented.

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5.5.6 Make a motion for one of the following actions:

5.5.6.1 Approve (with a specific continuing review interval for initial or continuing review when applicable): Made when all criteria for approval are met.

5.5.6.2 Modifications Required to Secure Approval (with a specific continuing review interval for initial or continuing review when applicable): Made when IRB members require specific modifications such that an IRB staff member can determine whether an investigator has made the required changes without judging whether a change meets the regulatory criteria for approval. When making this motion, the assigned primary reviewer restates the modifications required by the IRB members and the IRB member's reasons for those changes.

5.5.6.3 Defer: Made when the research does not qualify for Approval or Modifications Required to Secure Approval and the IRB has recommendations that might make the protocol approvable. When making this motion, the assigned primary reviewer describes the IRB member's reasons for the decision and describes recommendation to make the research approvable.

5.5.6.4 Disapprove: Made when the research does not qualify for Approval or Modifications Required to Secure Approval and the IRB has no recommendations that might make the protocol approvable. When making this motion, the assigned primary reviewer describes the IRB member's reasons for the decision.

5.5.6.5 Suspension or Termination of IRB Approval: Made when current approved research does not qualify for Approval or Modifications Required to Secure Approval. When making this motion, have the primary reviewer use HRP-321 - WORKSHEET - Review of Information Items to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects. The assigned primary reviewer describes the IRB member's reasons for the decision.

5.5.7 For motions of "Approval" or "Modifications Required to Secure Approval", for initial and continuing reviews, include the risk level and approval period. Confirm whether the continuing review interval should be annual, or more frequently than annual based on considerations such as the nature and level of risks, the degree of uncertainty regarding the risks,

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subject vulnerability, investigator experience, the IRB's experience with the investigator or sponsor, the projected rate of subject enrollment, or whether the study involves novel procedures.

5.5.8 For modifications in response to a previous Suspension of IRB approval:

5.5.8.1 Have the primary reviewer summarize any corrective actions taken by the Principal Investigator.

5.5.8.2 Based on this new information, determine whether the corrective actions are sufficient to address the issues that prompted the suspension.

5.5.8.2.1 If so, make a motion for the IRB to approve the modification, which will lift the suspension of IRB approval.

5.5.8.2.2 If not, make an appropriate motion and identify the additional action items are required to protect subjects.

5.5.9 Review any modifications required to secure approval to ensure that the IRB staff has recorded them.

5.5.9.1 Ensure that the required modifications include all final contingencies listed in the "Notes" section of the Pre-Review activity.

5.5.9.2 For a pending financial interest review indicate that a determination that the financial interest is not a conflict of interest or has been eliminated can be verified by the IRB staff, but if there is a management plan, it must return to the convened IRB for review.

5.6 For each agenda item that is new information (Unanticipated Problem Involving Risks to Subjects or Others, Serious Non-Compliance, Continuing Non-Compliance, Suspension of IRB Approval, or Terminations of IRB Approval):

5.6.1 Have the primary reviewer use HRP-321 - WORKSHEET - Review of Information Items to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects.

5.6.2 Restate the IRB's consensus regarding any actions that need to be taken to protect subjects.

5.6.3 Make a motion for the IRB's determination(s) regarding the action items (e.g., the motion is for the Principal Investigator to provide the IRB additional information regarding the status of currently enrolled subjects).

5.7 Open the floor for additional discussion.

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5.8 Call for a vote.

5.9 Only IRB members may vote.

5.9.1 If a member and an alternate are both present, only one may vote.

5.9.1.1 Consultants may not vote.

5.9.1.2 For a motion to be approved, it needs the approval of more than half of the members present at the meeting. (If there are 10 or 11 members present at the meeting, 6 votes are required for approval, which is greater than 5 and 5.5, respectively.)

5.10 Re-invite IRB members with a Conflicting Interest back into the meeting.

5.11 Provide any written information provided by a member or consultant to the IRB staff.

5.12 Adjourn the meeting when notified by IRB staff that quorum has been lost or when there is no further business.

6 MATERIALS

6.1 HRP-040 - SOP - IRB Meeting Preparation

6.2 HRP-301 - WORKSHEET - Review Materials

6.3 HRP-305 - WORKSHEET - Quorum and Expertise

6.4 HRP-314 - WORKSHEET - Criteria for Approval

6.5 HRP-321 - WORKSHEET - Review of Information Items

6.6

7 REFERENCES

7.1 21 CFR §50.20, §50.25, §50.27, §56.109, §56.111.

7.2 45 CFR §46.109, §46.111, §46.116, §46.117.

7.3 AAHRPP elements I.1.F, I.5.A, I.5.D, I.6.B, I.7.A, I-9, II.1.B, II.1.D, II.1.E, II.2.D, II.2.G, II.2.E-II.2.E.2, II.2.F-II.2.F.3

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HRP-042 SOP: IRB Meeting Attendance Monitoring

1 PURPOSE

1.1 This procedure establishes the process to monitor quorum at convened IRB meetings.

1.2 The process begins when the IRB staff member responsible for monitoring quorum notifies the IRB chair that quorum has been attained.

1.3 The process ends when the meeting is adjourned.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 None

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 At meetings consult HRP-305 - WORKSHEET - Quorum and Expertise to determine that the meeting is appropriately convened by meeting the “QUORUM REQUIREMENTS” and notify the IRB chair when the meeting is appropriately convened.

5.2 Before each protocol consult HRP-305 - WORKSHEET - Quorum and Expertise to determine that the meeting is appropriately convened by meeting the “EXPERTISE REQUIREMENTS” and notify the IRB chair when the meeting is not appropriately constituted for the review of that protocol.

5.3 When a member leaves the meeting room for any reason (including a Conflicting Interest) consult HRP-305 - WORKSHEET - Quorum and Expertise to determine that the meeting continues to be appropriately convened by meeting the “QUORUM REQUIREMENTS” and notify the IRB chair when the meeting is not appropriately convened.

6 MATERIALS

6.1 HRP-305 - WORKSHEET - Quorum and Expertise

7 REFERENCES

7.1 45 CFR §46.108(b)

7.2 21 CFR §56.108(c)

7.3 AAHRPP elements II.1.D, II.1.E, II.2.D

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HRP-043 SOP: IRB Meeting Minutes

1 PURPOSE

1.1 This procedure establishes the process to record minutes for convened meetings.

1.2 The process begins when the meeting is called to order.

1.3 The process ends when the minutes are approved by the IRB chair or IRB Manager.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 Minutes are to comply with regulatory and guidance requirements.

3.2 Minutes are to record separate deliberations for each action.

3.3 Minutes are provided to the IRB chair or IRB manager within 2 business days of meeting completion for approval.

3.4 IRB members may make corrections to minutes.

3.5 The IRB writes minutes and makes them available for review by the committee by the next IRB meeting. Minutes are made available to the Institutional Official/ Organizational Official (IO/OO).

3.6 Minutes may not be altered by anyone including a higher authority once accepted by the convened IRB.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 Execute the “Convene Meeting” activity

5.2 Record each voting member (regular members and alternates) present at the meeting at any time. (Do not record non-voting members under “Attendance Table”)

5.2.1 Name.

5.2.2 Status: E.g., chair, vice chair, scientific member, non-scientific member, unaffiliated member, representative of vulnerable population (specify), prisoner representative, Veterans Administration (VA) representative, or alternate member.

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5.2.3 For alternate members who are substituting for a regular member, indicate the name of the regular member for whom the alternate member is substituting.

5.2.4 Whether the member was present by teleconference.

5.3 Record the total number of members in HRP-601 - DATABASE - IRB Roster. Exclude alternate members in this count.

5.4 Record the number of members required for quorum. Divide the number of members by two and select the next whole number. For example, if there are 10 IRB members on the HRP-601 - DATABASE - IRB Roster, then 10/2 = 5 and the next whole number is 6. If there 11 IRB members on the HRP-601 - DATABASE - IRB Roster, then 11/2=5.5 and the next whole number is 6.

5.5 Indicate whether members present by teleconference received all pertinent material before the meeting and were able to actively and equally participate in all discussions. Delete if no members were present by teleconference.

5.6 Record the meeting start time.

5.7 For each submission reviewed record in the "Submit Committee Review" activity or "Submit RNI Committee Review" activity, as appropriate:

5.7.1 Motion: Approved, Modifications Required to Secure Approval, Deferred, Disapproved, Suspended, or Terminated. For initial or continuing review add the period of approval to the motion.

5.7.2 Risk Level: Minimal Risk or more than Minimal Risk.

5.7.3 Refer to HRP-302 - WORKSHEET - Approval Intervals to calculate approval intervals (if applicable).

5.7.4 Last Day of Approval Period: Record the study expiration date.

5.7.5 Recommended Changes and Reasons: If the motion is Modifications Required to Secure Approval or Deferral/Disapproval, complete the table with the required changes and corresponding reasons. If no recommended changes, indicate "None."

5.7.6 Controverted Issues and their Resolutions: Summarize the issues where IRB members expressed a difference of opinion. For each issue indicate the resolution or indicate that there was none. If no controverted issues, indicate "None."

5.7.7 Determinations and findings that require documentation: If the research involves waiver or alteration of consent, waiver of written documentation of consent, children, pregnant women, neonates, Prisoners, or adults with impaired decision-making capacity, enter "See attached Supporting Documents" and ensure that the corresponding completed checklist is uploaded as a supporting document. If no determinations that require documentation, indicate "None."

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5.7.8 RNI Determinations: Record the determination of Unanticipated Problem Involving Risks to Subjects or Others, suspension or termination of IRB approval, serious non-compliance, continuing non-compliance, non-compliance that is neither serious nor continuing, allegation of non-compliance with no basis in fact, or none of the above.

5.7.9 RNI Considerations: Record requirements determined by the IRB, for example modification to the protocol or ask subjects to re-consent.

5.7.10 Additional Information and Notes: Summarize issues useful to understand the agenda item. For example, a brief history of recent IRB actions

5.7.11 Supporting documents: For any determinations that require documentation, upload the appropriate checklist(s), or any other appropriate supporting documents.

5.7.12 Vote: Record as the number of members for, against, abstaining, absent, or recused. List the names of IRB members who were absent or recused. Do not count votes of consultants. If both a regular IRB member and the alternate IRB member are present at the meeting record the vote of just one.

5.7.12.1 For: Voting for the motion.

5.7.12.2 Against: Voting against the motion.

5.7.12.3 Abstain: Present for the vote, but not voting “For” or “Against.”

5.7.12.4 Absent: Listed under “Members Present” but not present for the discussion and vote on this protocol for reasons other than a Conflicting Interest. List the names of absent members in the vote. For example: “For: 7 Against: 3 Abstain: 2 Absent: 2 (Alice Baker, Charlie Delta) Recused: 0 Substitutions: 0.”

5.7.12.5 Recused: Listed under “Members Present” but not present for the discussion and vote on this protocol for because of a Conflicting Interest. List the names of recused members in the vote. For example: “For: 7 Against: 3 Abstain: 2 Absent: 0 Recused: 2 (Evelyn Foxtrot, George India) Substitutions: 0.”

5.7.12.6 Substitutions: Listed under “Members Present” When regular members and their alternate(s) are listed under “Members Present” and an alternate member substitutes for the regulator member, identify the name of the alternate to indicate which individual is serving as the voting member for this vote. May be deleted if there are no substitutions. For example: “For: 7 Against: 3 Abstain: 2 Absent: 0 Recused: 0 Substitutions: 1 (Evelyn Foxtrot substituted for George India).”

5.8 Record the meeting end time.

5.9 Execute the “Prepare Minutes” activity and combine the attendee information with the generated submission-specific determinations.

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5.10 Revise minutes for accuracy and provide them to the IRB chair or IRB manager for review and approval.

5.11 Once approved by the IRB chair or IRB manager, execute the “Close Meeting” activity.

5.12 Email minutes to:

5.12.1 Veterans Administration (VA) Research and Development Committee

5.12.2 When an affiliate IRB is the IRB of Record, the affiliate may either:

5.12.2.1 Provide VA with unredacted copies of meeting minutes, or

5.12.2.2 Provide VA with redacted copies of meeting minutes and permit relevant VA personnel (including, but not limited to, ORO staff, local VA Research Office staff, local RCOs, and R&D Committee members) to review the unredacted meeting minutes within two business days of a written request from VA. Such review may occur at the affiliate site during normal business hours, or as otherwise mutually acceptable to VA and the affiliate.

5.13 The minutes will show on the next agenda for that IRB committee under “Previous meetings with minutes for approval” for the IRB members at the next convened meeting to review and accept.

5.14 Once accepted, execute the “Approve Minutes” activity to finalize the minutes.

6 MATERIALS

6.1 HRP-501 - TEMPLATE MINUTES

7 REFERENCES

7.1 21 CFR §56.115(a)(2)

7.2 45 CFR §46.115(a)(2)

7.3 VHA Directive 1200.05(3) Amended July 13, 2023

7.4 AAHRPP elements I-9, II.1.D, II.1.E, II.2.D, II.2.G, II.2.E-II.2.E.2, II.5.B

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HRP-044 SOP: Not Otherwise Approvable Research

1 PURPOSE

1.1 This procedure establishes the process for the organization to review research that is not otherwise approvable.

1.2 This process begins when the IRB determines that research involving children, pregnant women, as subjects is not otherwise approvable, but presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting those subjects' health or welfare.

1.3 The process ends when the federal agency or the Institutional Official/ Organizational Official (IO/OO) or designee communicates a decision to the IRB.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 For HHS-funded or conducted research and FDA-regulated research involving children, the research may proceed only if the HHS Secretary or his or her designee/Commissioner of Food and Drugs, after consulting with a panel of experts in pertinent disciplines (e.g., science, medicine, education, ethics, law) and following an opportunity for public review and comment, makes a determination as indicated in the applicable regulation.

3.2 When research is not otherwise approvable, but because the research is not subject to regulatory approval no government agency will conduct a review of this research to determine whether it can be approved, this organization will conduct its own review that parallels the regulatory process.

3.3 The criteria used to make a determination are:

3.3.1 That the research in fact satisfies the conditions of IRB approvable research in HRP-414 - CHECKLIST - Neonates of Uncertain Viability, or HRP-416 - CHECKLIST - Children, or HRP-412 - CHECKLIST - Pregnant Women.

3.3.2 All of the following criteria are met:

3.3.2.1 The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children or pregnant women.

3.3.2.2 The research will be conducted in accordance with sound ethical principles;

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3.3.2.3 Adequate provisions are made for soliciting the assent of children, the permission of their parents or guardians, and the consent of subjects as required by HRP-314 - WORKSHEET - Criteria for Approval, HRP-414 - CHECKLIST - Neonates of Uncertain Viability, or HRP-416 - CHECKLIST – Children.

4 RESPONSIBILITIES

4.1 IRB staff members carry out the procedures in Sections 5.1 and 5.2.

4.2 The IO/OO or designee carries out these procedures in Section 5.3.

5 PROCEDURE

5.1 For research involving children, when using HRP-416 - CHECKLIST – Children and the IRB determines the research meets the criteria for category 21 CFR §50.54/45 CFR §46.407 "*Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children*," proceed as follows:

5.1.1 For DHHS, the research may proceed only after OHRP has reviewed and approved the research. Refer to DRAFT guidance Research Involving Children as Subjects and Not Otherwise Approvable by an IRB: Process for Referrals to FDA and OHRP for appropriate next steps. Contact OHRP OHRP@hhs.gov for additional information and the appropriate next steps.

5.1.2 For FDA-regulated research, the research may proceed only after the FDA has reviewed and approved the research. Refer to Process for Handling Referrals to FDA Under 21 CFR 50.54 - Additional Safeguards for Children in Clinical Investigations for appropriate next steps. Contact the FDA opt@fda.gov for additional information and the appropriate next steps.

5.1.3 For research conducted or funded by the Department of Defense (DOD), the research may proceed when the DoD institutions demonstrate to the Senior Designated Official (SDO) that the IRB has fulfilled its duties in accordance with Part 407 of Subpart D of Part 46 of Title 45, CFR, and Section 50.54 of Title 21, CFR. Work with the study investigator to contact the institution's assigned DOD point of contact (e.g. HRPO/HPA/EDO) for the study to determine next steps.

5.1.4 For all other research, refer to Section 5.3.

5.2 For research involving pregnant women, fetuses, or neonates, when using HRP-412 - CHECKLIST - Pregnant Women, HRP-413 - CHECKLIST - Non-Viable Neonates, and/or HRP-414 - CHECKLIST - Neonates of Uncertain Viability and the IRB determines the research meets the criteria for category §46.207 "*Research not otherwise approvable which presents an opportunity to understand, prevent, or*

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alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates," proceed as follows:

5.2.1 For DHHS-regulated research, the research may proceed only after the Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the FEDERAL REGISTER, has reviewed and approved the research. Contact OHRP OHRP@hhs.gov for additional information and the appropriate next steps.

5.2.2 For research conducted or funded by the Department of Defense (DOD), the research may proceed when the DoD institutions demonstrate to the Senior Designated Official (SDO) that the IRB has fulfilled its duties in accordance with Subpart B of 45 CFR §46 and the SDO must receive explicit written approval from the DoD Office of Human Research Protections (DOHRP). Work with the study investigator to contact the institution's DOD assigned point of contact (e.g. HRPO/HPA/EDO) for the study to determine next steps.

5.2.3 For all other research, refer to Section 5.3.

5.3 For research that is not otherwise approvable and not subject to regulatory approval by a government agency, proceed as follows:

5.3.1 Identify a panel of five or more experts in pertinent disciplines (e.g., science, medicine, education, ethics, and law) and relevant subject advocates to review the protocol.

5.3.2 Screen for Conflicting Interests of panel members and do not use panel members with a Conflicting Interest.

5.3.3 Inform potential experts that they will be asked to provide individual written recommendations and that their reports, as well as their identities, will be publicly available during the public review and comment period.

5.3.4 Publish in a form accessible to the public:

5.3.4.1 A request for written comments, including an Internet link to the protocol, relevant sections of grant applications, parental permission and assent documents, and relevant excerpts from the IRB minutes and correspondence.

5.3.4.2 The date and location of the expert panel meeting (to be held a minimum of 30 days after the notice is posted).

5.3.4.3 Indicate that the panel meeting will be open to the public and that the public will be given an opportunity to comment at the panel meeting.

5.3.4.4 Note that written comments on posted materials must be submitted at least 7 days before the day of the panel meeting

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to be considered by the panelists (which will allow the public 21 days to comment on posted materials);

5.3.4.5 Indication that the panelists' reports/recommendations (see below) will be posted 14 days after the panel meets.

5.3.4.6 Invite comments for up to 30 days after the meeting of the convened panel for review and consideration by the panel.

5.3.5 Open the meeting to the public.

5.3.6 After the convened panel discussion occurs and public comments are received, have each panel member write an independent recommendation as to whether the protocol should proceed, proceed with modifications, or not proceed.

5.3.7 Post panel reports on the organization's website for informational purposes for 30 days after the panel meeting.

5.3.8 Review the panel deliberations, reports, public comments, and make one of the following recommendations within 90 days of the convened panel meeting:

5.3.8.1 The organization approves support of the research as submitted;

5.3.8.2 The organization approves support of the research, but with required and/or recommended modifications; or

5.3.8.3 The organization disapproves support of the research.

5.3.9 Inform the IRB and the investigator.

5.3.10 Post the decision on the organization's Website.

6 MATERIALS

6.1 HRP-314 - WORKSHEET - Criteria for Approval

6.2 HRP-412 - CHECKLIST - Pregnant Women

6.3 HRP-414 - CHECKLIST - Neonates of Uncertain Viability

6.4 HRP-416 - CHECKLIST - Children

7 REFERENCES

7.1 45 CFR §46.207, 45 CFR §46.407

7.2 21 CFR §50.24(e), 21 CFR §50.54(b), 21 CFR §812.66

7.3 AHRPP elements I.1.D, II.1.D, II.2.E-II.2.E.2, II.4.A

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HRP-050 SOP: Conflicting Interests of IRB Members

1 PURPOSE

1.1 This procedure establishes the process to identify and manage Conflicting Interest of IRB members.

1.2 The process begins when an IRB member is asked to review an IRB submission.

1.3 The process ends when an IRB member has either identified a Conflicting Interest and notified IRB staff, or when an IRB member has determined that he or she does not have a Conflicting Interest.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 IRB members are responsible to know the definition of Conflicting Interest and self-identify when they have a Conflicting Interest.

4 RESPONSIBILITIES

4.1 IRB members (regular and alternate) follow these procedures.

5 PROCEDURE

5.1 Before reviewing research, IRB members are to determine whether they have a Conflicting Interest with research.

5.2 If an IRB member has a Conflicting Interest for review outside a meeting (e.g., the expedited procedure), he or she is to notify the IRB staff and return all materials.

5.3 If an IRB member has a Conflicting Interest for review of a submission for which he or she has been assigned as a primary or scientific reviewer, he or she is to notify the IRB staff so the submission can be re-assigned.

5.4 If an IRB member has a Conflicting Interest for review of research at a meeting, he or she is to notify the meeting chair, stay in the meeting room only to answer questions about the research, and to leave the meeting room for discussion and voting regarding that research.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 21 CFR §56.107(e)

7.2 45 CFR §46.107(e)

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7.3 AAHRPP elements I-9, II.1.D

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HRP-051 SOP: Consultation

1 PURPOSE

1.1 This procedure establishes the process for the IRB to obtain consultants.

1.2 The process begins when the IRB staff or IRB member has identified the need for consultation.

1.3 The process ends when the consultant has provided additional expertise to the IRB.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The IRB invites consultants with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.

3.2 Consultants with a Conflicting Interest may not provide information to the IRB.

4 RESPONSIBILITIES

4.1 For review by a convened IRB, IRB staff members carry out these procedures.

4.2 For Non-Committee Review, the Designated Reviewer or Staff Reviewer carries out these procedures.

5 PROCEDURE

5.1 Identify a consultant with the required expertise who can provide a review. Identify individuals as follows:

5.1.1 IRB members from other committees

5.1.2 Other employees of the organization

5.1.3 External consultants

5.2 Contact the consultant and determine availability for review.

5.3 Determine whether the consultant has a Conflicting Interest as defined in HRP-001 - SOP – Definitions. If so, obtain another consultant.

5.4 Use HRP-301 - WORKSHEET - Review Materials to determine which documents to make available to the consultant so the IRB can obtain the additional expertise needed, and make these documents available to the consultant. If the additional expertise needed does not require review of any materials, no materials need be provided.

5.5 For review by the convened IRB:

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5.5.1 Make the consultant's written comments, if any, available to the IRB members attending the meeting.

5.5.2 If the consultant did not provide a written report or if requested by an IRB member, invite the consultant to the IRB meeting.

5.6 For Non-Committee Review:

5.6.1 Directly obtain the information (oral or written) from the consultant.

5.6.2 Document information received with the name of the consultant.

6 MATERIALS

6.1 HRP-001 - SOP - Definitions

6.2 HRP-301 - WORKSHEET - Review Materials

7 REFERENCES

7.1 21 CFR §56.107(f)

7.2 45 CFR §46.107(e)

7.3 AAHRPP elements I.1.F, I-9, II.1.D, II.1.E, II.2.E-II.2.E.2

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HRP-052 SOP: Post-Review

1 PURPOSE

1.1 This procedure establishes the process for communications after a protocol is reviewed.

1.2 The process begins when:

1.2.1 A Designated Reviewer has completed a Non-Committee Review and provided completed materials to the IRB staff; OR

1.2.2 An IRB meeting has adjourned, and the IRB chair or IRB manager has approved the minutes; OR

1.2.3 An IRB staff member has verified that modifications required to secure approval have been made.

1.3 The process ends when all correspondence related to IRB determinations and actions have been sent and additional tasks have been completed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The IRB reports its findings and actions to the investigator.

3.2 The IRB reports its findings and actions to the institution.

3.3 When the IRB disapproves research, it provides the investigator with a statement of the reasons for the decision and gives the investigator an opportunity to respond in person or in writing.

3.4 Communication of review results to investigators are to be completed within 10 business days of the IRB meeting or 2 business days following the receipt of the completed Non-Committee Review materials.

3.5 When a modification is reviewed to lift a suspension for a previous Suspension of IRB Approval, the state of the study will change from “Suspended” to “Approved” when the modification is approved.

3.6 Reporting of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; and Unanticipated Problem Involving Risks to Subjects or Others to outside agencies is to take place within 30 business days from the determination of a reportable problem.

3.6.1 Reporting to OHRP only occurs for non-exempt Human Research that:

3.6.1.1 Is HHS-supported or conducted;

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3.6.1.2 Is conducted or supported by a Federal Agency that has adopted the Common Rule and has not approved a separate assurance, other than the FWA, for the research; OR

3.6.1.3 The institution has chosen to apply the Common Rule on its FWA to all its non-exempt Human Research regardless of the source of support.

3.6.2 Reporting to the FDA only occurs for FDA-regulated Human Research.

3.6.3 Reporting to OHRP or the FDA should not occur if any of the above criteria are not met.

3.7 If the report is determined to be an unanticipated problem involving risk to subjects or others for a multi-site study AND did not occur locally (meaning at any site under this IRB's purview) (e.g. the sponsor submits a protocol modification that includes a newly identified risk), reporting to OHRP and the FDA is not required.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 If the Non-Committee Review indicated a Conflicting Interest or a lack of expertise, follow HRP-031 - SOP - Non-Committee Review Preparation.

5.2 For initial reviews, continuing reviews, or modifications:

5.2.1 If the communication is an IRB determination of Approved:

5.2.1.1 For DHHS-regulated research involving prisoners, if HRP-415 – CHECKLIST – Prisoners reflects prisoners as a class or prisoners as controls, await OHRP approval before proceeding.

5.2.1.2 For NIJ-supported research, send the IRB approved Privacy Certificate to the IRB Chair or authorized institutional representative for signature.

5.2.1.2.1 Execute "Add Comment" and upload the signed Privacy Certificate to Supporting Documents; send notification to the PI/PI Proxy/Primary Contact.

5.2.1.3 Execute the "Finalize Documents" to stamp and accept all changes for attached documents.

5.2.1.4 Execute the "Prepare Letter" activity and modify the letter as needed.

5.2.1.5 Execute the "Send Letter" activity.

5.2.2 If the communication is an IRB determination other than Approved:

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5.2.2.1 Execute the “Prepare Letter” activity and modify the letter as needed.

5.2.2.2 Execute the “Send Letter” activity.

5.3 Refer to HRP-303 - WORKSHEET - Communication of Review Results to determine if any paper-based letters need to be sent.

5.3.1 Send the letter to the inside addresses and cc list as directed by the letter.

5.4 For continuing reviews or modifications to studies where enrollment is suspended and the submission does not change the enrollment suspension status, execute the “Suspend” activity in the study workspace, and document that the enrollment to the study remains suspended.

5.5 For determinations of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others:

5.5.1 If the determination was Serious Non-Compliance; Continuing Non-Compliance; or Unanticipated Problem Involving Risks to Subjects or Others:

5.5.1.1 Execute the "Prepare Letter" activity and modify the appropriate letter as needed.

5.5.1.2 Execute the "Send Letter" activity.

5.5.2 If the determination was Suspension of IRB Approval:

5.5.2.1 Execute the “Suspend” activity in the study workspace.

5.5.2.2 Execute the “Prepare Letter” activity in the study workspace and modify the letter as needed.

5.5.2.3 Execute the “Send Letter” activity.

5.5.3 If the determination was Termination of IRB Approval:

5.5.3.1 Execute the “Terminate” activity in the study workspace.

5.5.3.2 Execute the “Prepare Letter” activity in the study workspace and modify the letter as needed.

5.5.3.3 Execute the “Send Letter” activity.

5.5.4 When reporting to OHRP only, complete the *OHRP Incident Report Form*[xxiv].

5.5.5 If reporting to both OHRP and any other outside agency concurrently, utilize the OHRP Incident Report Form email confirmation and HRP-520a – LETTER – External Report – OHRP and Other Agencies.

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5.5.6 If reporting to other outside agencies NOT including OHRP, complete HRP-520 – LETTER – External Report NOT Including OHRP.

6 MATERIALS

6.1 HRP-031 - SOP - Non-Committee Review Preparation

6.2 HRP-303 - WORKSHEET - Communication of Review Results

6.3 HRP-520 - LETTER - External Report NOT Including OHRP

6.4 HRP-520a - LETTER - External Report OHRP and Other Agencies

7 REFERENCES

7.1 45 CFR §46.103(b)(4)(i), 45 CFR §46.109(d), 45 CFR §46.207, 45 CFR §46.305(c), 45 CFR §46.306(a)(1), 45 CFR §46.407, Informed Consent Requirements in Emergency Research (OPRR Letter, 1996)

7.2 21 CFR §56.108(a)(1), 21 CFR §109(e), 21 CFR §50.24(e), 21 CFR §50.54(b), 21 CFR §812.66

7.3 VHA Directive 1058.01 October 22, 2020

7.4 AAHRPP elements I.1.A, I.5.D, I-9, II.1.D, II.1.E, II.2.A, II.2.G, II.2.H, II.2.E-II.2.E.2, II.2.F-II.2.F.3, III.2.D

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HRP-054 SOP: Institutional Conflicts of Interest

1 PURPOSE

1.1 This procedure establishes the process to identify institutional financial interests that may cause an institutional conflict of interests.

1.2 The process begins when the Organizational Official/ Institutional Official (IO/OO) or designee is informed of a change in the institution's financial holdings outside of standard investments.

1.3 The process ends when the IRB staff are provided an updated list of the institution's financial holdings.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 An institutional financial conflict of interests exists when any of the following might affect the design, conduct, or reporting of research:

- 3.1.1 Licensing, technology transfer, patents
- 3.1.2 Investments of the organization
- 3.1.3 Gifts to the organization when the donor has an interest in the research
- 3.1.4 Financial interests of senior administrative officials
- 3.1.5 Other financial interests

3.2 Senior administrative officials are required to disclose their financial interests to the Conflict of Interests Officer:

- 3.2.1 Upon joining the organization
- 3.2.2 Every year
- 3.2.3 When there are changes to financial interests

3.3 The Technology Transfer Office, Research Grants Office, legal counsel, and the Conflict of Interests Officer are to notify the IO/OO or designee of any change in the institution's financial holdings not controlled by the institution's investment managers related to:

- 3.3.1 Licensing (e.g., licensing or technology transfer agreements)
- 3.3.2 Investments of the organization
- 3.3.3 Gifts to the organization when the donor has an interest in the research
- 3.3.4 Financial interests of senior administrative officials
- 3.3.5 Other financial interests

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3.4 The fiduciary responsibility of the institution's investment managers is to maintain a diversified portfolio of holdings that that meets the institution's goals in terms of capital appreciation, income, and risk. IO/OO may not influence the decisions of the institution's investment managers. This institution considers such investments to be similar to diversified mutual funds and not subject to disclosure under this policy.

3.5 The evaluation and management of an institutional conflict of interest may not vary by funding or regulatory oversight.

3.6 If an institutional financial holding related to prospective or ongoing Human Research is identified, it will be managed according to HRP-055 - SOP - Financial Conflicts of Interests.

4 RESPONSIBILITIES

4.1 The IO/OO or designee carries out these responsibilities.

5 PROCEDURE

5.1 Upon receipt of information of a change in financial interest update the list of investments that are not controlled by the institution's investment managers. Include information about the name of the company, the names of related companies, and affected products or services.

5.2 Provide a copy of the updated list to the IRB staff.

6 MATERIALS

6.1 HRP-055 - SOP - Financial Conflicts of Interests

7 REFERENCES

7.1 AAHRPP elements I.6.A, I-9

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HRP-055 SOP: Financial Conflicts of Interest

1 PURPOSE

1.1 This procedure establishes the process to evaluate a report of an individual financial interest of an investigator or research staff Related to the Research or an institutional financial interest Related to the Research.

1.2 The process begins when COI Office determines that an investigator or research staff has reported a financial interest Related to the Research or the IRB staff have detected an institution financial interest Related to the Research.

1.3 The process ends when the COI Office has evaluated the reported interest and communicated the results of this evaluation to the IRB.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The Research Compliance Director serves as the Conflicts of Interests Officer.

3.2 For any or all steps of this procedure, the Conflicts of Interests Officer may have the Conflicts of Interests Committee follow the procedure whenever the Conflicts of Interests Officer believes that institutional consensus is needed to make a decision.

3.3 Individuals are considered to have an institutional responsibility and are subject to this policy when they are involved in any of the following:

- 3.3.1 The design, conduct, or reporting of research
- 3.3.2 Research consultation
- 3.3.3 Teaching
- 3.3.4 Professional practice
- 3.3.5 Institutional committee memberships
- 3.3.6 Service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards

3.4 Individuals subject to this policy are required to complete financial conflicts of interest training initially, at least every four years, and immediately when:

- 3.4.1 Joining the organization.
- 3.4.2 Financial conflicts policies are revised in a manner that changes investigator requirements.
- 3.4.3 Non-compliant with financial conflicts policies and procedures.

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3.4.4 The financial conflicts of interest training requirements listed in SOP-055 supersede those listed in Policy Title: Financial Conflicts of Interest in Research.

3.5 Individuals subject to this policy are required to disclose their institutional responsibility to conduct research and the financial interests Related to the Research:

3.5.1 As part of an annual campaign.

3.5.2 When joining the organization as a researcher.

3.5.3 When initiating or joining a research project for the first time.

3.5.4 Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.

3.6 Additionally, individuals involved in the design, conduct, or reporting of research are required to disclose the presence of financial interests related to a research project in the SmartForm in the electronic IRB system at the following time points

3.6.1 On submission of an initial review.

3.6.2 As part of continuing review.

3.6.3 Via modification within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.

3.7 Travel disclosures are to include the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration.

3.8 Significant Financial Interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

3.8.1 With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

3.8.2 With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or

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dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

3.8.3 Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

3.9 Violations of this policy or proscribed management plans can lead to:

3.9.1 Loss or restriction of privileges to conduct research

3.9.2 Other employment actions as allowed by Human Resources Policies and Procedures.

3.10 Records related to disclosures and management of financial conflicts of interest are to be retained for at least three years from completion of the research.

4 RESPONSIBILITIES

4.1 The COI Officer carries out these procedures or ensures that a committee follows these procedures.

5 PROCEDURE

5.1 Ensure committee members do not participate in the review of any conflict of interests in which the member has Conflicting Interest.

5.2 Review the reported financial interest and the research protocol.

5.2.1 If the financial interest and research protocol has already been reviewed, and if needed, managed, notify the IRB staff of this determination in writing and stop processing subsequent steps of this procedure.

5.3 Determine whether the reported financial interest is related to the research.

5.3.1 If the financial interest is not related to the research, notify the IRB staff of this determination in writing and stop processing subsequent steps of this procedure.

5.4 Determine whether the reported financial interest could directly and significantly affect the design, conduct, or reporting (i.e., the reported financial interest is a conflict of interests) of the Human Research.

5.4.1 If there is no conflict of interests, notify the IRB staff of this determination in writing and stop processing subsequent steps of this procedure.

5.5 If a conflict of interests exists, determine under what circumstances, if any, should a conflicted individual (in the case of individual financial interest) or the organization (in case of institutional financial interest) be allowed to participate in:

5.5.1 Subject recruitment.

5.5.2 Prescreening for inclusion/exclusion criteria.

5.5.3 The consent process.

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5.5.4 The clinical treatment of subjects, separate from the research interventions or procedures.

5.5.5 Clinical evaluation of subjects during the research, separate from the research interventions or procedures, including adverse event evaluation and reporting.

5.6 Create a written management plan, considering the following options:

5.6.1 Public disclosure of the financial interests.

5.6.2 Disclosure of the financial interests to subjects.

5.6.3 Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest.

5.6.4 Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.

5.6.5 Reduction or elimination of the financial interest (e.g., sale of an equity interest).

5.6.6 Severance of relationships that create financial conflicts.

5.6.7 Modification of the research plan.

5.6.8 Involvement of external individuals in key portions of the protocol

5.6.9 Use of an external IRB.

5.6.10 A retrospective review.

5.6.11 A mitigation report.

5.6.12 A plan to monitor and enforce the implementation of the management plan.

5.7 Provide the written management plan to the involved individual or office for comment and review.

5.8 Finalize the written management plan.

5.9 Provide the IRB staff of the reviewing IRB with the written management plan so the IRB can make the final decision as to whether the financial interest and its management, if any, allows the research to be approved.

5.10 When required provide the final determination to the funding or regulatory agencies.

5.11 Maintain a copy of determinations and management plans in the records.

6 MATERIALS

6.1 None

7 REFERENCES

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7.1 42 CFR §50

7.2 45 CFR §94

7.3 AAHRPP elements I.6.A, I.6.B, I.7.A

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HRP-060 SOP: Annual Evaluations of the HRPP

1 PURPOSE

1.1 This procedure establishes the process to conduct annual evaluations of the Human Research Protection Program (HRPP).

1.2 The process begins the first business day of each June.

1.3 The process ends when all evaluations have been completed and communicated to those evaluated.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The human research protection program is evaluated annually.

3.2 The subject outreach program for enhancing the understanding of subjects, prospective subjects, and communities is accomplished by making the document HRP-104 - BROCHURE - Should I Take Part in Research available to the patient population.

4 RESPONSIBILITIES

4.1 The IRB Manager or their designee ensures completion of these procedures.

5 PROCEDURE

5.1 Have the Institutional Official/ Organizational Official (IO/OO) or designee evaluate the following resources provided to the human research protection program and make adjustments as part of the budgeting process.

5.1.1 Space

5.1.2 HRPP educational program

5.1.3 Legal counsel

5.1.4 Conflicts of interests

5.1.5 Quality improvement plan

5.2 Have the IO/OO or designee evaluate HRP-065 - SOP - Continuity Planning for HRPP Disruptions and make changes when appropriate.

5.2.1 When updates to HRP-065 - SOP - Continuity Planning for HRPP Disruptions are made, the IRB Director will designate appropriate IRB staff to make changes to associated educational materials for the HRPP research community.

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5.3 Have the IO/OO or their designee establish the annual compliance, quality, efficiency and effectiveness goals of the HRPP using HRP-603 - DATABASE - Quality and Compliance Improvement Tracker.

5.3.1 Review progress made towards the previous year's program goals.

5.3.2 Revise existing goals and/or create new goals.

5.4 Evaluate whether the number of IRBs is appropriate to the volume and types of research reviewed.

5.4.1 Provide a copy of the evaluation to the IO/OO or designee.

5.4.2 If the number of IRBs is not appropriate to the volume and types of research reviewed, work with the IO/OO or designee to modify the IRB structure.

5.5 Have the IO/OO or designee evaluate the knowledge, skills, and performance of each IRB chair using HRP-326 - WORKSHEET - Performance Evaluation for IRB Chairs.

5.5.1 Communicate the results of the evaluation to each IRB chair and the IO/OO or designee.

5.5.2 If needed, work with each IRB chair to develop a plan to improve the individual's knowledge, skills, and performance.

5.6 Have the IRB chair or IRB manager evaluate the knowledge, skills, and performance of each regular and alternate IRB member using HRP-327 - WORKSHEET - Performance Evaluation for IRB Members.

5.6.1 Have the IRB Chair or IRB Manager utilize HRP-327 - WORKSHEET - Performance Evaluation for IRB Members to complete the evaluation. Communicate the results of the evaluation to each IRB member and the IO/OO or designee.

5.6.2 Send a copy of HRP-562 - LETTER - IRB Member Appreciation to the IRB member's supervisor.

5.6.3 If needed, work with each IRB member to develop a plan to improve the individual's knowledge, skills, and performance.

5.7 Follow the Human Resources annual employee evaluation process to evaluate the knowledge, skills, and performance of IRB staff. Use HRP-328 - WORKSHEET - Performance Evaluation for IRB Staff as part of the evaluation.

5.7.1 Document the results of this evaluation as part of the annual employee evaluation process.

5.7.2 Provide a copy of the evaluation to the IO/OO or designee.

5.7.3 Provide each IRB staff with a copy of his or her evaluation.

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5.7.4 If needed, work with each IRB staff person to develop a plan to improve the individual's knowledge, skills, and performance.

5.8 Verify IRB registrations are current, consistent with HRP-080 - SOP - IRB Formation and Registration.

5.9 Verify the federalwide assurance (FWA) is current, consistent with HRP-080 - SOP - IRB Formation and Registration.

5.10 Verify HRP-601 - WORKSHEET - IRB Roster is current and use HRP-304 - WORKSHEET - IRB Composition to evaluate whether the composition of the IRB meets regulatory and organizational requirements.

5.10.1 Provide a copy of the evaluation to the IO/OO or designee.

5.10.2 If the composition of an IRB does not meet regulatory and organizational requirements, work with the IO/OO or designee to modify the IRB composition.

5.11 Check whether each member of a Veteran's Administration (VA) IRB or VA representative has been a member longer than 2 years, and if so, send the member HRP-560 - LETTER - IRB Member Appointment.

5.12 Evaluate whether there are outstanding updates that need to be made to standard operating procedures and associate checklists and worksheets.

5.12.1 If needed, work with IRB staff to develop a plan to implement necessary updates consistent with HRP-071-SOP-Toolkit Management.

5.13 Evaluate the subject outreach plan.

5.13.1 Consider the following areas when evaluating the outreach plan:

5.13.1.1 Whether the existing scope and content of HRPP outreach materials, including HRP-104 – BROCHURE – Should I Take Part in Research, continue to be adequate;

5.13.1.2 Whether modifications to existing outreach materials are necessary;

5.13.1.3 Whether or not the HRPP's existing materials are being regularly utilized by the IRB Office or by members of the research community in their own interaction with the communities in which they conduct research;

5.13.1.4 Whether there are new opportunities to provide outreach activities to the community, and;

5.13.1.5 Whether additional information is needed from the research community to assess the extent to which outreach materials are used and outreach activities take place.

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5.13.2 Provide a copy of the evaluation to the IO/OO or designee.

5.13.3 If the subject outreach program is not meeting organizational goals, work with the IO/OO or designee to modify the plan. Modifications may include, but are not limited to:

5.13.3.1 Modifying existing outreach materials;

5.13.3.2 Developing new materials;

5.13.3.3 Surveying the research community to identify and participate in additional outreach opportunities, and;

5.13.3.4 Working directly with community organizations to identify and participate in additional outreach opportunities.

6 MATERIALS

6.1 HRP-065 - SOP - Continuity Planning for HRPP Disruptions

6.2 HRP-071 - SOP - Toolkit Management

6.3 HRP-080 - SOP - IRB Formation and Registration

6.4 HRP-104 - BROCHURE - Should I Take Part in Research

6.5 HRP-304 - WORKSHEET - IRB Composition

6.6 HRP-326 - WORKSHEET- Performance Evaluation for IRB Chairs

6.7 HRP-327 - WORKSHEET - Performance Evaluation for IRB Members

6.8 HRP-328 - WORKSHEET - Performance Evaluation Criteria for IRB Staff

6.9 HRP-560 - LETTER - IRB Member Appointment

6.10 HRP-562 - LETTER - IRB Member Appreciation

6.11 HRP-601 - DATABASE - IRB Roster

6.12 HRP - 603-DATABASE - Quality and Compliance Improvement Tracker

7 REFERENCES

7.1 AAHRPP elements I.1.A, I-2, I.4.B, II.1.A-D

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HRP-061 SOP: Quarterly Evaluations of the HRPP

1 PURPOSE

1.1 This procedure establishes the process to conduct quality improvement of the Human Research Protection Program (HRPP).

1.2 The process begins the first business day of each quarter.

1.3 The process ends when all evaluations have been completed and if needed, acted upon.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The goal of the quality improvement plan is to achieve and maintain compliance and to achieve targeted levels of quality, efficiency, and effectiveness of the HRPP.

3.2 Objectives of the quality improvement program are to:

3.2.1 Improve compliance of investigators with their responsibilities.

3.2.2 Improve compliance of minutes with regulatory compliance.

3.2.3 Increase efficiency of recording and finalizing minutes.

3.3 The measures of the quality improvement program are defined in:

3.3.1 HRP-430 - CHECKLIST - Investigator Quality Improvement Assessment

3.3.2 HRP-431 - CHECKLIST - Minutes Quality Improvement Assessment

4 RESPONSIBILITIES

4.1 The IRB Manager or their designee ensures completion of these procedures.

5 PROCEDURE

5.1 Conduct Investigator QI Assessment:

5.1.1 At least quarterly, complete HRP-534 - LETTER - Investigator QI Assessment and send HRP-430 - CHECKLIST - Investigator Quality Improvement Assessment to a minimum of 5 investigators.

5.2 Complete HRP-431 - CHECKLIST - Minutes Quality Improvement Assessment on the minutes of the previous quarter. Track compliance and the days required to complete minutes.

5.3 Review the results of HRP-430 - CHECKLIST - Investigator Quality Improvement Assessment and HRP-431 - CHECKLIST - Minutes Quality Improvement Assessment to track results and examine for significant trends.

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5.4 Send the results to the IRB manager and Institutional Official/ Organizational Official (IO/OO) or designee.

5.4.1 If the results of any evaluations demonstrate inconsistency, recurring noncompliance or misinterpretation of HRPP requirements, high variability, or are outside performance targets, work with the IRB manager and IO/OO to implement an intervention.

5.4.2 Interventions may include policy and procedure modifications, education and training efforts, system modifications, and/or other corrective actions.

5.4.3 Document and track the intervention using HRP-603 - DATABASE - Quality and Compliance Improvement Tracker.

6 MATERIALS

6.1 HRP-430 - CHECKLIST - Investigator Quality Improvement Assessment

6.2 HRP-431 - CHECKLIST - Minutes Quality Improvement Assessment

6.3 HRP-534 - LETTER - Investigator QI Assessment

6.4 HRP-603 - DATABASE - Quality and Compliance Improvement Tracker

7 REFERENCES

7.1 AAHRPP elements I.5.A, I.5.B, I.5.D, I-9

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HRP-063 SOP: Expiration of IRB Approval

1 PURPOSE

1.1 This procedure establishes the process for a Designated Reviewer to determine whether current subjects may continue in expired research.

1.2 The process begins when the Designated Reviewer is notified of a request by an investigator of a request for current subjects to continue in expired research.

1.3 The process ends when the Designated Reviewer has communicated a decision and documented the decision in writing.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 If research is granted “Modifications Required to Secure Approval” and expires before responsive materials are reviewed and approved, these procedures are to be followed.

4 RESPONSIBILITIES

4.1 A Designated Reviewer is responsible to follow these procedures.

5 PROCEDURE

5.1 Determine from the investigator which subjects need to continue in the expired research, what procedures are being requested to continue, and why.

5.2 Do not allow new subjects to be enrolled under any circumstances.

5.3 Determine which subjects can continue in the research based on these principles:

5.3.1 In general, research procedures should be safely discontinued.

5.3.2 In general, the only research procedures that should continue are those that are not available outside of the research context. If the required procedures can be provided as standard of care, these should be provided as such.

5.3.3 In general, research procedures conducted to collect data with no direct benefit to the subject should not continue.

5.3.4 In some cases, an ethical issue may be raised where the above general principles may not be followed.

5.4 Communicate with the investigator using HRP-532 - LETTER - Conti Subj Expired Research.

6 MATERIALS

6.1 HRP-532 - LETTER - Conti Subj Expired Research

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7 REFERENCES

7.1 AAHRPP elements II.2.E-II.2.E.2, II.2.F-II.2.F.3

7.2

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HRP-064 SOP: NIH Genomic Data Sharing (GDS) Institutional Certification

1 PURPOSE

1.1 This procedure establishes the process to certify approval for investigator submission of large-scale human genomic data to an NIH-designated data repository.

1.2 The process begins when an investigator contacts IRB staff for certification of the genomic data sharing plan.

1.3 The process ends when the Institutional Official/ Organizational Official (IO/OO) has certified and communicated to the investigator.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Investigators must request certification from IRB staff prior to investigator submission of large-scale human genomic data or approval of funding.

4 RESPONSIBILITIES

4.1 The IRB Director or designee verifies for the IO/OO that all data meet criteria for submission to the data repository.

5 PROCEDURE

5.1 Use HRP-332 - WORKSHEET - NIH GDS Institutional Certification to evaluate and document whether the investigator's genomic data sharing plan meets the criteria for submission to a NIH-designated data repository.

5.2 Populate the applicable NIH Extramural Institutional Certification form. Pass the letter to the IO/OO for review and certification.

5.2.1 Provide NIH Provisional Institutional Certification when required by investigators prior to IRB review of the data sharing plan.

5.3 Save a copy of the signed form in IRB Office records.

5.4 Communicate certification approval to the investigator and provide a copy of the signed GDS Institutional Certification form for the investigator to forward to the NIH.

6 MATERIALS

6.1 HRP-332 - WORKSHEET - NIH GDS Institutional Certification

7 REFERENCES

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7.1 National Institutes of Health Final Genomic Data Sharing Policy (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html)

7.2 NIH Institutional Certifications (https://grants.nih.gov/policy-and-compliance/policy-topics/sharing-policies/gds/institutional-certifications)

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HRP-065 SOP: Continuity Planning for HRPP Disruptions

1 PURPOSE

1.1 This SOP establishes the process for initiating a response to an emergency, disaster, or other disruptive event impacting the HRPP or essential HRPP operations. Challenges to HRPP operations or the conduct of Human Research may arise, for example, from:

1.1.1 Extreme weather events.

1.1.2 Natural disasters.

1.1.3 Man-made disasters.

1.1.4 Infectious disease outbreaks.

1.1.5 Loss or failure of facilities, equipment and/or information security standards.

1.1.6 Significant and unexpected loss of institutional funding and/or workforce.

1.2 The process starts when an emergency/disaster situation or other significant disruption impacting the HRPP has occurred, or in preparation for scenarios where a potential emergency situation or significant disruption is imminent and HRPP operations and/or the ability of investigators to conduct Human Research is, or is likely to be, adversely impacted.

1.3 The process ends when the impact to the HRPP and the conduct of Human Research is assessed, and appropriate guidance is provided to HRPP personnel and the broader Human Research community.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 HRPP leadership defers to designated institutional leadership and institution-wide emergency response planning and limits HRPP-specific emergency response planning only to those areas of operations or human research protections not otherwise covered by institution-level plans.

3.2 The HRPP evaluates its emergency response plans at least annually in accordance with the HRP-101 - Human Research Protection Program Plan and HRP-060 - SOP - Annual Evaluations of the HRPP.

4 RESPONSIBILITIES

4.1 The IRB Director or designee is responsible for carrying out these procedures.

5 PROCEDURE

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5.1 If an emergency/disruption has occurred, or there is an imminent possibility of an upcoming emergency/disruption, assess the nature of the event and the appropriate response.

5.1.1 Consult HRP-101 - Human Research Protection Program Plan to reference existing HRPP specific or institution specific emergency preparedness plans or information already in place.

5.1.2 Contact the IO/OO and/or designated institutional personnel responsible for institutional level emergency preparedness, where applicable, and determine whether there are (or will be) institution level emergency preparedness plans relevant to the current or anticipated emergency.

5.1.2.1 If yes, proceed in accordance with those plans and determine whether further actions and/or notification specific to the human research community is necessary.

5.1.2.2 Based on the nature of the emergency/disruption, further action may include determining the types of studies for which study initiation should be postponed, the types of studies for which recruitment should be halted but research activities continued with existing subjects, and the types of studies that can continue via alternate mechanisms. In making this determination, consider whether the study:

5.1.2.2.1 Presents a likelihood of direct benefit to subjects;

5.1.2.2.2 Does not involve interaction or intervention that creates increased risk;

5.1.2.2.3 Involves direct interaction or intervention but can manage risks by conducting study procedures via alternate mechanisms;

5.1.2.2.4 Will have an adverse impact on resources required to address the emergency/disruption.

5.2 Assess whether the emergency/disruption has or could impact IRB operations:

5.2.1 If the current or anticipated emergency/disruption will prevent any upcoming IRB meetings from properly convening in-person, and an in-person meeting was planned, determine whether the meeting can be conducted virtually or via teleconference.

5.2.1.1 If yes, work with IRB members and staff to arrange for a virtual meeting. Follow HRP-040 - SOP - IRB Meeting Preparation to confirm quorum and availability of IRB members.

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5.2.1.2 If a virtual meeting is also not feasible under the circumstances caused by the emergency/disruption, determine whether to cancel or reschedule the meeting(s).

5.2.1.3 If currently approved Human Research has or will expire prior to IRB review due to the IRB meeting cancelation/rescheduling, follow HRP-063 - SOP - Expiration of IRB Approval.

5.2.2 If IRB staff will be unable to complete their protocol processing and review responsibilities during the emergency/disruption, or if capacity will be limited for a period of time:

5.2.2.1 Work with the staff to use any available capacity to prioritize processing submissions related to assuring the safety of research subjects. E.g., continuing review submissions and submissions (new studies, modifications, and reportable new information) related to responding to and/or mitigating risks resulting from the emergency/disruption.

5.2.2.2 If currently approved Human Research has or will expire prior to IRB review due to IRB office capacity limitations follow HRP-063 - SOP - Expiration of IRB Approval.

5.2.2.3 Work with the IO/OO to notify the research community of the IRB Office's limited capacity to process and review submissions.

5.2.2.4 When the emergency/disruption no longer presents a limitation to IRB Office functions, work with the IO/OO to notify IRB members and staff and the research community that normal business operations have resumed.

5.2.3 If the impact to local IRB operations will be extensive or long-lasting, determine whether reliance on an external IRB(s) is required.

5.2.3.1 If reliance on one or more external IRBs is required and the necessary reliance agreements are not currently in place, work with the IO/OO to identify appropriate candidates for external IRB reliance and follow HRP-801 - SOP - Establishing Reliance Agreements.

5.2.4 If data or records (paper or electronic) are unavailable during the current or anticipated emergency/disruption, implement alternative procedures to access and back up data/records. Consult with local IT support and/or electronic system vendors, when appropriate.

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5.3 Assess whether the emergency/disruption necessitates additional flexibility in IRB review processes. If yes:

5.3.1 Review HRP-352 - WORKSHEET - Additional Emergency-Disruption Review Considerations with the IRB Chair(s) and staff in advance of upcoming IRB meetings.

5.3.2 Communicate to IRB Members (including Designated Reviewers performing non-committee reviews) that the additional considerations in the worksheet may be incorporated into IRB reviews where appropriate to maximize regulatory flexibility while continuing to ensure research subject safety during the emergency/disruption.

5.3.3 Determine whether additional communications to the research community are necessary to inform investigators of any additional measures the IRB will take to maximize regulatory flexibility during the emergency.

5.4 Assess whether the emergency/disruption has or could impact some or all investigators' ability to conduct Human Research. If yes:

5.4.1 Notify the research community of the need for protocol-specific emergency/disruption risk mitigation planning. Use HRP-542 - LETTER - Implementation of HRPP Emergency-Disruption Response Plan.

5.4.2 Provide investigators with copies of (or links to) HRP-108 - FLOWCHART - Study-Specific Emergency-Disruption Risk Mitigation Planning.

5.4.3 Provide investigators with copies of (or links to) HRP-351 - WORKSHEET - Protocol-Specific Emergency-Disruption Risk Mitigation Planning.

5.4.4 If the emergency/disruption has or could impact clinical care standards which could in turn impact research, develop guidance for researchers that clarifies what does and does not require IRB review (e.g., screening procedures mandated by the health care system in which a clinical trial is being conducted).

5.4.5 When the emergency/disruption no longer presents a limitation to Human Research activities, work with the IO/OO to notify the research community that normal business operations have resumed.

5.5 Evaluate whether the nature of the emergency/disruption has or could pose additional threats or risks to specific aspects of the broader HRPP. For example, man-made disasters, industrial accidents, or terrorist threats could potentially impact some chemical, biological, or radiologic facilities to a greater extent than other facilities; cybersecurity attacks could broadly impact institutional

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data/records, and unanticipated cuts/freezes in funding and/or workforce could impact the ability to carry out HRPP responsibilities.

5.5.1 If yes, and if broader institution-level emergency preparedness measures do not already address these specific threats, work with the IO/OO and appropriate institutional leadership (e.g., Grants and Contracts Office, Billing Compliance, Facilities/Environmental Services, Information Technology) to escalate and address any additional threats or risks.

6 MATERIALS

6.1 HRP-040 - SOP - IRB Meeting Preparation

6.2 HRP-060 - SOP - Annual Evaluations of the HRPP

6.3 HRP-063 - SOP - Expiration of IRB Approval

6.4 HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN

6.5 HRP-108 - FLOWCHART - Study-Specific Emergency-Disruption Risk Mitigation Planning

6.6 HRP-351 - WORKSHEET - Protocol-Specific Emergency-Disruption Risk Mitigation Planning

6.7 HRP-352 - WORKSHEET - Additional Emergency-Disruption Review

6.8 HRP-542 - LETTER - Implementation of HRPP Emergency-Disruption Response Plan

6.9 HRP-801 - SOP - Establishing Reliance Agreements

7 REFERENCES

7.1 AAHRPP Element I.1.H

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HRP-066 SOP: Institutional Review Board Federal Inspections

1 PURPOSE

1.1 This procedure establishes the process to manage federal regulatory inspections of the IRB.

1.2 The process begins when the IRB is notified of an upcoming inspection.

1.3 The process ends when the regulatory agency notifies the IRB the inspection has concluded, based on the agency's procedures and the findings observed. E.g., the inspection process may conclude at the exit interview if no findings are observed, or additional determination letters/reports and further follow-up from the IRB may be required.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 IRB records subject to oversight by the agency conducting the inspection are made accessible for inspection in accordance with HRP-072 - SOP - IRB Records Retention.

4 RESPONSIBILITIES

4.1 The Institutional Official/Organizational Official (IO/OO) is responsible for the acknowledgement and oversight of the IRB inspection. Additionally, is it the responsibility of the IO/OO to review any written response to findings raised during the inspection.

4.2 The IRB Manager or designee is responsible for carrying out these procedures.

5 PROCEDURE

5.1 If notification of the inspection is provided in advance, ask the inspector for the following details (if not provided):

5.1.1 Inspector's name and contact information.

5.1.2 Date and time the inspection will start.

5.1.3 Anticipated duration of the inspection.

5.1.4 In person or virtual.

5.1.5 Scope of the inspection and inspection type (i.e., surveillance/not-for-cause vs. directed/for-cause).

5.1.6 Any specific areas of concern, materials or files to have available for review, and/or individuals they will interview.

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5.2 Notify the IO/OO, IRB chair(s), IRB members, IRB staff, and all other pertinent parties of the inspection.

5.2.1 If applicable, notify IT the inspector will need read-only access to applicable studies within the electronic system, based on the agency conducting the inspection.

5.2.2 Notify Huron Consulting Group of the inspection.

5.3 Communicate expectations and responsibilities of IO/OO, IRB chair(s) and IRB staff during, and in preparation of, the inspection.

5.3.1 The IO/OO, IRB chair(s), and IRB Manager should be available for interview (including the entrance and exit interviews) and/or consultation during the inspection.

5.3.2 Designate at least one senior level staff member to be the inspector's point of contact, responsible for:

5.3.2.1 Participating in the entrance briefing.

5.3.2.2 Answering questions on behalf of the institution.

5.3.2.3 Always being available to the inspector during the inspection.

5.3.2.4 Locating all requested information and/or individuals the inspector requests interviews with.

5.3.2.5 Preparing documents.

5.3.2.6 Making copies.

5.3.2.7 Debriefing with the inspector.

5.3.2.8 When necessary, assigning additional staff members the responsibility of supporting the point of contact (e.g., in locating information, making copies, and/or providing IT expertise when inspections are conducted remotely).

5.4 Prepare to provide the following to the inspector:

5.4.1 HRPP Toolkit documents including all SOPs, general documents, forms, worksheets, and checklists.

5.4.1.1 Review HRP-105 - OHRP FDA Written Procedure Crosswalk to ensure all information is correct and includes up-to-date document versions.

5.4.2 Recent updates to the IRB registration and federal wide assurance (FWA) in accordance with HRP-080 - SOP - IRB Formation and Registration and HRP-081 - SOP - IRB Removal.

5.4.3 A list of active protocols subject to oversight by the agency conducting the inspection.

5.4.3.1 Include/identify any protocols meeting criteria specifically requested by the inspector (e.g. studies involving children).

5.4.4 IRB membership records, including HRP-601 - DATABASE - IRB Roster.

5.4.5 IRB meeting minutes.

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5.4.5.1 Minutes that have not yet been finalized should be identified as drafts.

5.4.6 Organizational (or personnel) charts identifying:

5.4.6.1 The IRB office within the institutional reporting structure.

5.4.6.2 IRB staff within the IRB's reporting structure.

5.4.7 IRB records, as identified in HRP-070 - SOP - IRB Records.

5.4.7.1 If an electronic submission system is utilized, determine whether the inspector will be provided read-only access or hard copy files.

5.4.8 If the inspection is occurring on-site:

5.4.8.1 A private office or conference room for the inspector to work in that, when possible, is not located directly in the IRB office but in the vicinity and is spacious enough to accommodate meetings with multiple individuals.

5.4.8.2 Access to the building, as well as a copy machine and internet.

5.5 At the start of the inspection:

5.5.1 Ask the inspector to present their credentials (if not already provided). Ensure the individual conducting the inspection has the authority to do so.

5.5.1.1 Confirm the center (e.g., CDER, CDRH) that has requested the inspection.

5.5.1.2 Questions or concerns regarding the legitimacy of the credentials should be directed to the agency conducting the interview.

5.5.2 For inspections conducted by the Food & Drug Administration (FDA), ask the inspector for FDA Form 482 "Notice of Inspection" (if not provided).

5.5.3 If on-site, provide an orientation to the facility to the inspector and escort them to their workspace.

5.5.4 During the entrance briefing:

5.5.4.1 Provide the inspector with a copy of HRP-105 - OHRP FDA Written Procedure Crosswalk.

5.5.4.2 Request a daily debrief at the end of each day. The inspector may not be required to provide this service, but if willing, provides an opportunity to clarify questions.

5.6 Document all activities that take place during the inspection to facilitate addressing any findings and/or responding to questions following the inspection. Documentation should replicate records the inspector maintains. This includes (but is not limited to) maintaining:

5.6.1 A list of all individuals who attend the entrance briefing, all debrief meetings, and the exit interview, as well as minutes of these meetings.

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5.6.2 All documents provided by the inspector to the IRB.
5.6.3 A list of all materials provided to the inspector.
5.6.4 Questions asked by the inspector and corresponding responses.
5.6.5 A list of all staff interviewed by the inspector and notes on any post-interview debriefs.
5.6.6 A list of all attendees and notes on any convened board meetings the inspector observes.
5.6.6.1 IRB meeting minutes should document the presence of the inspector.
5.6.6.2 Questions should only be directed to the inspector at the start and/or close of the meeting; they should not participate in the review/discussion of materials on the agenda.
5.6.7 Copies of all documents the inspector copies.

5.7 During the exit interview, request clarification as necessary on the following:
5.7.1 Any discrepancies or findings identified, either verbally or in writing by the inspector and their rationale.
5.7.2 Next steps, including if and when a formal inspection report or evaluation will be provided to the IRB and how and when to respond to the report.
5.7.3 Any other anticipated actions that may be taken by the regulatory agency.

5.8 Following the inspection:
5.8.1 Debrief with the IO/OO and IRB chair(s) to review findings and determine appropriate corrective actions measures. Respond, in writing, as directed by the regulatory agency to all written reports/evaluations.
5.8.1.1 If the inspection was conducted by the FDA and a Form 483 "Inspectional Observations" was issued, respond within 15 business days.[xxv]
5.8.2 Ensure all corrective actions are specific, measurable, designed to address the root cause of the non-compliance, and include a timeline for implementation.
5.8.2.1 Following implementation, at an appropriate time based on the action, evaluate all corrective actions to confirm the non-compliance has been appropriately addressed.
5.8.3 Promptly implement all corrective actions and, if applicable, all actions required by the regulatory agency.

6 MATERIALS

6.1 HRP-024 - SOP - New Information
6.2 HRP-070 - SOP - IRB Records
6.3 HRP-072 - SOP - IRB Records Retention
6.4 HRP-080 - SOP - IRB Formation and Registration

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6.5 HRP-081 - SOP - IRB Removal

6.6 HRP-105 - OHRP FDA Written Procedure Crosswalk

6.7 HRP-601 - DATABASE - IRB Roster

7 REFERENCES

7.1 FDA Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors "FDA Institutional Review Board Inspections", January 2006.

7.2 Office for Human Research Protection's Compliance Oversight Assessments, January 2024.

7.3 Public Responsibility in Medicine & Research (PRIM&R) & Bankert, E.A. (2005, 2021). *Institutional Review Board: Management and Function* (2nd & 3rd ed.). Jones & Bartlett Publishers.

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HRP-070 SOP: IRB Records

1 PURPOSE

1.1 This procedure establishes the process to maintain IRB records.

1.2 The process begins when records are received or created.

1.3 The process ends when records have been filed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 IRB records are to include:

- 3.1.1 Protocol files.
- 3.1.2 Minutes of IRB meetings.
- 3.1.3 Copies of all correspondence between the IRB and the investigators.
- 3.1.4 Current and all previous IRB member rosters.
- 3.1.5 Current and all previous IRB member files.
- 3.1.6 Current and all previous policies and procedures.

3.2 Protocol files are to include, as applicable:

- 3.2.1 All submitted materials.
- 3.2.2 Protocols.
- 3.2.3 Investigator brochures.
- 3.2.4 Scientific evaluations.
- 3.2.5 Recruitment materials.
- 3.2.6 Consent documents.
- 3.2.7 DHHS-approved sample consent document and protocol, when they exist.
- 3.2.8 Progress reports submitted by investigators.
- 3.2.9 Reports of injuries to subjects.
- 3.2.10 Records of continuing review activities, including the rationale for requiring continuing review of research that otherwise would not require continuing review when applicable under the 2018 Rule.
- 3.2.11 Data and safety monitoring board reports.
- 3.2.12 Amendments.
- 3.2.13 Reports of unanticipated problems involving risks to subjects or others.
- 3.2.14 Documentation of non-compliance.

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3.2.15 Correspondence between the IRB and investigator related to the protocol.

3.2.16 Significant new findings and statements about them provided to subjects.

3.2.17 For initial and continuing review of research by the expedited procedure:

3.2.17.1 The specific permissible category.

3.2.17.2 Description of action taken by the reviewer.

3.2.17.3 Any findings required under the regulations.

3.2.17.4 The rationale for a determination that research that otherwise meets a category for expedited review is greater than Minimal Risk.

3.2.18 For exemption determinations the specific category of exemption.

3.2.19 Unless documented in the IRB minutes determinations required by the regulations and protocol-specific findings supporting those determinations for.

3.2.19.1 Waiver or alteration of the consent process.

3.2.19.2 Research involving pregnant women, fetuses, and neonates.

3.2.19.3 Research involving children.

3.2.19.4 Research involving adults unable to consent.

3.2.19.5 Significant/non-significant device determinations.

3.2.20 For each protocol's initial and continuing review, the frequency for the next continuing review, including the rationale for requiring continuing review for protocols approved by expedited review that otherwise would not require continuing review.

3.2.21 The institution will maintain record of all research conducted by the organization reviewed by an external IRB. Records will include all materials identified in section 3.2

3.3 Policies and procedures include:

3.3.1 Checklists.

3.3.2 Forms.

3.3.3 SOPs.

3.3.4 Template letters.

3.3.5 Template minutes.

3.3.6 Worksheets.

3.4 IRB member files include a resume for each IRB member.

4 RESPONSIBILITIES

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4.1 IRB staff members are responsible to carry out these procedures.

5 PROCEDURE

5.1 Minutes of IRB meetings: Save minutes in electronic system.

5.2 Store all protocol-specific information (communications, documents, determinations) in the electronic system.

5.3 File correspondence NOT related to a specific protocol in an electronic folder related to that person or topic.

5.4 IRB member rosters: Save in IRB member roster electronic folder

5.5 IRB membership records (e.g., curricula vita and resumes): Save in IRB member electronic files.

5.6 Policies and procedures:

5.6.1 File current policies and procedures in the policies and procedures current file.

5.6.2 File replaced policies and procedures in the policies and procedures history file.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 AAHRPP elements I.1.A, I-9, II.5.A

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HRP-071 SOP: Toolkit Management

1 PURPOSE

1.1 This procedure establishes the process to create and update standard operating procedures and associated checklists and worksheets.

1.2 The process begins when the IRB manager or Institutional Official/ Organizational Official (IO/OO) or designee determines that a standard operating procedure needs to be created or modified.

1.3 The process ends when the new or revised standard operating procedure has been approved and filed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 For all new or revised standard operating procedures, review is conducted of all associated Toolkit documents and if additional changes are warranted, each document is updated per the procedures below.

4 RESPONSIBILITIES

4.1 The IRB manager carries out these procedures.

5 PROCEDURE

5.1 For a new Toolkit document:

- 5.1.1 Assign a number.
- 5.1.2 Assign an author and approver.
- 5.1.3 Have the author create the standard operating procedure following HRP-505 - TEMPLATE SOP.
- 5.1.4 Have the approver review and approve the document.

5.2 For a revision to a previously approved Toolkit documents:

- 5.2.1 Edit the current document using the tracked changes feature in MS Word.
- 5.2.2 Update Section 2 (Revisions from Previous Version) and include:
  - 5.2.2.1 A short summary of changes,
  - 5.2.2.2 The date of the most recent previous approval.
- 5.2.3 Have the approver review and approve the document.

5.3 Once approved by the approver:

- 5.3.1 Update the approval/effective date.
- 5.3.2 File and maintain the approved revised document in the standard operating procedure files.

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5.3.3 When necessary, update HRP-100 - HRPP Toolkit Table of Contents, HRP-105 - OHRP FDA Written Procedure Crosswalk, and all other applicable Toolkit documents to reflect the new/revised document.

5.3.4 Post the approved procedure on the Human Research Protection Program public, MaineHealth internal, and the electronic system library sites as applicable.

5.3.5 File and retain the previous version in the standard operating procedure files.

5.3.6 Send an email to affected individuals informing them of the change.

6 MATERIALS

6.1 HRP-100 - HRPP Toolkit Table of Contents

6.2 HRP-105 - OHRP FDA Written Procedure Crosswalk

6.3 HRP-505 - TEMPLATE SOP

7 REFERENCES

7.1 AAHRPP elements I-9, II.5.A

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HRP-072 SOP: IRB Records Retention

1 PURPOSE

1.1 This procedure establishes the process to retain IRB records.

1.2 The process begins each year in June.

1.3 The process ends when records that no longer need to be retained are destroyed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Protocol files are to be retained as long as required by law and then destroyed.

3.2 All records not in protocol files are retained indefinitely.

3.3 Records may be maintained in printed form or electronically.

3.4 Protocols in which no subject enrollment occurred or no research was conducted are to be retained the same as protocols where research was conducted.

3.5 All records for research conducted or funded by a Common Rule department or agency are to be accessible for inspection and copying by authorized representatives of that agency at reasonable times and in a reasonable manner.

3.6 Records maintained that document compliance or non-compliance with Department of Defense DOD) regulations shall be made accessible for inspection and copying by representatives of the DOD at reasonable times and in a reasonable manner as determined by the supporting DOD component.

3.7 All records for research subject to FDA regulations are to be accessible for inspection and copying by authorized representatives of FDA at reasonable times and in a reasonable manner.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 Destroy protocol files for the Department of Defense (DOD) research when approved by the Department of Defense. The agency may require submitting records to the Department of Defense for archiving.

5.2 Destroy all other protocol files when the protocol has been closed, withdrawn, or terminated more than 6 years after completion of research unless otherwise required by law.

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5.2.1 In the case of multi-center research, 6 years after completion of research is referenced to the organization's involvement in the research, not the entire study.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 AAHRPP elements I.1.A, I-9, II.5.A, 11.5B

7.2 DoDI 3216.02

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HRP-080 SOP: IRB Formation and Registration

1 PURPOSE

1.1 This procedure establishes the process to form a new IRB or update the OHRP IRB registration of an existing IRB.

1.2 The process begins when the Institutional Official/ Organizational Official (IO/OO) or designee determines the need for a new IRB or updated OHRP IRB registration.

1.3 The process ends when the IRB is registered, the federalwide assurance (FWA) is updated (if needed), and all members have completed training (if needed).

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.

3.2 A FWA will be submitted or updated as follows:

3.2.1 To engage in human subjects research that is not exempt from the regulations, and is conducted or supported by any HHS agency.

3.2.2 To list the institution's legal components that operate under different names that will be covered by the FWA and the city and state or country where the component is located.

3.2.3 To designate all internal IRBs (or external IRBs that review the largest percentage of research if the institution does not have an internal IRB) that will review research covered by the FWA.

3.2.4 Within 90 days after changes regarding the legal name of the institution, the Human Protections Administrator, or the Signatory Official.

3.3 FWAs are renewed every 5 years, even if no changes occur. Any renewal or update approved by OHRP begins a new 5-year effective period.

3.4 IRB registrations on file with OHRP will be made or updated as follows:

3.4.1 To register any additional IRB before it is designated under an FWA and reviews research conducted or supported by HHS.

3.4.2 Within 90 days after changes regarding the contact person who provided the IRB registration information, the IRB chairperson, or changes to the IRB membership roster.

3.4.3 Within 30 days of the change if an FDA-regulated IRB decides to review additional types of FDA-regulated products (e.g., to review device studies

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if it only reviewed drug studies previously) or to discontinue reviewing clinical investigations regulated by FDA.

3.4.4 Within 30 days of permanent cessation of the IRB's review of HHS-conducted or supported research when an institution disbands a registered IRB that it is operating.

3.4.5 IRB registration must be renewed every 3 years, even if no changes occur. Any renewal or update accepted by OHRP begins a new 3-year effective period.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

4.2 The IO/OO or designee appoints IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs.)

5 PROCEDURE

5.1 For new IRBs:

5.1.1 Determine from the IO/OO or designee whether the IRB will conduct all reviews without limitation or will be limited to certain types of reviews. Indicate this on the "IRB Scope" tab of HRP-601 - DATABASE - IRB Roster.

5.1.1.1 Select:

5.1.1.1.1 At least five individuals to serve as IRB members.

5.1.1.1.2 Additional individuals to serve as alternate IRB members, if needed.

5.1.1.1.3 At least one of the individuals to be the IRB chair.

5.1.1.2 Follow HRP-082 - SOP - IRB Membership Addition for each IRB member.

5.1.1.3 Use HRP-304 - WORKSHEET - IRB Composition and revise the selected individuals as needed to ensure that the IRB is appropriately constituted.

5.1.1.4 Notify the IRB manager when all individuals have completed training.

5.1.1.5 Using the "Create Committee" SmartForm, create the new committee in the system.

5.1.1.6 Once training is completed, add committee members to the system with the Committee Member role.

5.1.1.7 Assign any designees eligible to conduct non-committee reviews using the "Update Eligible Designated Reviewers" activity.

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5.2 File a new FWA, or update an existing, by following the instructions available at the OHRP website: https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/index.html

5.3 Register the new IRB, or update an existing IRB's OHRP registration as required by this policy, by following the instructions available at the OHRP website: https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/irb-registration/new-irb-registration/index.html.

6 MATERIALS

6.1 HRP-082 - SOP - IRB Membership Addition

6.2 HRP-202 - FORM - IRB Member Information

6.3 HRP-304 - WORKSHEET - IRB Composition

6.4 HRP-601 - DATABASE - IRB Roster

7 REFERENCES

7.1 45 CFR §46.103, 45 CFR §46.107, 45 CFR §46.108, 45 CFR §46.115(a)(5).

7.2 21 CFR §56.107, 21 CFR §56.115(a)(5).

7.3 AAHRPP elements I.1.A, II.1.A-C

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HRP-081 SOP: IRB Removal

1 PURPOSE

1.1 This procedure establishes the process to remove an IRB.

1.2 The process begins when the Institutional Official/Organizational Official (IO/OO) or designee determines that an IRB is no longer needed.

1.3 The process ends when the IRB is unregistered with OHRP and the Federalwide Assurance (FWA) is updated.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.

3.2 Any termination or non-renewal of OHRP IRB registration of any IRB relied on by a VA medical facility for review and oversight of VA research must be reported to the local VA medical facility per the facility's required reporting timelines.

3.2.1 The VA medical facility Director must report this to ORO promptly, but no later than 5 business days after VA medical facility personnel first become aware.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 For internal IRBs:

5.1.1 For each IRB member who will no longer serve as an IRB member prepare HRP-561 - LETTER - IRB Member Thank You, have them signed by the IO/OO or designee and send to the former IRB members.

5.1.2 Unregister the IRB with OHRP.[xxvi]

5.1.3 Remove the IRB from the FWA.[xxvii]

5.1.4 Remove members from HRP-601 - DATABASE - IRB Roster.

5.1.5 Remove the individual's Committee Member role in the system by executing the "Edit Members" activity, updating the individual's record to include the IRB Membership End Date and deleting them from the list of IRB Committee Members.

5.1.6 Execute "Edit Committee Info" and note in the description that the IRB has been removed, including the date of removal.

5.1.7 File:

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5.1.7.1 DATABASE: IRB Roster (HRP-601)

5.1.7.2 FWA

5.1.7.3 HRP-561 - LETTER - IRB Member Thank You

5.2 For external IRBs follow the requirements of the inter-institutional agreement or contract.

6 MATERIALS

6.1 HRP-561 - LETTER - IRB Member Thank You

6.2 HRP-601 - DATABASE - IRB Roster

7 REFERENCES

7.1 45 CFR §46.107, 45 CFR §46.103(b)(3), 45 CFR §46.115(a)(5).

7.2 21 CFR §56.107, 21 CFR §56.115(a)(5).

7.3 AAHRPP elements II.1.A, II.1.C

7.4 VHA Directive 1200.05(3), Amended July 13, 2023

7.5 VHA Directive 1058, November 8, 2024

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HRP-082 SOP: IRB Membership Appointment

1 PURPOSE

1.1 This procedure establishes the process to appoint and re-appoint an IRB member.

1.2 The process begins when an individual expresses interest, is nominated or applies to join the IRB in consultation with the Institutional Official/ Organizational Official (IO/OO) (this may be a completely new IRB member, or re-appointment of a previous member).

1.3 The process ends when the IRB roster is updated and the new member has completed training.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.

3.2 IRB members /alternates are appointed for a three-year term. Members/alternates are eligible for re-appointment at the end of their term.

3.3 The following individuals may not be appointed as IRB members or be involved in the day-to-day operations of the IRB:

3.3.1 Those responsible for business development for the organization (e.g., director of grants and contracting, the vice president for research, deans of research who are responsible for raising funds or garnering support for research, senior officers).

3.3.2 Those who own equity in the organization.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

4.2 The IO/OO or designee appoints/re-appoints IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs.).

5 PROCEDURE

5.1 Have the individual complete HRP-202 - FORM - IRB Member Information.

5.2 Obtain a copy of the individual's résumé or curriculum vita.

5.3 Use the information in the completed HRP-202 - FORM - IRB Member Information and the individual's résumé or curriculum vita to determine if the individual qualifies as a scientist or nonscientist, and if they are affiliated or unaffiliated[xxviii].

5.4 Interview the individual to assess suitability and availability.

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5.4.1 Determine from the IO/OO or designee whether the individual will be a regular IRB member, alternate IRB member, or IRB chair.

5.4.2 In any instance for which the scientific or non-scientific status or affiliation status of a newly appointed or re-appointed IRB member may be questionable, the IO/OO or designee will be consulted before proceeding with the appointment.

5.4.3 For Veterans Administration (VA) representatives, communicate with the Veterans Administration (VA) Medical Center Director in writing to obtain confirmation of the appointment.

5.5 Schedule a time for the applicant to attend and observe an IRB meeting, as applicable.

5.6 Add the individual to HRP-601 - DATABASE - IRB Roster.

5.7 Complete HRP-304 - WORKSHEET - IRB Composition and revise the membership as needed to ensure that the IRB is appropriately constituted.

5.8 Prepare HRP-560 - LETTER - IRB Member Appointment for the individual.

5.9 Provide to the IO/OO or designee for review and approval:

5.9.1 HRP-202 - FORM - IRB Member Information.

5.9.2 Résumé or curriculum vita.

5.9.3 Completed HRP-560 - LETTER - IRB Member Appointment.

5.9.4 Complete HRP-591 - LETTER - MH New Member Welcome Letter.

5.10 If not approved, select another individual and restart at 5.1.

5.11 Once the appointment and welcome letters are signed:

5.11.1 Send the signed HRP-560 - LETTER - IRB Member Appointment to the individual.

5.11.2 Send the signed HRP-591 - LETTER - MH New Member Welcome Letter.

5.11.3 Send HRP-906 - POLICY - MH IRB Member Recusal Agreement for completion and return.

5.11.4 Send HRP-907 - POLICY - MH IRB Confidentiality Agreement for completion and return.

5.11.5 Send HRP-905 - POLICY - MH IRB Member Disclosure of Conflicting Interests for reference.

5.11.6 If the individual requires training, schedule the individual for training.

5.11.7 Upon return of HRP-906 - POLICY - MH IRB Member Recusal Agreement and HRP-907 - POLICY - MH IRB Confidentiality Agreement update the registration of all affected IRBs[xxix]

5.12 File:

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5.12.1 HRP-601 - DATABASE - IRB Roster.

5.12.2 Signed IRB appointment/re-appointment letter.

5.12.3 HRP-202 - FORM - IRB Member Information.

5.12.4 Résumé or curriculum vita.

5.12.5 Any other signed agreements.

5.12.6 HRP-906 - POLICY - MH IRB Member Recusal Agreement

5.12.7 HRP-907 - POLICY - MH IRB Confidentiality Agreement

5.13 Notify the IRB manager when the individual has completed training.

5.14 Assign individual the “Committee Member” role in the system.

5.15 If the individual is designated to conduct non-committee reviews, update the “Update Eligible Designated Reviewers” activity.

6 MATERIALS

6.1 HRP-202 - FORM - IRB Member Information

6.2 HRP-304 - WORKSHEET - IRB Composition

6.3 HRP-560 - LETTER - IRB Member Appointment

6.4 HRP-601 - DATABASE - IRB Roster

6.5 HRP-591 - LETTER - MH New Member Welcome Letter

6.6 HRP-905 - POLICY - MH IRB Member Disclosure of Conflicting Interests

6.7 HRP-906 - POLICY - MH IRB Member Recusal Agreement

6.8 HRP-907 - POLICY - MH IRB Confidentiality Agreement

7 REFERENCES

7.1 45 CFR §46.107, 45 CFR §46.108(a)(2), 45 CFR §46.115(a)(5).

7.2 21 CFR §56.107, 21 CFR §56.115(a)(5).

7.3 VHA Directive 1200.05 January 7, 2019

7.4 AAHRPP elements I.1.E, II.1.A-C

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HRP-083 SOP: IRB Membership Removal

1 PURPOSE

1.1 This procedure establishes the process to remove an IRB member.

1.2 The process begins when an IRB member resigns or is removed from one or more IRBs. This procedure applies if an individual is a member of more than one IRB and is being removed from some but not all IRBs.

1.3 The process ends when the IRB registration is updated.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The Institutional Official/ Organizational Official (IO/OO) or designee may remove IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs) with consultation from the IRB manager and IRB chair(s).

3.2 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 Remove the individual from HRP-601 - DATABASE - IRB Roster.

5.2 Complete HRP-304 - WORKSHEET - IRB Composition to ensure that the IRB is appropriately constituted.

5.2.1 If not, identify one or more replacement members and follow HRP-082 - SOP - IRB Membership Addition.

5.3 Prepare HRP-561 - LETTER - IRB Member Thank You, have it signed by the IO/OO or designee and send to the individual.

5.4 Update the registration of all affected IRBs.[xxx]

5.5 File:

5.5.1 HRP-601 - DATABASE - IRB Roster.

5.5.2 HRP-561 - LETTER - IRB Member Thank You.

5.6 Remove individual's "Committee Member" role in the system by executing the "Edit Members" activity, updating the individual's record to include the IRB Membership End Date and deleting them from the list of IRB Committee Members.

6 MATERIALS

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6.1 HRP-082 - SOP - IRB Membership Addition

6.2 HRP-304 - WORKSHEET - IRB Composition

6.3 HRP-561 - LETTER - IRB Member Thank You

6.4 HRP-601 - DATABASE - IRB Roster

7 REFERENCES

7.1 45 CFR §46.107, 45 CFR §46.103(b)(3), 45 CFR §46.115(a)(5)

7.2 21 CFR §56.107, 21 CFR §56.115(a)(5)

7.3 AAHRPP elements II.1.A, II.1.C

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HRP-084 SOP: IRB Meeting Scheduling and Notification

1 PURPOSE

1.1 This procedure establishes the process to schedule and notify individuals of convened meetings.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Scheduled meetings are to occur at intervals appropriate for the quantity, complexity, and frequency of required actions, and to permit adequate oversight of the progress of approved research.

3.2 Additional meetings may be scheduled on an ad hoc basis.

4 RESPONSIBILITIES

4.1 The IRB manager carries out these procedures.

5 PROCEDURE

5.1 Create a schedule of meetings for each IRB.

5.1.1 Execute the “Create Meeting” SmartForm in the system for each scheduled meeting.

5.2 Post the schedule on the organization’s Web site.

5.3 Notify the following individuals of the updated schedule with an email providing a link to the IRB Web page with the schedule information:

5.3.1 IRB members.

5.3.2 Investigators and research staff on the IRB email list.

5.3.3 Institutional Official / Organizational Official (IO/OO) or designee.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 ICH-GCP E6 1.4.2

7.2 AAHRPP elements I-9, II.2.D

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HRP-090 SOP: Informed Consent Process for Research

1 PURPOSE

1.1 This procedure establishes the process to obtain informed consent from subjects, the Legally Authorized Representative (LAR) of adults unable to consent, or the parents or guardians of children.

1.2 The process begins when an individual identifies a subject as a potential candidate for a research study.

1.3 The process ends when a subject or the subject's LAR provides legally effective informed consent or declines to do so.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 In this procedure "investigator" means a principal investigator or an individual authorized by the principal investigator and approved by the IRB to obtain consent for the specific protocol, such as a co-investigator, research assistant, or coordinator.

3.2 In this procedure "subject/representative" means:

3.2.1 The subject when the subject is an adult capable of providing consent.

3.2.2 LAR when the subject is an adult unable to give consent.

3.2.3 One or both biologic or adoptive parents when the subject is a child or in the absence of a parent a person other than a parent authorized under applicable law to consent on behalf of the child to general medical care.

3.3 If the subject/representative understands more than one language, whenever possible, conduct the consent process in the preferred language of the subject/representative.

3.4 If the subject is an adult unable to consent:

3.4.1 The IRB must have specifically approved the protocol to allow the enrollment of adults unable to consent.

3.4.2 Permission is obtained from a LAR.

3.4.3 A LAR must be in the class or persons approved by institutional policy or the IRB. See HRP-013 - SOP - LARs, Children, and Guardians.

3.5 If the subject is a child:

3.5.1 The IRB must have specifically approved the protocol to allow the enrollment of children.

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3.5.2 Permission is obtained from both parents unless:

3.5.2.1 One parent is deceased, unknown, incompetent, not reasonably available;

3.5.2.2 Only one parent has legal responsibility for the care and custody of the child; or

3.5.2.3 The IRB has specifically approved the protocol to allow the permission of one parent regardless of the status of a second parent.

3.5.3 In the absence of a parent permission may be obtained from an individual authorized to consent under applicable law on behalf of a child to general medical care.

3.6 If the subject/representative cannot speak English:

3.6.1 The IRB must have specifically approved the protocol to allow the enrollment of non-English speaking.

3.7 Conduct all discussions in a private and quiet setting.

3.8 Any knowledgeable individual may:

3.8.1 Review the study with subject/representative to determine preliminary interest.

3.8.2 If the subject/representative is interested, notify an investigator.

3.8.3 If the subject/representative is not interested, take no further steps regarding recruitment or enrollment.

4 RESPONSIBILITIES

4.1 The principal investigator is responsible to ensure these procedures are carried out.

5 PROCEDURE

5.1 If the consent process will be documented in writing with the long form of consent documentation:

5.1.1 All consent documents and methods for obtaining informed consent must be approved by the IRB of record prior to use, including the use of electronic signatures, electronic consent documents, and/or remote consent processes.

5.1.2 The Consenting Professional(s) must be delegated by the PI to obtain informed consent and be appropriately qualified by education, licensure, and experience to effectively communicate information about the study procedures, risks, benefits, and alternatives with the participant.

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5.1.3 The participant must receive a copy of the consent form prior to deciding whether to participate or not. The participant must be provided sufficient time to read it and ask questions before signing it.

5.1.4 Participant Specific Requirements

5.1.4.1 Prior to obtaining informed consent from a participant, the Consenting Professional(s) must assess whether any variations to the informed consent process are necessary for that participant. This may include, but is not limited to:

5.1.4.1.1 Non-English speaking individuals
5.1.4.1.2 Individuals with Limited English Proficiency
5.1.4.1.3 Individuals with impaired decision-making capacity
5.1.4.1.4 MaineHealth Employees/Students
5.1.4.1.5 Incarcerated individuals
5.1.4.1.6 Pregnant and lactating individuals
5.1.4.1.7 Neonates and children
5.1.4.1.8 Blind individuals
5.1.4.1.9 People unable to read and/or write, or with low literacy and/or numeracy
5.1.4.1.10 Legally Authorized Representative

5.1.4.2 If any variations in the informed consent process are necessary for one or more participants, these variations must be approved by the IRB of record prior to informed consent being obtained.

5.1.5 When a potential participant is identified, the current IRB approved consent form(s) is used to obtain informed consent prior to performing any research-specific procedures. It is the responsibility of the consenting professional to confirm that the documents used are the most recently approved version(s). and that the consent form is in a language understandable to the subject/representative. The language should be understandable by a person who is educated to no higher than an 8th grade level and non-technical language should be used in the description of the research. The IRB may require or allow different readability standards based upon the characteristics of the target participant population.

5.1.6 Provide a copy of the consent form to the subject/representative. Whenever possible provide the consent form to the subject/representative in advance of the consent discussion.

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5.1.7 The informed consent discussion must take place in a location that minimizes the possibility of coercion or undue influence and allows for sufficient opportunity for the participant to ask questions and consider whether or not to participate.

5.1.8 If the subject/representative cannot read, or is physically unable to talk or write, obtain an impartial witness to be present during the entire consent discussion to attest that the information in the consent form and any other information provided was accurately explained to, and apparently understood by, the subject/representative, and that consent was freely given. The witness may be a family member or friend. The witness may not be a person involved in the design, conduct, or reporting of the research study.

5.1.9 For participants with Limited English Proficiency (LEP), informed consent must be obtained in a language that the participant (or their LAR/guardian) can understand. When a prospective participant does not understand the language spoken by the individual obtaining consent and/or the consent materials are translated, the informed consent discussion must include a MaineHealth-certified interpreter. Exceptions regarding the interpreter may be approved by the MaineHealth IRB on a case-by-case basis, but family members or acquaintances are not permitted as interpreters.

5.1.10 The Consenting Professional reviews the most recently approved informed consent form with the participant, providing adequate explanation of the purpose, procedures, expected risks, benefits, voluntary nature of participation, cost and time commitment associated with participating in the research. Explain the details in such a way that the subject/representative understands what it would be like to take part in the research study.

5.2 If the consent process will be documented in writing with the short form of consent documentation:

5.2.1 Obtain the current IRB approved short consent form and summary (same as the English consent form used for long form of consent documentation).

5.2.2 Verify that you are using the most current IRB-approved version of the study specific short consent form and summary and that the short consent form is in a language understandable to the subject/representative.

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5.2.3 Provide copies to the subject/representative. Whenever possible provide the short consent form and summary to the subject/representative in advance of the consent discussion.

5.2.4 Obtain the services of an MaineHealth certified interpreter fluent in both English and the language understood by the subject/representative.

5.2.5 Obtain the services of an impartial witness who is fluent in both English and the language spoken by the subject/representative to be present during the entire consent discussion to attest that the information in the short consent form, summary, and any other information provided was accurately explained to, and apparently understood by, the subject/representative, and that consent was freely given. The witness and the interpreter may be the same person. If possible, it is recommended that the witness should not be related to the subject[xxxi]. The witness may not be a person involved in the design, conduct, or reporting of the research study.

5.2.6 Have the interpreter translate the summary (not the short consent form) to the subject/representative. Begin with a concise and focused presentation of the key information that is most likely to assist the subject/representative to understand the reasons why one might or might not want to participate in the research.

5.2.7 Through the interpreter explain the details in such a way that the subject/representative understand what it would be like to take part in the research study. When necessary, provide a different or simpler explanation to make the information understandable.

5.2.8 Have the subject/representative read the short consent form or have the interpreter read the short consent form to the subject/representative.

5.3 If the requirement for written documentation of the consent process has been waived by the IRB (Verbal Consent):

5.3.1 Verbal consent refers to all instances where informed consent is obtained via a verbal-only process (i.e., no written documentation of informed consent is obtained).

5.3.2 The use of a verbal consent process must be approved by the IRB of record and the study sponsor prior to being used for research.

5.3.3 When approved, verbal consent may be obtained either in person or via a remote process

5.3.4 Obtain the current IRB approved script.

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5.3.5 Verify that you are using the most current IRB-approved version of the study specific script and that the script language is understandable to the subject/representative.

5.3.6 If applicable, the potential participant must be provided a copy of the research information sheet that outlines the details of their participation in advance of the informed consent discussion.

5.3.7 If the subject/representative cannot speak English, obtain the services of a MaineHealth certified interpreter fluent in both English and the language understood by the subject/representative.

5.3.8 Read the script (or have an interpreter translated the script) with the subject/representative. Begin with a concise and focused presentation of the key information that is most likely to assist the subject/representative to understand the reasons why one might or might not want to participate in the research. Explain the details in such a way that the subject/representative understands what it would be like to take part in the research study.

5.3.9 It may be necessary to obtain HIPAA authorization from participants who provide verbal consent. If HIPAA authorization is not incorporated into the information sheet, it is recommended that a waiver of documentation of HIPAA authorization also be requested from the IRB of record.

5.4 If the consent process will be conducted using Remote Consent ("e-consent")

5.4.1 Remote consent refers to all instances where the participant and the Consenting Professional are not in the same physical location during the informed consent discussion and signing of the informed consent document.

5.4.2 The IRB of record and sponsor (as applicable) must approve the use of remote consent procedures prior to utilizing remote procedures to obtain informed consent from participant(s).

5.4.3 Remote consent may be completed via telephone, videoconferencing, or use of a desktop, mobile, or web-based application or similar technology.

5.4.4 Remote consent may be obtained with wet-ink signatures on a paper/hard copy of the informed consent document or with electronic signatures as described in HRP-091 - SOP - Written Documentation of Consent.

5.4.5 The following elements must be included in the informed consent process in addition to the required elements outlined in this document.

5.4.5.1 The informed consent form must be provided to the participant for review prior to the remote consent process. These items can

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be provided to the participant in paper form by mail or fax, in PDF or equivalent form electronically, or through a desktop, mobile, or web-based application remotely.

5.4.5.2 The Consenting Professional must verify the identity of the participant prior to initiating the informed consent discussion. Verification of identity can be accomplished by direct (or video) observation, or by using information from official identification, such as a birth certificate, a government-issued passport, or a driver's license, or via security questions.

5.5 Invite and answer the subject/representative's questions.

5.6 Give the subject/representative time to discuss taking part in the research study with family members, friends and other care providers as appropriate.

5.7 Invite and encourage the subject/representative to take the written information home to consider the information and discuss the decision with family members and others before making a decision.

5.8 Ask the subject/representative questions to determine whether all of the following are true, and if not, either continue the explanation or determine that the subject/representative is incapable of consent:

5.8.1 The subject/representative understands the information provided.

5.8.2 The subject/representative does not feel pressured by time or other factors to make a decision.

5.8.3 The subject/representative understands that there is a voluntary choice to make.

5.8.4 The subject/representative is capable of making and communicating an informed choice.

5.9 If the subject/representative has questions about treatments or compensation for injury, provide factual information and avoid statements that imply that compensation or treatment is never available.

5.10 Once a subject/representative indicates that he or she does not want to take part in the research study, this process stops.

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5.11 If the subject/representative agrees to take part in the research study:

5.11.1 If the subject is a child:

5.11.1.1 Whenever possible explain the research to the extent compatible with the child's understanding.

5.11.1.2 Request the assent (affirmative agreement) of the child unless:

5.11.1.2.1 The capability of the child is so limited that the child cannot reasonably be consulted.

5.11.1.2.2 The IRB determined that assent was not a requirement.

5.11.1.3 Once a child indicates that he or she does not want to take part in the research study, this process stops.

5.11.2 If the subject is an adult unable to consent:

5.11.2.1 Whenever possible explain the research to the extent compatible with the adult's understanding.

5.11.2.2 Request the assent (affirmative agreement) of the adult unless:

5.11.2.2.1 The capability of the adult is so limited that the adult cannot reasonably be consulted.

5.11.2.2.2 The IRB determined that assent was not a requirement.

5.11.2.3 Once an adult unable to consent indicates that he or she does not want to take part in the research study, this process stops.

5.11.3 Obtain written documentation of the consent process according to HRP-091 - SOP - Written Documentation of Consent.

5.11.4 If the research requires more than one informed consent document, the process outlined above must be followed for each informed consent document.

5.11.5 All informed consent procedures must be completed prior to the initiation of any research related tests, procedures, or study-specific interventions.

5.12 HIPAA Authorization

5.12.1 For studies utilizing identifiable health information (i.e., protected health information or "PHI"), it is necessary for participants to provide authorization for the use and disclosure of their PHI for the purpose of the research as mandated by the Health Insurance Portability and Access Act (HIPAA). The HIPAA Authorization may be embedded within the consent form or provided as a separate document.

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5.12.2 If the HIPAA Authorization is a separate document, once reviewed and signed by the participant or Legally Authorized Representative, the Consenting Professional must provide a copy of the HIPAA Authorization to the participant and for upload into the participant's electronic medical record.

6 MATERIALS

6.1 Long form of consent documentation:

6.1.1 Consent form

6.2 Short form of consent documentation:

6.2.1 Short consent form

6.2.2 Summary (same information as the English consent form used for long form of consent documentation)

6.3 Requirement for written documentation of the consent process has been waived by the IRB:

6.3.1 Consent script (same as consent form used for long form of consent documentation except that signature block is optional)

6.4 HRP-013 - SOP - LARs, Children, and Guardians

6.5 HRP-091 - SOP - Written Documentation of Consent

7 REFERENCES

7.1 21 CFR §50.20, 50.25

7.2 45 CFR §46.116

7.3 AAHRPP element I-9

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HRP-091 SOP: Written Documentation of Consent

1 PURPOSE

1.1 This procedure establishes the process to document the informed consent process in writing.

1.2 The process begins when a subject agrees to take part in a research study.

1.3 The process ends when the consent process is documented in writing, including in an electronic format, to the extent required by this procedure.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 In this procedure "investigator" means a principal investigator or an individual authorized by the principal investigator and approved by the IRB to obtain consent for the specific protocol, such as a co-investigator, research assistant, or coordinator.

3.2 In this procedure "subject/representative" means:

3.2.1 The subject when the subject is an adult capable of providing consent.

3.2.2 The Legally Authorized Representative (LAR) when the subject is an adult unable to give consent.

3.2.3 One or both biologic or adoptive parents when the subject is a child or in the absence of a parent, a person authorized under applicable law to consent on behalf of the child to the child's general medical care.

4 RESPONSIBILITIES

4.1 The principal investigator is responsible to ensure these procedures are carried out.

5 PROCEDURE

5.1 If the consent process will be documented in writing with the long form of consent documentation:

5.1.1 Verify that the consent form is in language understandable to the subject/representative.

5.1.2 Once the research has been thoroughly described to the participant, all the participant's questions have been answered to their satisfaction, and, if the participant agrees to take part in the research, the participant, Legally Authorized Representative, or an individual appropriate under

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state and federal laws clearly and accurately records the following information on the signature page where indicated

5.1.2.1 Printed Name

5.1.2.2 Signature

5.1.2.3 Date of Consent

5.1.2.4 Time of Consent (if applicable)

5.1.3 If a line exists to countersign, the Consenting Professional must countersign the informed consent form with the relevant above information.

5.1.4 Have the following individuals personally sign and date (or otherwise "make their mark" on) the consent document:

5.1.4.1 Subject/Representative

5.1.4.1.1 If the subject/representative can only "make their mark," document in a note to the subject's file: the method used for communication with the prospective subject/representative, the reason for the lack of a signature and date, and the date consent was obtained[xxxii].

5.1.4.1.2 If the subject/representative is physically unable to sign the consent form, note this on the consent form and document in a note to the subject's file: the method used for communication with the prospective subject/representative, and the specific means by which their agreement was communicated[xxxii].

5.1.4.2 Person obtaining consent

5.1.5 If the IRB required written documentation of assent, note on the signature block one of the following:

5.1.5.1 Assent of the child was obtained.

5.1.5.2 Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

5.1.6 If an impartial witness was part of the consent process:

5.1.6.1 Print the name of the impartial witness on the consent document.

5.1.6.2 Have the impartial witness personally sign and date the consent document to attest that the information in the consent document and any other information provided was accurately

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explained to, and apparently understood by, the subject, and that consent was freely given.

5.1.7 Provided copies of the signed and dated consent document to the subject/representative. This may be accomplished either by making a photocopy or by having the above individuals sign and date two copies of the consent document.

5.2 If the consent process will be documented in writing with the short form of consent documentation:

5.2.1 Verify that the short consent form is in language understandable to the subject/representative.

5.2.2 Print the name of the following individuals on the short form consent document and the summary:

5.2.2.1 Subject/Representative

5.2.2.2 Person obtaining consent

5.2.2.3 Impartial witness

5.2.3 Have the following individuals personally sign and date the short form consent document and/or the summary:

5.2.3.1 Subject/Representative sign short form consent document

5.2.3.2 Person obtaining consent sign summary

5.2.3.3 Impartial witness sign both short form consent document and summary

5.2.4 If the IRB required written documentation of assent, note on the signature block on the short consent document one of the following:

5.2.4.1 Assent of the child was obtained.

5.2.4.2 Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

5.2.5 Provide a copy of the signed and dated short consent document and a copy of the signed and dated summary to the subject/representative. This may be accomplished either by making photocopies or by having the above individuals sign and date two copies of the short consent document and summary.

5.2.6 If the study is FDA regulated[xxxii], obtain a translated copy of the IRB-approved English version of the long form consent promptly and submit to the IRB for review.

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5.2.6.1 After IRB approval of the translated version, provide it to the subject or LAR as soon as possible.

5.3 If the consent process will be documented in writing and if the consent process will be conducted using Remote Consent ("e-consent"):

5.3.1 Wet ink signature - If the informed consent form is supplied in paper form or electronic form for the participant to print to paper, the participant is instructed to sign and date form and return the signed document to the investigator by mail, fax or a scanned copy via email.

5.3.2 Electronic signature - If the informed consent form is supplied remotely a desktop, mobile or web-based application for the participant to sign electronically, the participant is instructed to sign through the appropriate system. See Section 5.6 for requirements related to electronic signatures.

5.3.3 The informed consent must be signed and dated by the Consenting Professional upon receipt of the document signed by the participant. The date must reflect the date the document is signed by the Consenting Professional, not the date of the informed consent discussion. Any discrepancy between the date of the participant's signature and the date of the Consenting Professional's signature must be explained in the informed consent process documentation.

5.3.4 The informed consent document is not considered complete and research procedures cannot begin until both the participant and the Consenting Professional have signed (if required).

5.4 If the requirement for written documentation of the consent process has been waived by the IRB and the IRB determined that the subject/representative had to be offered the opportunity to document his or her consent in writing, offer the subject/representative the option to document his or her consent in writing.

5.4.1 If the subject/representative declines, take no further action.

5.4.2 If the subject/representative accepts, follow the process to document consent in writing with the long or short form of consent documentation.

5.5 Place the signed and dated documents in the subject's binder.

5.6 Document the consenting process (i.e. written narrative) for all interventional research.

5.7 If the consent process will be documented using Electronic Signatures ("e-consent")

5.7.1 The use of an electronic platform to obtain signatures on an informed consent document must be approved by the IRB of record prior to being used for a particular study.

5.7.2 The electronic system used to collect electronic signatures must comply with all applicable laws and regulations regarding the use of electronic

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systems in the conduct of research, including HIPAA and FDA 21CFR Part 11.

5.7.3 The Consenting Professional must ensure that the participant receives of copy of the fully signed document in an accessible format (e.g. paper copy, electronic copy via email, electronic copy retained within the electronic platform, etc.).

5.7.4 All requirements outlined in Section 5.1 and 5.2 still apply.

6 MATERIALS

6.1 If the consent process will be documented in writing with the long form of consent documentation:

6.1.1 Consent document

6.2 If the consent process will be documented in writing with the short form of consent documentation:

6.2.1 Short consent document

6.2.2 Summary (same content as the long form of consent documentation).

7 REFERENCES

7.1 21 CFR §50.27

7.2 45 CFR §46.117

7.3 https://www.fda.gov/media/88915/download

7.4 AAHRPP element I-9

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HRP-801 SOP: Establishing Reliance Agreements

1 PURPOSE

1.1 The purpose of this process is to execute Authorization Agreements with other institutions and agreements with individuals for reliance for non-exempt human research.[xxxiii]

1.2 This process begins when an institution/organization or collaborating independent investigator or collaborating institutional investigator at a non-assured institution has been identified for a potential Authorization Agreement.

1.3 This process ends when an Institutional Profile has been established or an Individual Investigator Agreement (IIA) has been executed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 HRP-101 - Human Research Protection Program Plan details the criteria for reviewing for or relying on other institutions/organizations or reviewing for unaffiliated individuals.

3.2 An institution or individual must be engaged in non-exempt Human Research as determined by using HRP-311 - WORKSHEET – Engagement Determination for IRB reliance to occur.

3.3 The institution may leverage an existing Institutional Profile to collect information requested in the Institutional Profile SmartForm. For example, Institutional Profiles created for IREx or the SMART IRB platform are acceptable.

3.4 The institution may leverage the SMART IRB agreement, the OHRP Authorization Agreement template or create a local Authorization Agreement to establish reliance.

3.5 This institution does allow an unaffiliated individual or individual affiliated with an organization that does not have an Federalwide Assurance (FWA) to request reliance on this institution's FWA and IRB via an IIA.

3.6 This institution may leverage the OHRP IIA template or create a local IIA to establish reliance.

4 RESPONSIBILITIES

4.1 The Reliance Coordinator or IRB staff generally carry out these procedures. The IO/OO or HRPP Director may also participate in reliance determinations.

5 PROCEDURE

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5.1 If the request is for IRB reliance on or by an institution, determine whether the criteria for reviewing for or relying on other institutions/organizations are met:

5.1.1 Review HRP-101 - Human Research Protection Program Plan to determine if basic criteria are met.

5.1.1.1 If the criteria have not been met, do not execute an Authorization Agreement. Prepare HRP-856 – LETTER – Decline Reliance on an External IRB, or HRP- 850 - LETTER - Decline to Serve and send to the other institution/organization.

5.1.1.2 If the request is for your institution to rely on another institution's IRB, use HRP-832 - WORKSHEET - Considerations for Relying on an External IRB to inform your determination of whether your institution will rely on another institution's IRB.

5.1.1.3 If an institution is requesting to rely on your institution's IRB, use HRP-833 - WORKSHEET - Considerations for Serving as the sIRB to inform your determination of whether your institution's IRB will serve as the sIRB.

5.1.2 If the criteria have been met, for an institution/organization, execute an Authorization Agreement with that institution/organization. (Use of the SMART IRB Agreement is documented via a letter of acknowledgement or use of their Online Reliance System on a study specific basis.)

5.1.2.1 Indicate in the Authorization Agreement the conditions under which you serve as the IRB of record for that institution/organization.

5.1.2.2 Indicate in the Authorization Agreement the conditions under which that institution/organization will serve as the IRB of record for you.

5.1.2.3 Include the following in the Authorization Agreement, or as (an) addendum(s):

5.1.2.3.1 A communication plan. Use HRP-830 - WORKSHEET - Communication and Responsibilities to create a communication plan.

5.1.2.3.2 Consent form instructions, including instructions for the institution/organization to provide local contact information and details regarding compensation for research-related injuries.

5.1.2.3.3 Recruitment material instructions.

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5.1.2.3.4 New information reporting instructions.

5.1.2.3.5 Required terms.

5.1.2.3.6 Negotiable terms.

5.1.2.3.7 The process for adding participating sites or additional research to existing Authorization Agreement (if this is a master agreement).

5.1.2.3.8 Relevant tribal, state, or non-US laws, regulations, or policies, such as age of majority, circumstances that affect the age of consent, who can serve as a Legally Authorized Representative, and other information that may not be identified elsewhere in the Authorization Agreement.

5.1.2.4 Use HRP-802 - SOP - Management of Institutional Profiles to record the collected information in the Institutional Profile SmartForm.

5.1.3 If the criteria within HRP-832- WORKSHEET - Considerations for Ceding IRB Review or HRP-833- WORKSHEET - Considerations for Serving as the sIRB have not been met, do not execute an Authorization Agreement. Prepare HRP-856 – LETTER – Decline Reliance on an External IRB, or HRP-850 - LETTER – Decline to Serve and send to the other institution/organization.

5.2 If the request is for a Collaborating Individual Investigator or Collaborating Institutional Investigator to rely on your institution, determine whether the criteria have been met:

5.2.1 Confirm the individual does not need their institution to obtain its own FWA (e.g., they are the prime awardee, or routinely conduct human subjects research).[xxxiv]

5.2.2 Review HRP-101 - Human Research Protection Program Plan to determine if basic criteria are met.

5.2.2.1 If the criteria have not been met, do not execute an IIA. Prepare HRP-850 - LETTER – Decline to Serve and send to this institution's study team.

5.2.2.2 If the criteria have been met, execute IIA with the individual.

5.2.3 Upload the finalized IIA under "Other Attachments" in the study application.

6 MATERIALS

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6.1 HRP-021 - SOP - Pre-Review
6.2 HRP-101 - Human Research Protection Program Plan
6.3 HRP-802 - SOP - Management of Institutional Profiles
6.4 HRP-830 - WORKSHEET - Communication and Responsibilities
6.5 HRP-832 - WORKSHEET - Considerations for Ceding IRB Review
6.6 HRP-833 - WORKSHEET - Considerations for Serving as the sIRB
6.7 HRP-850 - LETTER - Decline to Serve
6.8 HRP-856 - LETTER - Decline Reliance on an External IRB
6.9 HRP-861 - WORKBOOK - Institutional Profiles

7 REFERENCES

7.1 Single IRB Exception Determinations: https://www.hhs.gov/ohrp/regulations-and-policy/single-irb-exception-determinations/index.html
7.2 SMART IRB Agreement: https://smartirb.org/agreement/
7.3 OHRP Authorization Agreement template: https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/irb-authorization-agreement/index.html
7.4 Extending an FWA to Cover Collaborating Investigators (2005): https://www.hhs.gov/ohrp/regulations-and-policy/guidance/extension-of-institutional-fwa-via-individual-investigator-agreement/index.html

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HRP-802 SOP: Institutional Profile Management

1 PURPOSE

1.1 The purpose of this process is to manage Institutional Profiles.

1.2 This process begins when this institution receives new or updated information from another institution/organization that impacts the content of the Institutional Profile.

1.3 This process ends when updated information has been communicated to appropriate parties.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Any substantive changes to an Institutional Profile may result in an amended Authorization Agreement. Any non-substantive changes, e.g., contact information updates, do not require an amended Authorization Agreement.

3.2 The institution may leverage an existing Institutional Profile to collect information requested in the Institutional Profile SmartForm. For example, Institutional Profiles created for IREx or the SMART IRB platform are acceptable.

4 RESPONSIBILITIES

4.1 The Reliance Coordinator or IRB staff generally carries out these procedures.

5 PROCEDURE

5.1 If no Institutional Profile exists for a site for which this institution is being asked to serve as the single IRB, or an IRB on which this institution is being asked to rely, update the Institutional Profile SmartForm with information about the external institution/organization.

5.1.1 Gather this information from any of the following sources:

5.1.1.1 SMART IRB Agreement online Profile

5.1.1.2 IREx Online Profile

5.1.1.3 Information included in the IRB Authorization Agreement (IAA)

5.1.1.4 Direct communication with the Human Research Protection Program (HRPP) of the external institution/organization

5.1.1.4.1 HRP-815 - FORM Institutional Profile can be used to collect this information

5.2 If a relying site or reviewing IRB provides updated information for an existing Institutional Profile, update the Institutional Profile SmartForm with the information.

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5.3 If an amended Authorization Agreement is needed, file the updated HRP-815 - FORM - Institutional Profile with the amended Authorization Agreement.

5.4 Determine whether the updates impact any existing studies. If so, develop a plan for how to address the impact.

5.5 Communicate these updates and any plans to address impacts to appropriate parties as needed.

6 MATERIALS

6.1 HRP-815 - FORM - Institutional Profile

7 REFERENCES

7.1 None

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HRP-804 SOP: External IRB Post-Review

1 PURPOSE

1.1 The purpose of this process is to conduct post-review for submissions where this institution is being asked to rely on an external IRB.

1.2 This process begins when a request to cede oversight has been submitted and pre-review has been completed.

1.3 This process ends when all correspondence related to IRB determinations and actions have been sent and additional tasks have been completed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 None.

4 RESPONSIBILITIES

4.1 The Reliance Coordinator or IRB staff generally carries out these procedures.

5 PROCEDURE

5.1 For studies where IRB oversight has been ceded to an external IRB:

5.1.1 Execute the “Record sIRB Decision” activity and complete the form with the information in the external IRB approval letter. Upload the external IRB determination letter in the designated space for “External IRB Approval Letter” if not already attached under “Other Attachments” in the study application.

5.1.2 Execute the “Finalize Documents” activity if necessary.

5.1.3 Execute the “Prepare Letter” activity to generate and edit HRP-857 - LETTER - Acknowledge External IRB if necessary.

5.1.4 Execute the “Send Letter” activity if applicable.

6 MATERIALS

6.1 HRP-857 - LETTER - Acknowledge External IRB

7 REFERENCES

7.1 None

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HRP-805 SOP: External IRB Updates

1 PURPOSE

1.1 The purpose of this process is to ensure that the relying institution is made aware of updates approved by the external IRB or when the local investigator makes changes at the site level.

1.2 This process begins when the local site investigator submits newly approved materials from the external IRB or when the local investigator submits local site changes.

1.3 This process ends when an external IRB submission has been updated.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 An investigator relying on an external IRB must update the site record with changes approved by the external IRB, including providing notification of Continuing Review approval if requested, using the "Update Study Details" activity.

3.2 If changes are made at the local site that affect institutional requirements (including changes to personnel, conflicts of interest or management plan, change triggering an ancillary review, funding, HIPAA, changes in recruitment plans (i.e. methods) or changes to institutionally required consent language) on an external IRB on an external IRB study, the investigator must update the site record using the "Create Site Modification" activity.

3.3 The site record must be updated with any reportable new information occurring locally that is determined by the external IRB to be Serious Non-Compliance, Continuing Non-Compliance, or an Unanticipated Problem Involving Risks to Subjects or Others, using the "Report New Information" activity.

3.4 The site record must be updated with any breach of confidentiality of a local subject, unresolved complaints from participants or others, using the "Reportable New Information" activity.

4 RESPONSIBILITIES

4.1 The Reliance Coordinator or IRB staff generally carry out these procedures.

5 PROCEDURE

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5.1 If the item includes updates to the local site information (Site Modification for study team members or other parts of the site), review the updates using HRP-830 - WORKSHEET - Communication and Responsibilities.

5.1.1 If the item is a personnel change, ensure the personnel are qualified and have required training.

5.1.2 If the item is a change to a conflict of interest management plan, follow HRP-055 – SOP - IRB Review of Financial Conflicts of Interest.

5.1.3 If the item is a change to HIPAA authorization waivers or alterations and the local site is serving as the Privacy Board, review and document the appropriate waivers using HRP-441-CHECKLIST for HIPAA Waiver of Authorization.

5.1.4 If the item is a change triggering an ancillary review, execute the Manage Ancillary Review activity and assign the appropriate ancillary review organization or individual as outlined in HRP-309 - WORKSHEET - Ancillary Review Matrix.

5.2 If the item was determined to be Serious Non-Compliance or Continuing Non-Compliance or an Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) or breach of confidentiality, unresolved complaint from subjects or others that occurred locally:

5.2.1 If the external IRB has not notified the local IRB of the event, contact the external IRB, request additional information and documentation as needed, and confirm reporting requirements as described in the reliance agreement terms.

5.2.2 Notify the IO/OO of the event.

5.2.3 Consult with the HRPP Director or designee to determine whether any additional actions are needed, including local review of the event.

5.2.3.1 If local review is required, follow HRP-024 - SOP - New Information to review the event.

5.2.3.2 In coordination with the HRPP Director or designee, notify other local departmental offices as appropriate (i.e., department leadership, deans, privacy, quality, or risk management).

5.2.4 Respond to the external IRB with any edits requested to any applicable reporting requirement letter(s) or file the report with any appropriate agency(ies) in accordance with oversight requirements outlined in the Authorization Agreement terms.

5.3 If the item is an update to the overall study (Update to Study Details for funding, study scope, recruitment plan (i.e. method) or study related documents and template), review the updates in accordance with the roles and responsibilities of your institution as outlined in HRP-830 - WORKSHEET - Communication and Responsibilities.

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5.3.1 If your institution allows investigators to complete the submission via the "Finalize Updates" activity in the system:

5.3.1.1 The assigned IRB Coordinator or IRB staff uses the link in the email notification to navigate to the Study Update submission workspace.

5.3.1.2 Review the study updates and if they are satisfactory, determine if the changes require an update to the sIRB Decision:

5.3.1.2.1 If yes, from the main study workspace, execute the "Return to Post Review" activity.

5.3.1.2.2 Execute the edit "sIRB Decision" activity and complete the SmartForm, indicating whether or not documents need to be finalized or a letter needs to be sent.

5.3.1.2.3 If applicable, execute the "Finalize Documents" activity and then the "Send Letter" activity to send HRP-859 - TEMPLATE LETTER - Acknowledge External IRB Update.

5.3.1.2.4 If no, no further action is necessary.

5.3.1.3 If the item includes study updates that are not satisfactory:

5.3.1.3.1 Contact the investigator and request the changes needed by posting a comment in the submission workspace. Instruct the investigator to submit these changes by creating a new Study Update; or

5.3.1.3.2 Execute the "Update Study Details" activity in the main study workspace to make additional changes on behalf of the investigator. Notify the investigator of these changes by posting a comment in the study workspace.

5.3.1.3.3 If the study update includes changes to the sIRB decision, execute the "Edit sIRB Decision" activity and complete the SmartForm, indicating whether documents need to be finalized or a letter needs to be sent.

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5.3.1.3.3.1 If applicable, execute the “Finalize Documents” and then the “Send Letter” activities.

5.3.2 If your institutional policy requires that the IRB Reliance Coordinator or IRB staff execute the “Finalize Updates” activity in the system:

5.3.2.1 Review the updates and if they are satisfactory, determine if the changes require an update to the sIRB Decision:

5.3.2.1.1 If yes, execute the “Edit sIRB Decision” activity and complete the SmartForm, indicating whether documents need to be finalized or a letter needs to be sent.

5.3.2.1.2 If applicable, execute the “Finalize Documents” activity and then the “Send Letter” activity to send HRP-859 - TEMPLATE LETTER - Acknowledge External IRB Update.

5.3.2.1.3 If no, no further action is necessary.

5.3.2.2 If the item includes other updates and are not satisfactory:

5.3.2.2.1 Contact the investigator by posting a comment in the submission workspace with requested changes. Instruct the investigator to edit the submission.

5.3.2.2.2 When the investigator edits the submission, confirm that the requested changes were made.

5.3.2.3 Review the updates and if they are satisfactory, determine if the changes require an update to the sIRB Decision:

5.3.2.3.1 If yes, execute the “Edit sIRB Decision” activity and complete the SmartForm, indicating whether documents need to be finalized or a letter needs to be sent.

5.3.2.3.2 If applicable, execute the “Finalize Documents” activity and then the “Send Letter” activity to send HRP-859 - TEMPLATE LETTER - Acknowledge External IRB Update.

5.3.2.3.3 If no, no further action is necessary.

6 MATERIALS

6.1 HRP- 024 - SOP - New Information

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6.2 HRP-055 - SOP - IRB Review of Financial Conflicts of Interest

6.3 HRP-309 - WORKSHEET - Ancillary Review Matrix

6.4 HRP-441- CHECKLIST - HIPAA Waiver of Authorization

6.5 HRP-830 - WORKSHEET - Communication and Responsibilities

6.6 HRP-859 - LETTER - Acknowledge External IRB Update

7 REFERENCES

7.1 None.

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HRP-806 SOP: Review Request to Rely on External IRB

1 PURPOSE

1.1 This procedure establishes the process to ensure the criteria for this Institution to rely on an external IRB for review and oversight of non-exempt human research have been met.

1.2 This process begins when a study team submits a request to rely on an external IRB.

1.3 This process ends when the request to rely on an external IRB has been approved or declined.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The IO/OO or their designee has the authority to determine what IRBs the Institution will rely upon, as well as approve and rescind authorization agreements for IRBs.

3.2 Reliance on an external IRB requires an Authorization Agreement and an active local Institutional Profile, as well as a local review for compliance with local policies of the Institution.

4 RESPONSIBILITIES

4.1 The IRB Coordinator or IRB staff carry out these procedures.

5 PROCEDURE

5.1 Click on the Institutional Profile area in IRB system and determine if the external IRB has an active profile.

5.1.1 If there is an active profile and the IRB is not required to approve each individual request to rely for this external IRB (e.g. NCI CIRB), go to Section 5.2.2.

5.1.2 If there is not an active profile OR the IRB is required to approve each individual request to rely for this external IRB, proceed to next section.

5.2 Using HRP-832 - WORKSHEET - Criteria for Relying on an External IRB, determine if the study is eligible to rely on an external IRB of record.

5.2.1 If the study does not meet the criteria for reliance on an external IRB:

5.2.1.1 Execute the “Confirm Reliance” activity.

5.2.1.2 Indicate NO to the question #3 “Confirm reliance on the single IRB of record?”

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5.2.1.2.1 Prepare and send HRP-856- Reliance Determination Decline to Rely to communicate the determination to the Investigator.

5.2.1.2.2 If the Investigator chooses to submit a response to the IRB regarding the determination, proceed with step 5.1 above.

5.2.2 If the study is eligible to rely on an external IRB of record:

5.2.2.1.1 Determine if a valid authorization agreement is part of the Institutional Profile. If not, follow HRP-801 - SOP - Establishing Reliance Agreements to create a new authorization agreement.

5.2.2.2 Confirm that all local requirements and ancillary reviews are complete.

5.2.2.2.1 Human Subjects Training is complete.

5.2.2.2.2 Conflict of Interest management plan is in place when applicable and will be provided to IRB of Record.

5.2.2.2.3 Written consent to be used at this institution includes institutionally required language where applicable.

5.2.2.2.4 HIPAA Authorization language is combined with consent or provided as separate document to be used at this institution when applicable to the study.

5.2.2.2.5 Refer to the Institutional Profile or authorization agreement to determine institutional responsibilities.

5.2.2.2.6 Use HRP-441 CHECKLIST - HIPAA Waiver of Authorization when applicable and this institution will serve as Privacy Board.

5.2.2.2.7 Use HRP-064 -SOP - NIH GDS Institutional Certification and HRP-332 WORKSHEET - NIH GDS Institutional Certification when applicable and this institution is responsible for certification.

5.2.2.2.8 All relevant local ancillary review requirements have been met or are in progress in accordance with HRP-309 - WORKSHEET - Ancillary Review.

5.2.2.3 If any institutional requirements are not met, execute the "Request Pre-Review Clarification" activity from the investigator.

5.2.2.4 Offer the investigator the opportunity to update the submission.

5.2.2.5 Execute the "Confirm Reliance" activity:

5.2.2.5.1 Indicate YES or NO to the question "Confirm reliance on the single IRB of record?"

5.2.2.5.2 If you indicated YES and the investigator does not yet have external IRB approved documents for this

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site, and your institution requires these be provided, leave the study in "Pending sIRB Review" state and wait for the Investigator to log a comment with IRB approved documents. Communicate this requirement to the Investigator.

5.2.2.5.3 Draft and upload HRP-852 - LETTER - Permission to Rely on an External IRB, as needed (e.g., if documentation is required to be submitted to the external IRB).

5.2.2.5.4 If you indicated NO, see instructions above for when the study does not meet the criteria for reliance on an external IRB.

5.2.2.6 When the external IRB approved documents for this site (e.g., NCI CIRB) are submitted, or your institution does not require external IRB approved documents to be provided to the local IRB, execute the "Record sIRB Decision" activity and complete any information required by the local IRB.

5.2.2.6.1 Indicate NO to the question "Do you need to finalize documents or send a letter" unless finalizing documents and/or sending a letter is required. This moves the study to the Review Complete state.

5.2.2.6.2 Indicate YES if finalizing documents and/or sending a letter is required. This will move the study to the Post Review state.

5.2.2.7 Refer to HRP-804 - SOP - External IRB Post-Review.

6 MATERIALS

6.1 HRP-064 -SOP- NIH GDS Institutional Certification

6.2 HRP-309 - WORKSHEET - Ancillary Review Matrix

6.3 HRP-332 - WORKSHEET - NIH GDS Institutional Certification

6.4 HRP-441 - CHECKLIST - HIPAA Waiver of Authorization

6.5 HRP-801 - SOP - Establishing Reliance Agreements

6.6 HRP-804 - SOP - External IRB Post-Review

6.7 HRP-815 - FORM - Institutional Profile

6.8 HRP-832 - WORKSHEET - Considerations for Relying on External IRB

6.9 HRP-852 - LETTER - Permission to Rely on External IRB

6.10 HRP-857 - LETTER - Acknowledge External IRB

6.11 HRP-856 - LETTER - Decline Reliance on an External IRB

6.12 HRP-859 - LETTER - Acknowledge External IRB Update

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6.13 HRP-861 - WORKBOOK - Institutional Profiles

7 REFERENCES

7.1 SMART IRB Agreement: https://smartirb.org/agreement/

7.2 OHRP Authorization Agreement template: https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/irb-authorization-agreement/index.html

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HRP-1000 SOP: Human Research Determination

1 PURPOSE

1.1 This procedure establishes the process for determining whether an activity is Human Research.

1.2 The process begins when the IRB receives a request for local IRB review of Human Research.

1.3 The process ends when the "Submit Designated Review" activity is complete and completed materials are returned.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The Designated Reviewer utilizes all applicable worksheets in the determination of Human Research.

3.2 Applicable criteria in HRP-310 - WORKSHEET - Human Research Determination must be satisfied for the activity to be determined Human Research.

4 RESPONSIBILITIES

4.1 IRB staff and/or the Designated Reviewer carry out these procedures.

5 PROCEDURE

5.1 Review all materials and evaluate the activity for criteria of Human Research using HRP-310 - WORKSHEET - Human Research Determination.

5.2 If information is not complete or additional information is needed for determination, contact the investigator by executing the Request Pre-Review Clarifications Activity. Offer the investigator the opportunity to provide additional information.

5.2.1 Continue processing once the investigator responds to the request for additional information.

5.3 If the activity is not Human Research, complete the Pre-Review Activity and attach HRP-401 - CHECKLIST - Pre-Review.

5.3.1 Assign Designated Reviewer.

5.3.2 Complete HRP-402- CHECKLIST- Non-Committee Review.

5.3.3 Complete the Submit Designated Review activity.

5.4 If the activity is Human Research, determine the most likely level of review using HRP-312 - WORKSHEET - Exemption Determination and/or HRP-313 - WORKSHEET - Expedited Review

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5.4.1 Using the "Request Pre-Review Clarifications" activity, notify the investigator of the Human Research determination and request materials according to the most likely level of review.

5.4.1.1 Continue processing once the investigator responds to the request for additional information.

5.4.2 Complete HRP-401 - Checklist - Pre-Review

5.4.3 Complete the Pre-Review activity.

5.4.4 If the request can be handled as a Non-Committee Review and the principal investigator is not Restricted, Follow HRP-031 - SOP - Non-Committee Review Preparation.

5.4.5 If the request cannot be handled as a Non-Committee Review, place the protocol on the agenda for a convened meeting in an IRB with appropriate scope. Follow HRP-040 – SOP – IRB Meeting Preparation.

6 MATERIALS

6.1 HRP-031 - SOP - Non-Committee Review Preparation

6.2 HRP-040 - SOP - IRB Meeting Preparation

6.3 HRP-052 - SOP - Post-Review

6.4 HRP-308 - WORKSHEET - Pre-Review

6.5 HRP-310 - WORKSHEET - Human Research Determination

6.6 HRP-311 - WORKSHEET - Engagement Determination

6.7 HRP-312 - WORKSHEET - Exemption Determination

6.8 HRP-313 - WORKSHEET - Expedited Review

6.9 HRP-401 - CHECKLIST - Pre-Review

6.10 HRP-402 - CHECKLIST - Non-Committee Review

6.11 HRP-513 - LETTER - NHR Determination

7 REFERENCES

7.1 45 CFR §46.102

7.2 21 CFR §50.3, 21 CFR §56.102, 21 CFR §312.3, 21 CFR §812.2(a), 21 CFR §812.3(p)

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HRP-1001 SOP: Engagement Determination

1 PURPOSE

1.1 This procedure establishes the process for determining whether an activity is engagement.

1.2 The process begins when the IRB receives a request for local IRB review of engagement.

1.3 The process ends when the "Submit Designated Review" activity is complete and completed materials are returned.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The Designated Reviewer utilizes all applicable worksheets in the determination of engagement.

3.2 Applicable criteria in HRP-311 - WORKSHEET - Engagement must be satisfied for the activity to be determined engaged.

4 RESPONSIBILITIES

4.1 IRB staff and/or the Designated Reviewer carry out these procedures.

5 PROCEDURE

5.1 Review all materials and evaluate the activity for criteria of Engagement using HRP-311 - WORKSHEET - Engagement.

5.2 If information is not complete or additional information is needed for determination, contact the investigator by executing the Request Pre-Review Clarifications Activity. Offer the investigator the opportunity to provide additional information.

5.2.1 Continue processing once the investigator responds to the request for additional information.

5.3 If the activity is not engaged, complete the Pre-Review Activity and attach HRP-401 - CHECKLIST - Pre-Review.

5.3.1 Assign Designated Reviewer.

5.3.2 Complete HRP-402- CHECKLIST- Non-Committee Review.

5.3.3 Complete the Submit Designated Review activity.

5.4 If the activity is engaged, determine the most likely level of review using HRP-312 - WORKSHEET - Exemption Determination and/or HRP-313 - WORKSHEET - Expedited Review

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5.4.1 Using the "Request Pre-Review Clarifications" activity, notify the investigator of the engagement determination and request materials according to the most likely level of review.

5.4.1.1 Continue processing once the investigator responds to the request for additional information.

5.4.2 Complete HRP-401 - Checklist - Pre-Review

5.4.3 Complete the Pre-Review activity.

5.4.4 If the request can be handled as a Non-Committee Review and the principal investigator is not Restricted, Follow HRP-031 - SOP - Non-Committee Review Preparation.

5.4.5 If the request cannot be handled as a Non-Committee Review, place the protocol on the agenda for a convened meeting in an IRB with appropriate scope. Follow HRP-040 – SOP – IRB Meeting Preparation.

6 MATERIALS

6.1 HRP-031 - SOP - Non-Committee Review Preparation

6.2 HRP-040 - SOP - IRB Meeting Preparation

6.3 HRP-052 - SOP - Post-Review

6.4 HRP-308 - WORKSHEET - Pre-Review

6.5 HRP-311 - WORKSHEET - Engagement Determination

6.6 HRP-312 - WORKSHEET - Exemption Determination

6.7 HRP-313 - WORKSHEET - Expedited Review

6.8 HRP-401 - CHECKLIST - Pre-Review

6.9 HRP-402 - CHECKLIST - Non-Committee Review

6.10 HRP-513 - LETTER – Human Research Not Engaged

7 REFERENCES

7.1 45 CFR §46.102

7.2 21 CFR §50.3, 21 CFR §56.102, 21 CFR §312.3, 21 CFR §812.2(a), 21 CFR §812.3(p)

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HRP-1002 SOP: PI Proxy

1 PURPOSE

1.1 This policy establishes who is permitted to serve as PI proxy in the electronic platform and under what circumstances the PI proxy may submit in the electronic system on behalf of the PI.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The Principal Investigator (PI) can assign one or more proxies who can perform all actions normally restricted to the PI in the electronic system, including submitting initial applications, modifications, continuing reviews, and clarification responses. PI proxies receive the same email notifications as the PI. A PI proxy will have the ability to enter information on behalf of the PI. **The PI still holds ultimate responsibility for the study and for all actions taken by the PI proxy and is expected to be aware of and have approved information prior to submission on their behalf**.

3.2 The Research Compliance Office and/or MaineHealth IRB reserves the right to revoke the use of PI proxy.

4 RESPONSIBILITIES

4.1 Investigators are to follow this policy when identifying a PI proxy(ies) and a PI proxy is to follow this policy when executing their role.

4.2 Investigators are expected to create internal processes to ensure appropriate PI proxy usage.

5 PROCEDURE

5.1 This section should describe how a PI proxy is appointed.

5.1.1 PI navigates to the study in the electronic system.

5.1.1.1 On the left side select Assign PI Proxy.

5.1.1.1.1 Select the member(s) of the study team who will serve as PI Proxy(ies).

6 MATERIALS

6.1 None

7 REFERENCES

None

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[i] 45 CFR 46.102(h)
[ii] 15 U.S.C. 9401(3)
[iii] 21 CFR 50.3(c), 21 CFR 56.102(c)
[iv] U.S. Department of Health and Human Services, "Coded Private Information or Specimens Use in Research, Guidance (2008)," 2008. [Online]. Available: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html.
[v] 45 CFR 46
[vi] https://www.fda.gov/news-events/public-health-focus/expanded-access
[vii] 21 CFR 56.102(d)
[viii] 45 CFR 46.104(d)
[ix] 45 CFR 46.102(d)
[x] The terms "Human Subject Research," "Research Involving Human Subjects," "Clinical Research," "Clinical Investigation," "Clinical Study" and similar phrases are considered to be synonyms for the term Human Research.
[xi] Definitions of "identifiable private information" and "identifiable biospecimen" are included in FDA's proposed rule to amend part 50, Protection of Human Subjects, and part 56, Institutional Review Boards (87 FR 58733, September 28, 2022). In that rule, the proposed definitions of "identifiable private information" and "identifiable biospecimen" harmonize with the revised Common Rule's definitions of these terms (45 CFR 46.102(e)(5) and (6)).
[xii] https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2008-september-18-letter-attachment/index.html
[xiii] AAHRPP Evaluation Instrument (2018-10-15); http://www.aahrpp.org/apply/web-document-library/domain-i-organization
[xiv] The phrase "ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests" should not be interpreted to include the inherent risks certain categories of subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).
[xv] 45 CFR 303(c)
[xvi] National Institutes of Health, "What Health Information is Protected by the Privacy Rule?," National Institutes of Health, [Online]. Available: https://privacyruleandresearch.nih.gov/pr_07.asp.
[xvii] See OHRP guidance "Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events: OHRP Guidance (2007)" at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html
[xviii] A "request for an approval or determination" includes approval of new research, response to modifications required to secure approval, continuing review of research, modification to previously approved research, request for study closure, or a determination whether an activity is exempt Human Research or is not Human Research.
[xix] Per OHRP correspondence dated 07/22/2011, protocol exceptions are considered changes to previously approved research and eligible for review via expedited procedure.
[xx] Refer to the VA application process for the use of a commercial IRB approved by ORD: https://www.research.va.gov/programs/epros/irb_relationships.cfm
[xxi] Per FDA correspondence dated 5/6/2025, "21 CFR 50.23(a) (3) requires that the documentation required in 21 CFR 50.23(a) or (b) be submitted to the IRB within 5 working days after the use of the test article. However, if there is time for this information to be provided to the IRB before the administration of the test article, and the information was sufficient for the IRB's needs, then there would be no expectation that the information would need to be subsequently submitted to the IRB again."
[xxii] "The IRB chairperson (or designated IRB member) would consider the same information that the full IRB would consider to determine whether to approve the treatment when reviewing and concurring for individual patient expanded access use." Per FDA correspondence dated 10/10/17.
[xxiii] "Tabled" is not an action of the IRB, but is a status based on the inability of the IRB to take an action because of reasons of quorum.
[xxiv] https://oashsps.my.site.com/ohrpwebforms/s/incident-web-form
[xxv] FDA Bioresearch Monitoring Program (BIMO) Compliance Program Manual – Institutional Review Boards
[xxvi] See http://www.hhs.gov/ohrp/assurances/. Use the Web site: http://ohrp.cit.nih.gov/efile/.
[xxvii] See http://www.hhs.gov/ohrp/assurances/. Use the Web site: http://ohrp.cit.nih.gov/efile/.
[xxviii] See OHRP's IRB Registration Process FAQ "How do I determine the various categories of members for the IRB roster?" and FDA's IRB FAQs on IRB Membership for additional guidance.
[xxix] See http://www.hhs.gov/ohrp/assurances/. Use Web site: http://ohrp.cit.nih.gov/efile/.

[xxx] See http://www.hhs.gov/ohrp/assurances/. Use the Web site: http://ohrp.cit.nih.gov/efile/.
[xxxi] FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023) https://www.fda.gov/media/88915/download
[xxxii] FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023) https://www.fda.gov/media/88915/download
[xxxiii] If your institution participates in the NCATS SMART IRB program, then you may choose to replace this SOP with SMART IRB documentation or to supplement this SOP with SMART IRB documentation.
[xxxiv] Extending an FWA to Cover Collaborating Investigators (2005) | HHS.gov: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/extension-of-institutional-fwa-via-individual-investigator-agreement/index.html

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