VCU Research and Innovation

HRP-001 | 02/1/2024| Author: T. Bechert | Approver: S. Brooks

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 Added terms for collaborating individual investigator and individual investigator agreement, added UPIRTSO footnote; 2/1/24.

3 POLICY

3.1 Adverse Event (AE): For Veterans Administration (VA) human subjects research any untoward physical or psychological occurrence in a human subject participating in research, whether or not considered related to the subject's participation in research.

3.1.1 Adverse events are untoward diagnostic or therapeutic incidents, iatrogenic injuries, or other occurrences of harm or potential harm directly associated with care or services delivered by VA providers.

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

3.3 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.

3.4 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.

3.5 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.

3.6 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.

3.7 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.

3.8 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:

3.8.1 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.

3.8.2 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.

3.9 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.

3.9.1 For Veterans Administration (VA) research, Collaborative (Study) Research involves human subjects research activities involving investigators from VA and at least one non-VA institution. Collaborative Research includes VA and non-VA institutions.

3.10 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:

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

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

3.10.3 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.

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

3.10.5 Board or executive relationship, regardless of compensation.

3.10.6 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.

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

3.11 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.

3.11.1 For Veterans Administration (VA) research Continuing Non-Compliance means repeated instances of noncompliance with applicable laws, regulations, policies, agreements, or determinations of a research review committee or the prolonged persistence of noncompliance occurring after its identification, awareness, or implementation of a corrective action intended to effectively resolve the noncompliance.

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

3.13 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.

3.14 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.

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

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

3.17 Human Research: Any activity that either:[1]

3.17.1 Is Research as Defined by DHHS and involves Human Subjects as Defined by DHHS; or

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

3.18 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:

3.18.1 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.

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

3.18.3 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).

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

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

3.19 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.

3.20 Immediate Family: any person who resides in the same household and is a dependent of the investigator.

3.21 Individual Investigator Agreement: a permissible mechanism under which an institution holding an Office for Human Research Protections (OHRP)-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.

3.22 Institutional Official/ Deputy Institutional Official (IO/DIO):

3.22.1.1 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)[2]. The IO is the Vice President for Research and Innovation.

[1] 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.

[2] https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2008-september-18-letter-attachment/index.html

3.22.2 For Veteran's Administration (VA) research, the Institutional Official (IO) is the individual legally authorized as Signatory Official to commit an institution to an FWA. The Signatory Official assures that human subjects' research to which the FWA applies is conducted in accordance with the terms of the assurance (see VHA Handbook 1058.03). The Principal Deputy Under Secretary for Health or designee is the IO for VHA Central Office, and VA facility Directors are the IOs for local VA facilities.

3.22.3 Deputy Institutional Official (DIO): The Deputy Institutional Official (DIO) is appointed by the IO to execute certain responsibilities for the IO as outlined in the appointment letter.

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

3.24 Investigation: A searching inquiry for facts; detailed or careful examination.

3.25 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.

3.25.1 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.

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

3.26 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.[3]

3.26.1 For research involving prisoners Minimal Risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

3.26.2 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:

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

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

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

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

3.28 Non-Committee Review: Any of the following:

3.28.1 Determination of whether an activity is Human Research.

3.28.2 Determination of whether Human Research is exempt from regulation.

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

3.28.4 Determinations of which subjects can continue in expired research.

3.28.5 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

[3] 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).

non-emergency individual patient expanded access IND with request for authorization to use alternative IRB review procedures.

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

3.29.1 In the case of research funded or conducted by the Department of Defense (DOD), Non-Compliance includes failure of a person, group, or institution to act in accordance with Department of Defense (DOD) instruction 3216.02, its references, or applicable requirements

3.29.2 In the case of Veterans Administration (VA) research, Non-Compliance is any failure to adhere to the requirements for overseeing, reviewing, approving, or conducting VA research set forth in law, regulation, policy, or study agreements (such as reliance agreements, memoranda of understanding, data use agreements), including any failure to conduct research in accordance with a VA study protocol approved by a research review committee.

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

3.31 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 which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

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

3.32 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.

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

3.33.1 A sponsor of the research;

3.33.2 A competitor of the sponsor of the research;

3.33.3 A product or service being tested; or

3.33.4 A competitor of the product or service being tested.

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

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

3.34.1.1 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.

3.34.1.2 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.

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

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

3.34.1.2.3 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).

3.34.1.3 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.

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

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

3.35 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:

3.35.1 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;

3.35.2 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

3.35.3 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.

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

3.37 Serious Adverse Event (SAE): An untoward occurrence, whether or not considered related to a subject's participation in Human Research, that results in death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly or birth defect, or that requires medical, surgical, behavioral, social or other intervention to prevent such an outcome.

3.38 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.

3.38.1 For Department of Defense (DOD) research Serious Non-Compliance includes failure of a person, group, or institution to act in accordance with Department of Defense (DOD) Instruction 3216.02 and its references such that the failure 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.

3.38.2 For Veterans Administration (VA) research Serious Non-Compliance is any failure to adhere to requirements for conducting Human Research that may reasonably be regarded as:

3.38.2.1 Presenting a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, or others, including their rights to privacy and confidentiality of identifiable private information;

3.38.2.2 Presenting a genuine risk of substantive harm to the safety, rights, or welfare of research personnel who conduct research;

3.38.2.3 Presenting a genuine risk of substantive reputational harm to the Veterans Administration (VA); or

3.38.2.4 Substantively compromising a VA medical facility's human research protection programs (HRPP).

3.39 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.

3.40 Suspension of IRB Approval: An action of the IRB, IRB designee, Institutional Official/Deputy Institutional Official, or designee of the Institutional Official/Deputy Institutional 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.

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

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

3.42.1 For Veterans Administration (VA) research, Termination of IRB Approval:

3.42.1.1 Refers to a permanent halt in all research activities due to concerns about the safety, rights, or welfare of human subjects, research personnel, or others, regardless of whether the action was taken by an investigator, facility official, research review committee, or external entity.

3.42.1.2 Does not refer to interruptions in research for other reasons, including the expiration of project approval periods.

3.43 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.[4]

3.43.1 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:

3.43.1.1 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.

3.43.1.2 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).

3.43.1.3 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.

3.43.2 For Veterans Administration (VA) research:

3.43.2.1 Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) is an incident, experience or outcome that is: unexpected; related or possibly related to participation in the research; and indicative of the research placing subjects or others at substantively greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized.

3.43.2.2 The term "unexpected" refers to an incident, experience, or outcome that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol-related documents and the characteristics of the study population.

[4] 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

3.43.2.3 The phrase “related to participation in the research” means a logical sequence of cause and effect shows that the study procedures were the reason for the incident, experience, or outcome. The phrase “possibly related to participation in the research” implies a lesser degree of certainty about causality and refers to an incident, experience, or outcome for which there is some evidence to reasonably suggest a causal relationship between study procedures and the incident, experience, or outcome.

3.43.2.4 An unexpected SAE that is related or possibly related to participation in human subjects research constitutes a UPIRTSO.

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 VHA Handbook 1058.01 dated October 22, 2020; VHA Directive 1004.08 dated October 31, 2018; VHA Directive 1200.05 dated January 7, 2019, amended January 8, 2021; VHA Directive 1058.03 dated September 17, 2020

7.4 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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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 IRB determines that the consent process no longer should be observed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

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

3.1.1 The IRB wants verification from sources other than the investigator that no material changes have taken place since prior IRB review.

3.1.2 There are Allegations or Findings of Non-Compliance.

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

3.2 The IRB, Institutional Official/ Deputy Institutional Official (IO/DIO), or designee designates who conducts the observation. The IRB may have the observation conducted by:

3.2.1 IRB staff.

3.2.2 IRB members.

3.2.3 Post-Approval Monitoring staff

3.2.4 A person recommended by the investigator.

3.2.5 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 Observe the consent process and determine whether the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject or the subject's Legally Authorized Representative (LAR), and that informed consent was freely given by the subject or the LAR.

5.1.1 If no, indicate that consent is not legally effective and the prospective subject may not be entered into the research.

5.1.2 If yes, document in writing that the consent process was observed and that informed consent was freely given by the subject or LAR.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 None

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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 None

3 POLICY

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

3.1.1 When research is conducted in the Commonwealth of Virginia, the list below indicates the individuals who may serve as LAR , in the specified decreasing order of priority:

(i) the parent or parents having custody of a prospective subject of human research who is a minor;
(ii) the agent appointed under an advance directive as defined in § 54.1-2982 of the Code of Virginia, executed by the person who is the prospective subject of human research, provided the advance directive authorizes the agent to make decisions regarding the person's participation in human research;
(iii) the legal guardian of a prospective subject of human research;
(iv) the spouse of a prospective subject of human research, except where a suit for divorce has been filed and the divorce decree is not yet final;
(v) an adult child of a prospective subject of human research;
(vi) a parent of a prospective subject of human research when the individual is an adult;
(vii) an adult brother or sister of a prospective subject of human research; or
(viii) any person or judicial or other body authorized by law or regulation to consent on behalf of a prospective subject of human research to such person's participation in the particular human research. [1]

3.1.1.1 Attorney-in-fact. Any person authorized by law or regulation, including appointment under a durable power of attorney, to consent on behalf of a prospective subject to that subject's participation in human research. The attorney-in-fact shall not be employed by the person, institution or agency conducting the human research. No official or employee of the institution or agency conducting or authorizing the research shall be qualified to act as a legally authorized representative.[2]

3.1.2 Additional Considerations.[3]

[1] 12VAC5-20-10.

[2] 12VAC5-20-10.

[3] For limitations on LARs in Virginia, see VA Code Ann. § 32.1-162.18 (2016).

3.1.2.1 If two or more persons who qualify as legally authorized representatives and have equal decision-making priority inform the Principal Investigator (PI) or attending physician that they disagree (with each other) as to participation of the prospective subject in human research, the subject shall not be enrolled in the human research that is the subject of the consent.

3.1.2.2 In the case of persons suffering from organic brain diseases causing progressive deterioration of cognition for which there is no known cure or medically accepted treatment, the implementation of experimental courses of therapeutic treatment to which a legally authorized representative has given informed consent shall not constitute the use of force, unless prior knowledge of participant refusal is known.

3.1.3 Legally emancipated minors (with legal documentation to verify such status) are permitted to make all decisions concerning research participation as would someone 18 and older who is also decisionally-capable. Contact legal counsel for more information.

3.1.4 For research conducted outside Virginia, consult legal counsel to determine who is a LAR. Determinations regarding who can serve as a LAR are based on the law of the jurisdiction in which the research is being conducted.

3.1.4.1 For studies approved on or after January 21, 2019 (or converted to the new regulations) that are NOT FDA or DoJ regulated, the 2018 Common Rule includes the following additional language regarding LARs: "If there is no applicable law addressing the issue, legally authorized representative means an individual 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."

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

3.2.1 For research conducted in Virginia, individuals under the age of 18 years are children, unless legally emancipated as previously described.

3.2.1.1 If the research on a specific treatment involves only treatments or procedures for which minors may legally consent to certain treatments, the participants under age 18 would not meet the definition of "children" as defined in 45 CFR 46.402(a). In this situation, participants may provide their own informed consent, and parental permission (or a waiver thereof) is not needed[4].

3.2.1.2 If a proposed activity includes any intervention or interaction, apart from those specific treatments, for which the subject has not yet reached the legal age of consent, that person must be considered a child.

3.2.1.3 Consult with legal counsel and/or the HRPP if there are questions about the treatments or procedures for which a minor may provide their own consent, or the scope of research activities in a study.

3.2.2 Unless the IRB has waived the requirement to obtain consent, when research involves a child, consent may only be obtained from biologic or adoptive parents or guardian, which is an individual who is authorized under applicable state law to consent on behalf of the child to general medical care[5].

3.2.3 Before obtaining permission from an individual who is not a parent or legal guardian, consult with legal counsel.

3.2.4 For research conducted outside Virginia, consult with legal counsel to determine who is a child.

3.3 The IRB must specifically approve the use of a LAR for adults or children in court-appointed or state custody.

[4] VA Code § 54.1-2969.

[5] This is the DHHS and FDA definition of "guardian."

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 12VAC5-20-10

7.4 VA Code Ann. § 32.1-162.18 (2016)

7.5 VA Code § 54.1-2969

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

VCU Research and Innovation

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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 Revised pre-review reference; 2/1/24.
2.2 Revised triage procedures to align with updated processes; 10/9/24.

3 POLICY

3.1 Incoming submissions to the IRB office are assigned to a member of the HRPP staff for pre-review within two business days of receipt.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 For a submission appearing in the unclaimed tab in RAMS-IRB that is a request for an approval or determination[1] by this institution's IRB that does not include other pSites, refer to the staff list to assign for review by an available, appropriately trained staff member. Consider the number of submissions currently in process for each staff member to ensure an equitable distribution of workload, or assign per established rotation taking into account when staff will be out of office (reference ORSP shared calendar). Staff will follow HRP-021 - SOP - Pre-Review.

5.1.1 If the submission is a response to modifications required to secure approval received more than 30 days after the IRB review date, it will need to be re-assigned to the previously assigned IRB coordinator.

5.2 If the item is a request for an approval or determination by this institution's IRB, or 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.

5.3 If the item is an update to a study for which an external IRB is the IRB of record, the submission will automatically route to the initial IRB Administrator or Reliance Coordinator (or the first IRB staff assigned as coordinator) who will follow HRP-805 - SOP - External IRB Updates. Re-assign to active staff where applicable.

5.4 If the item includes new or modified contact information for independent investigators, update the contact information in the Reliance Tracker on Google Drive.

[1] 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. Submission of an updated list of study personnel is not considered a modification of research and is therefore not a "request for an approval or determination."

5.5 If the item is a notification of an emergency use of a test article in a life-threatening situation, assign to an IRB Administrator who will follow HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access. Notify the staff member, HRPP Director and IRB Chair of the assignment.

5.6 If the item is an investigator's request to continue subjects in expired research, the staff reviewer will have a Designated Reviewer follow HRP-063 - SOP - Expiration of IRB Approval.

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

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

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

5.7.1.2 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.

5.7.2 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-063 - SOP - Expiration of IRB Approval

6.5 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

VCU Research and Innovation

HRP-021 | 11/26/2024 | Author: T. Bechert | Approver: J. Opalesky

SOP: Pre-Review

1 PURPOSE

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.

1.1 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.

1.2 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 Revised the workflow to incorporate DUA review; 10/2/23.

2.2 Revised to incorporate HRP-803 - SOP - Reliance Pre-Review content per Huron HRPP Toolkit v5.1 release; 2/1/24.

2.3 Updated federal debarment link; additional administrative updates for clarity; added reference to HRP-815 - FORM - Institutional Profile; added process step for IIA, revised workflow for expanded access; 11/26/24.

3 POLICY

3.1 The assigned IRB Coordinator will conduct pre-review within 10 business days of assignment. The IRB Coordinator will consult with their supervisor when review exceeds turnaround expectations.

3.2 Any institution located in the United States that is engaged in federally-funded cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

3.3 An NIH funded study being conducted at more than one U.S. site involving non-exempt human subjects research may be subject to the NIH Single IRB policy and/or the revised Common Rule cooperative research provision (§46.114).

3.4 The VCU Post Approval Monitoring and Education program (PAM&E), when applicable, performs routine or for-cause audits on studies relying on an external IRB.

3.5 VCU evaluates requests for VCU IRB to serve as sIRB for federally funded or non-industry funded multi-site/collaborative research on a case-by-case basis.

3.6 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.

3.7 Single subject protocol exceptions are reviewed as modifications to previously approved research. [1]

3.8 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.

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 calendar days (RAMS-IRB will auto-withdraw the submission if not returned within 30 calendar days of the IRB review date):

5.1.1 Evaluate whether the investigator made the required modifications.

5.1.2 If the investigator made the required modifications, follow HRP-052 - SOP - Post-Review to issue an approval.

5.1.3 If the investigator did not make the required modifications or made unrequested modifications, execute the "Changes Requested by IRB staff" activity and offer the investigator the opportunity to correct the submission.

5.1.3.1 If the investigator will correct the submission, have the investigator make changes then execute the "Submit Changes" activity and stop processing the current submission until changes are received.

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

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 Authorization Agreements to collect the information needed to confirm reliance and create a new or updated HRP-815 - FORM - 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 next section.

5.4 If the request includes review of a collaborating independent investigator or collaborating institutional investigator, follow HRP-801 - SOP - Establishing Agreements to establish an Individual Investigator Agreement.

[1] Per OHRP correspondence dated 07/22/2011, protocol exceptions are considered changes to previously approved research and eligible for review via expedited procedure.

5.5 For all other submissions, complete HRP-401 - Checklist - Pre-Review or review the previously completed checklist and revise as needed, considering the items on HRP-308 - WORKSHEET - Pre-Review and note all remaining contingencies in the “Notes” section.

5.5.1 Perform the “Upload Administrative Documents” Activity to attach applicable documents:

5.5.1.1 HRP-401 - Checklist - Pre-Review.

5.5.1.1.1 Layer the revised pre-review checklist, when applicable, to the previous version.

5.5.1.2 All applicable special determination checklists for completion by the assigned reviewer(s).

5.6 When assigning to an IRB member for review, include HRP-314a - WORKSHEET - Criteria for Approval Reviewer Summary.

5.7 If the information is not complete, contact the investigator by selecting the “Changes Requested by IRB Staff” Activity. Offer the investigator the opportunity to provide additional information.

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

5.8 If the request is for an initial approval, use HRP-308 - Worksheet - Pre-Review to assess the completeness of the submission, identifying any incomplete responses or missing materials (e.g., missing informed consent process information). Also assess the following as it relates to the submission:

5.8.1 Search the RAMS-IRB system for all of the Principal Investigator’s open studies to determine if they have any studies requiring continuing review in a lapsed state. If the Principal Investigator has any lapsed studies, note in the “Notes” section of HRP-401 - Checklist - Pre-Review.

5.8.1.1 Request the Principal Investigator submit a continuing review or closure for any lapsed studies and determine whether any research activities have taken place during the lapse in IRB approval; if research has been conducted, request a Report to the IRB and refer the identified lapsed studies to the PAM&E Monitor.

5.8.2 If the study is FDA-regulated, and involves a new or unfamiliar investigator, search the FDA debarment list to see if the Principal Investigator is listed.

5.8.2.1 If the Principal Investigator is listed, note in the “Notes” section of HRP-401 - Checklist - Pre-Review.

5.8.3 If the study involves clinical elements being performed at a VCUHS site by clinicians who require VCUHS privileges, search the “Privileged Personnel List” on the VPR-IRB shared drive to confirm that they hold appropriate, current hospital privileges.

5.8.3.1 If personnel are not listed, note in the “Notes” section of HRP-401 - Checklist - Pre-Review.

5.8.4 Initiate COI ancillary review for COI Investigators by executing the “Create AIRS Review Request” activity. Select the checkbox for each name and click “OK” to complete the process.

5.8.4.1 Confirm the COI Status tab contains a Disposition Date and a final Disposition state (e.g., Complete - No COI, or where a management plan has been established) to proceed with review assignment or consult with the supervisor to determine whether review assignment may proceed concurrent to IRB review.

5.8.5 Confirm the Principal Investigator (and Medically or Psychologically Responsible Investigator, and Lead Student/Trainee Investigator, if applicable) have completed the required

CITI training by uploading their training completion certificate with the IRB submission. The PI is responsible for ensuring all other study staff have current CITI training.

5.8.6 If training is not complete, note in the "Notes" section of HRP-401- Checklist - Pre-Review. Notify the investigator. Review may proceed but the final determination letter may not be issued until the training certificate is provided.

5.8.7 If the study involves sharing a Limited Data Set (LDS) from VCU Health system to an internal entity, confirm a Data Use Agreement for LDS signed by investigator is provided. Send to HRPP Director for signature.

5.8.7.1 Log in to Docusign using VCU credentials.

5.8.7.2 Upload PDF of the DUA for LDS to Docusign.

5.8.7.3 Use Docusign to add fields for name, title, date, and signature.

5.8.7.4 Send to HRPP Director for completion. Docusign will send the signed PDF back once complete.

5.8.7.5 Upload finalized PDF to the "Admin Docs" tab in RAMS-IRB.

5.8.8 If there are any materials listed above, or reviewed as part of HRP-308 - Worksheet - Pre-Review that are missing or incomplete add all information to HRP-401 - Checklist - Pre-Review and upload to the submission under the "Admin Docs" tab.

5.8.8.1 Select the "Changes Requested by IRB Staff" Activity and inform them that they must address all missing or incomplete items before the new request for initial approval will be accepted.

5.8.9 If the submission is complete and there are no outstanding items, proceed to the step 5. 10 below.

5.9 If the submission is a continuing review, use HRP-308 - Worksheet - Pre-Review to assess the completeness of the submission, identifying any incomplete responses or missing materials. Also assess the following as it relates to the submission:

5.9.1 Review Private Comments from the parent submission to identify content relevant to follow-on submissions.

5.9.2 Initiate COI ancillary review for COI Investigators by executing the "Create AIRS Review Request" activity. Select the checkbox for each name and click "OK" to complete the process.

5.9.2.1 Confirm the COI Status tab contains a Disposition Date and a final Disposition state (e.g., Complete - No COI, or where a management plan has been established) to proceed with review assignment or consult with the supervisor to determine whether review assignment may proceed concurrent to IRB review.

5.9.3 Confirm the Principal Investigator (and Medically or Psychologically Responsible Investigator, and Lead Student/Trainee Investigator, if applicable) have completed the required CITI training by uploading their training completion certificate with the IRB submission. The PI is responsible for ensuring all other study staff have current CITI training.

5.9.3.1 If training is not complete, note in the "Notes" section of HRP-401- Checklist - Pre-Review. Notify the investigator. Review may proceed but the final determination letter may not be issued until the training certificate is provided.

5.9.4 If there are any materials listed above, or reviewed as part of HRP-308 - Worksheet - Pre-Review that are missing or incomplete add all information to HRP-401 - Checklist - Pre-Review and upload to the submission under the "Admin Docs" tab.

5.9.4.1 Select the “Changes Requested by IRB Staff” Activity and inform them that they must address all missing or incomplete items before the new request for initial approval will be accepted.

5.9.5 If the submission is complete and there are no outstanding items, proceed to section 5. 10 below.

5.10 If the submission is a modification to previously approved research, use HRP-308 - Worksheet - Pre-Review to assess the completeness of the submission, identifying any incomplete responses or missing materials. Also assess the following as it relates to the submission:

5.10.1 Review Private Comments or documents under the Admin Docs tab from the parent submission to identify content relevant to follow-on submissions (e.g., PAM&E monitoring reports resulting in study modification or requests with the modification to lift a suspension of IRB approval).

5.10.2 Newly added Principal Investigator (and Medically or Psychologically Responsible Investigator, and Lead Student/Trainee Investigator, if applicable): initiate COI ancillary review by executing the “Create AIRS Review Request” activity. Select the checkbox for each name and click “OK” to complete the process.

5.10.3 Confirm the COI Status tab contains a Disposition Date and a final Disposition state (e.g., Complete - No COI, or where a management plan has been established) to proceed with review assignment or consult with the supervisor to determine whether review assignment may proceed concurrent to IRB review.

5.10.4 Confirm the newly added Principal Investigator (and Medically or Psychologically Responsible Investigator, and Lead Student/Trainee Investigator, if applicable) have completed the required CITI training by uploading their training completion certificate with the IRB submission, if applicable. The PI is responsible for ensuring all other newly added study staff have current CITI training.

5.10.4.1 If training is not complete, note in the “Notes” section of HRP-401- Checklist - Pre-Review. Notify the investigator. Review may proceed but the final determination letter may not be issued until the training certificate is provided.

5.10.5 If there are any materials listed above, or reviewed as part of HRP-308 - Worksheet - Pre-Review that are missing or incomplete add all information to HRP-401 - Checklist - Pre-Review and upload to the submission under the “Admin Docs” tab.

5.10.5.1 Select the “Changes Requested by IRB Staff” Activity and inform them that they must address all missing or incomplete items before the new request for initial approval will be accepted.

5.10.6 If the submission is complete and there are no outstanding items, proceed to section 5. 10 below.

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

5.11.1 If the request can be handled as a Non-Committee Review and the Principal Investigator does not have any lapsed studies (applicable for initial review for approval only) and is not on the FDA debarment list (for FDA-regulated projects only), follow HRP-031 - SOP - Non-Committee Review Preparation.

5.11.2 If the request cannot be handled as a Non-Committee Review, including requests to lift a suspension of IRB approval, reassign the IRB Owner to the IRB meeting coordinator for the next available meeting and include a Reassign Owner Comment with any relevant review findings to facilitate selection of an IRB reviewer (e.g., vulnerable population inclusion, drug/device trial, lifting of a suspension). (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.[2])

5.11.3 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-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access and HRP-031 - SOP - Non-Committee Review Preparation.

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-314a - WORKSHEET - Criteria for Approval Reviewer Summary
6.12 HRP-323 - WORKSHEET - Criteria for Approval HUD
6.13 HRP-401 - CHECKLIST - Pre-Review
6.14 HRP-801 - SOP - Establishing Agreements
6.15 HRP-806 - SOP - Review Request to Rely on External IRB
6.16 HRP-815 - FORM - Institutional Profile
6.17 HRP-850 - LETTER - Decline to Serve
6.18 HRP-851 - LETTER - Invitation Decision
6.19 HRP-861 - WORKBOOK - Institutional Profiles

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

[2] Refer to the VA application process for the use of a commercial IRB approved by ORD: https://www.research.va.gov/programs/orppe/single_irb.cfm

VCU Research and Innovation

HRP-023 | 11/26/2024 | Author: T. Bechert | Approver: J. Opalesky

SOP: All Emergency Use, Compassionate Use (Device Only) and 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 IRB 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 Removed reference to FB tracking log, clarifications made to regulatory oversight of emergency use and device compassionate use, revisions to review requirements; 11/26/24.

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 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 The IRB Chair or Designated Reviewer carries out these procedures.

5 PROCEDURE

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 and not accompanied by a RAMS IRB submission, 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. Set a 5-day reminder to request the 5-day report.

5.1.1.2 If the actual emergency use did not follow FDA requirements, manage using HRP-024 - SOP - New Information as Non-Compliance.

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.

5.1.3 Non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested. If so, use HRP-314a - WORKSHEET - Criteria for Approval_Reviewer Summary to determine whether the proposed use meets the requirements under 21 CFR 50 and 56.111[1] and indicate the results of this determination to the IRB staff.

5.1.3.1 Execute the Finalize Review activity.

5.1.3.1.1 Indicate that continuing review is required.

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-314a - WORKSHEET - Criteria for Approval_Reviewer Summary

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 § 312.310.

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/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm432717.pdf

7.7 AAHRPP element 1.7.C

[1] "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.

VCU Research and Innovation

HRP-024 | 02/01/2024 | Author: T. Bechert | Approver: S. Brooks

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 Revised section 5.10 steps to post HRP-519 - Information Item; 10/2/23.

2.2 Minor formatting correction; 2/1/24.

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/Deputy Institutional Official (IO/DIO) 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 or national organization.

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) HSR must be reported immediately.

3.5 For Veterans Administration (VA) research:

3.5.1 The determination that Non-Compliance is Serious Non-Compliance or Continuing Non-Compliance must be determined and documented by the convened IRB.

3.5.2 The convened IRB must review notifications of apparent Unanticipated Problems Involving Risks to Subjects or Others, Serious Non-Compliance, Continuing Non-Compliance, and external Suspension of IRB Approval, or Termination of IRB Approval within 30 calendar days after receiving the notification.

3.5.3 The IRB Chair may take interim action on notifications of apparent Unanticipated Problems Involving Risks to Subjects or Others, Serious Non-Compliance or Continuing Non-Compliance as needed to eliminate apparent immediate hazards to subjects.

3.5.4 For Unanticipated Problems Involving Risks to Subjects or Others that are local research deaths, they must be reported orally to the IRB immediately upon becoming aware of the information.

3.5.5 An apparent unexpected Serious Adverse Event (SAE) that is related or possibly related to participation in human subjects research constitutes an apparent Unanticipated Problems Involving Risks to Subjects or Others.

3.5.6 Except where remediation requires substantial renovation or fiscal expenditure, hiring, legal negotiations, or other extenuating circumstances, remedial actions must be completed within 180 calendar days after any determination of Non-Compliance.

3.6 Requests to lift a suspension of IRB approval are reviewed by the convened IRB to determine whether all corrective actions are met.

4 RESPONSIBILITIES

4.1 The IRB staff members carry out this procedure.

5 PROCEDURE

5.1 Review each item of information and answer the following questions: (*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, consult the IRB chair or IRB manager.

5.3 If the IRB chair and IRB manager are 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.

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.

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.

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:

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

5.6.2.1.2Remove 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 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 For Veterans Administration (VA) research:

5.9.1 If the information represents an Unanticipated Problem Involving Risks to Subjects or Others that is a local research death:

5.9.1.1 Within one (1) business day after receiving written notification of the death, the IRB Chair or Designated Reviewer must assess and document whether any actions are warranted to eliminate apparent immediate hazards to subjects and, if so, initiate those actions.

5.9.1.2 Schedule the written notification, the immediate hazard assessment of the IRB Chair or Designated Reviewer, and the actions taken to date for the next convened IRB meeting, not to exceed 30 calendar days after the date of written notification. NOTE: This may require the IRB to convene an emergency session prior to its next scheduled meeting.

5.9.1.3 The IRB must determine and document within 30 calendar days of the convened IRB's initial review:

5.9.1.3.1 Whether the death was both unexpected and related or possibly related to participation in the research; and

5.9.1.3.2 What, if any, protocol or informed consent modifications are warranted. If modifications are warranted, the convened IRB must determine and document whether or not investigators must notify or solicit renewed/revised consent from previously enrolled subjects; and if so, when such notification or consent must take place and how it must be documented.

5.9.2 Within 5 business days of receipt of written notification of information that appears to represent an Unanticipated Problem Involving Risks to Subjects or Others, have the IRB Chair or a Designated Reviewer determine and document whether any actions are warranted to eliminate apparent immediate hazards to subjects (and if so, initiate those actions).

5.9.2.1 Schedule the written notification, the immediate hazard assessment of the IRB Chair or Designated Reviewer, and the actions taken to date for the next convened IRB meeting, not to exceed 30 calendar days after the date of written notification (this may require the IRB to convene an emergency session prior to its next scheduled meeting).

5.9.2.1.1 If the IRB determines that the problem or event is unexpected and related to or possibly related to participation in the research and indicative of the research placing subjects or others at substantively greater risk of harm than was previously known or recognized (i.e., whether the incident, experience or outcome constituted an actual Unanticipated Problem Involving Risks to Subjects or Others), the IRB must report in writing its determinations within 5 business days to:

5.9.2.1.1.1 VA Medical Facility Director.

5.9.2.1.1.2 ACOS/R&D.

5.9.2.1.1.3 The Research Compliance Officer (RCO).

5.9.3 If the information appears to represent Serious Non-Compliance or Continuing Non-Compliance, schedule the information for the next IRB meeting to be reviewed by the convened IRB, not to exceed 30 calendar days after the date of written notification (this may require the IRB to convene an emergency session prior to its next scheduled meeting).

5.9.4 If the IRB determines that the information constitutes Serious Non-Compliance or Continuing Non-Compliance, the IRB must report in writing its determinations within 5 business days to:

5.9.4.1 VA Medical Facility Director.

5.9.4.2 ACOS/R&D.

5.9.4.3 The RCO.

5.10 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 review and acknowledge using “Finalize Review” activity and if a response is expected, prepare and send HRP-519 - LETTER - Information Item via the “Log Public Comment” activity.

6 MATERIALS

6.1 HRP-025 - SOP – Investigations

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

6.3 HRP-052 - SOP - Post-Review

6.4 HRP-519 - LETTER - Information Item

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

7 REFERENCES

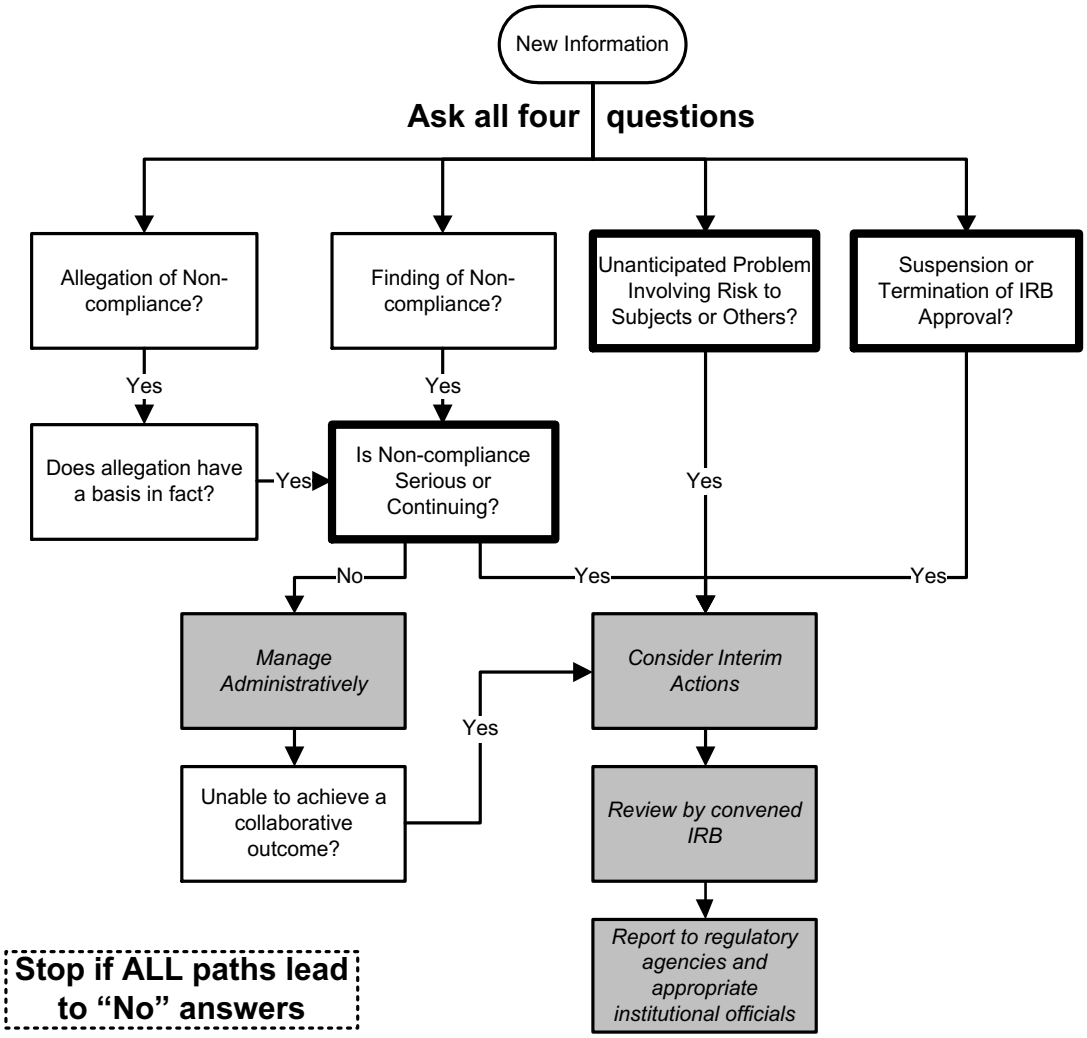
7.1 21 CFR §56.108(b)

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

7.3 VHA Directive 1058.01 October 22, 2020

7.4 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

7.5 Flowchart



VCU Research and Innovation

HRP-025 | 03/01/2024 | Author: T. Bechert | Approver: S. Brooks

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 in writing to the Institutional Official/Deputy Institutional Official (IO/DIO) or designee.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 None

4 RESPONSIBILITIES

4.1 The IO/DIO 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.

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 request a court stenographer to record all interviews.

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/DIO 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

VCU Research and Innovation

HRP-026 | 03/01/2024 | Author: T. Bechert | Approver: S. Brooks

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 Institutional Official/Deputy Institutional Official (IO/DIO) 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 Added step for submitting notification of suspension or termination of IRB Approval to the Chief Ethics and Compliance Officer; 10/6/23.

3 POLICY

3.1 The IRB chair or HRPP Director may institute a Suspension of IRB Approval when in the opinion of the IRB chair or HRPP Director 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/DIO 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.

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.

5.2 Ask the investigator for the number of Human Subjects currently involved in the research and request a contact list if the HRPP needs to notify current or former Human Subjects.

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 and the sponsor.

5.4.6 Notification to current Human Subjects.

5.4.7 Notification to former Human Subjects.

5.5 For Veterans Administration (VA) research, report the Suspension of IRB Approval or Termination of IRB Approval to the VA facility Director, the Associate Chief of Staff/R&D, and RCO within 5 business days 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 Termination.

5.7.1 Submit a copy of the letter to notify the Chief Ethics and Compliance Officer via the University Integrity and Compliance Office reporting system.

6 MATERIALS

6.1 HRP-041 - SOP - IRB Meeting Conduct

6.2 HRP-515 - LETTER - Suspension or 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 1058.01 October 22, 2020

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

VCU Research and Innovation

HRP-027 | 11/26/2024 | Author: T. Bechert | Approver: J. Opalesky

SOP: All Emergency Use, Compassionate Use (Device Only) and 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 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.

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 proposed 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 §812.36; 21 CFR §812.47.
7.3 (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.
7.4 AAHRPP element I.7.C

VCU Research and Innovation

HRP-030 | 03/01/2024 | Author: T. Bechert | Approver: S. Brooks

SOP: Designated Reviewers

1 PURPOSE

1.1 This procedure establishes the process for an IO or Deputy IO to designate IRB members who can conduct Non-Committee Reviews (e.g,, expedited reviews).

1.2 The process begins when the IO or Deputy IO instructs IRB staff to designate an Experienced IRB Member to conduct Non-Committee Reviews.

1.3 The process ends when the IRB member has been noted in the IRB 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.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

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

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

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

6 MATERIALS

6.1 HRP-601 - DATABASE - IRB Roster

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

VCU Research and Innovation

HRP-031 | 11/26/2024 | Author: T. Bechert | Approver: J. Opalesky

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 the Designated Reviewer if the staff member does not conduct the designated review.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Revised system steps; 11/26/24.

3 POLICY

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

3.2 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.”

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 Assign the reviewer:

5.1.1 For initial review, complete the “Assign Single Reviewer” activity.

5.1.1.1 For follow-on submissions, complete the “Send to Expedited” or “Send to Exempt” activity first, as appropriate.

5.1.2 Identify the appropriate administrative staff reviewer or Designated Reviewer.

5.1.2.1 Ensure the staff reviewer or Designated Reviewer is not a member of the study team.

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

5.2 Assign for review within three business days of receipt of a complete submission, or, proceed to conduct the designated review.

6 MATERIALS

6.1 HRP-301 - WORKSHEET - Review Materials

6.2 HRP-601 - DATABASE - IRB Roster

7 REFERENCES

7.1 21 CFR §56.110(b)

7.2 45 CFR §46.110(b)

7.3 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

VCU Research and Innovation

HRP-032 | 10/9/2024 | Author: T. Bechert | Approver: J. Opalesky

SOP: Non-Committee Review Conduct

1 PURPOSE

1.1 This procedure establishes the process for a Designated Reviewer to conduct a Non-Committee Review or a Limited IRB Review.

1.2 The process begins when the Designated Reviewer has the provided materials.

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

2 REVISIONS FROM PREVIOUS VERSION

2.1 Added reference to limited IRB review to purpose section; 2/1/24.

2.2 Removed reference to HRP-402, added grant review NHSR instruction, added process instructions to layer documents, clarified timing for confidentiality agreement and conflict of interest policy review for IRB consultants; 10/9/24.

3 POLICY

3.1 The Designated Reviewer may not disapprove research.

3.2 The Designated Reviewer utilizes all applicable worksheets in the review of research.

3.3 IRB consultants will sign a confidentiality agreement and conflict of interest policy review statement in advance of receiving materials or reviewing and consulting on studies

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 for approval 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 when appropriate).

4 RESPONSIBILITIES

4.1 The Designated Reviewer carries out these procedures.

5 PROCEDURE

5.1 Review all materials.

5.1.1 This includes the completed HRP-401 - CHECKLIST - Pre-Review and any previously completed special determination checklists uploaded to the Admin Docs tab.

5.2 If an initial review or a modification to add a new special determination, download the checklist(s) from the shared drive or Admin Docs tab and complete with the review.

5.3 Determine the required level of review:

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 Human Research approved using the expedited procedure, or

5.3.5 Human Research that requires review by a convened IRB.

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

5.5 Obtain a signed confidentiality statement and conflict of interest policy review statement for all IRB meeting guests and consultants.

5.6 Execute the “Finalize Review” activity. Reference any special determination checklists completed as part of the review.

5.6.1 For Center or Institute Administrative Grant Review submissions, finalize as Not Human Subjects Research.

5.6.2 Upload any relevant completed checklists using the “Upload Administrative Documents” activity.

5.6.2.1 Layer revised checklists, when applicable, over the previous version unless adding a new determination.

5.6.3 Complete review within 10 business days (or provide notification of any extenuating circumstances).

6 MATERIALS

6.1 HRP-051 - SOP - Consultation
6.2 HRP-312 - WORKSHEET - Exemption Determination
6.3 HRP-313 - WORKSHEET - Expedited Review
6.4 HRP-314 - WORKSHEET - Criteria for Approval
6.5 HRP-319 - WORKSHEET - Limited IRB Review
6.6 HRP-402 - CHECKLIST - Non-Committee Review
6.7 HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process
6.8 HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent
6.9 HRP-412 - CHECKLIST - Pregnant Women
6.10 HRP-413 - CHECKLIST - Non-Viable Neonates
6.11 HRP-414 - CHECKLIST - Neonates of Uncertain Viability
6.12 HRP-415 - CHECKLIST - Prisoners
6.13 HRP-416 - CHECKLIST - Children
6.14 HRP-417 - CHECKLIST - Cognitively Impaired Adults
6.15 HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research
6.16 HRP-441 - CHECKLIST - HIPAA Waiver of Authorization

7 REFERENCES

7.1 21 CFR §56.110(b)
7.2 45 CFR §46.110(b)
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

VCU Research and Innovation

HRP-040 | 10/9/2024 | Author: T. Bechert | Approver: J. Opalesky

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 7 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 Added confidentiality agreement and conflict of interest policy review for IRB meeting guests; incorporated additional meeting preparation workflow steps; 10/2/23.

2.2 Removed reference to retired FB Tracking Document, added step to finalize reviewer notes, added step to invite PAM&E monitor to Chair's meeting, clarified timing for confidentiality agreement and conflict of interest policy review for IRB consultants; 8/19/24.

2.3 Clarified that the agenda is closed at 8:00 a.m. Eastern Time 7 business days prior to a meeting; 10/9/24.

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 Review materials are provided to all IRB members at least 7 days before convened meetings; completed reviews are requested in advance of the meeting to allow follow-up by the IRB Chair and/or Principal Investigator.

3.7 IRB meeting guests will sign a confidentiality agreement and conflict of interest policy review statement in advance of attendance.

3.8 IRB consultants will sign a confidentiality agreement and conflict of interest policy review statement in advance of receiving materials or reviewing and consulting on studies.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures unless otherwise noted.

5 PROCEDURE

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 ready for assignment to a convened IRB meeting. The agenda is closed at 8 a.m. Eastern Time 7 business days prior to a meeting.

5.4 Begin to prepare an agenda for the meeting.

5.4.1 Assign each submission to the meeting date and select Reviewer 1 and 2 using the "Schedule for IRB Meeting" activity. The reviewers may not be a member of the study team.

5.4.2 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 Add comments for each agenda item regarding special determinations or other study status information identified.

5.4.4 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.

5.5 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 Obtain a signed confidentiality statement and conflict of interest policy review statement for all IRB meeting guests and consultants.

5.7 Securely send any protocol materials needed by non-IRB members for scientific or consultant review.

5.8 In the RAMS-IRB Meetings tab, select the upcoming meeting to produce an agenda and execute the "Generate Agenda" activity. Select "Yes" to replace the existing agenda document. Enter the date of the most recent IRB panel meeting agenda generated date through the upcoming meeting date to pull the completed expedited reviews onto the agenda. Download the created agenda .

5.8.1 Execute the "Send Agenda" activity to provide the agenda to the IRB members who are attending the meeting.

5.8.2 Provide meeting logistics, including circulation of a virtual meeting invitation, to members confirmed to attend, as indicated.

5.9 The assigned Reviewer 1 and Reviewer 2 will complete their review of the submission.

5.9.1 The reviewer will execute the "Finalize Reviewer 1 (or 2)" activity and document their written review of the submission; upload any new or revised special determination checklist drafts under the Admin Docs tab.

5.10 Perform additional review of agenda items and reviewer comments during weekly Chair's Meeting:

5.10.1 Facilitate clarification with the Principal Investigator for any items unresolved by reviewers or the IRB Chair.

5.10.2 Schedule the Principal Investigator to attend the IRB meeting for discussion, where applicable.

5.10.3 Invite the PAM&E monitor to attend the Chair's Meeting where monitoring reports are included in submissions on the agenda.

5.10.4 The IRB Chair or HRPP Director can add or remove items.

5.10.5 The IRB Chair finalizes the agenda.

5.11 Execute the "Meeting In Progress" activity in RAMS the day of the meeting.

6 MATERIALS

6.1 HRP-001 - SOP – Definitions

6.2 HRP-051 - SOP – Consultation

6.3 HRP-305 - WORKSHEET - Quorum and Expertise

6.4 HRP-601 - DATABASE - IRB Roster

7 REFERENCES

7.1 45 CFR §46.108(b)

7.2 21 CFR §56.108(b)

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

VCU Research and Innovation

HRP-041 | 10/09/2024 | Author: T. Bechert | Approver: J. Opalesky

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 Added consideration of meeting recordings and summary of voting (section 5.12.1.3); 10/6/23.

2.2 Clarified that recused IRB members are considered absent for the vote and therefore do not count toward quorum while recused; 10/9/24.

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 worksheets and checklists described in HRP-301 - WORKSHEET - Review Materials and listed below in “Section 6: 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.

3.10 Meeting recordings are not required but are not prohibited. When recordings are obtained, they are subject to IRB record retention and disposal procedures.

4 RESPONSIBILITIES

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

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

5 PROCEDURE

5.1 The IRB Coordinator may choose to record virtual meetings.

5.2 Call the meeting to order.

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

5.4 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.

5.5 Ask IRB members if there are any questions about the prior meeting minutes.

5.5.1 The IRB acknowledges receipt of the finalized minutes.

5.6 For each agenda item:

5.6.1 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.[1]

5.6.2 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.

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

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

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

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

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

5.7.4 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.

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

5.7.6 Make a motion for one of the following actions:

5.7.6.1 Approve (with a specific continuing review interval for initial or continuing review when applicable): Made when all criteria for approval are met. Include in motions for initial and continuing review the period of approval and the level of risk.

5.7.6.2 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

5.7.6.3 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.

[1] "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.

5.7.6.4 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.

5.7.6.5 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.

5.7.7 Obtain a second to the motion.

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

5.7.8.1 Ensure that the required modifications include all final contingencies in the Pre-Review activity.

5.7.8.2 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.

5.8 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):

5.8.1 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.

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

5.8.3 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).

5.8.4 For submissions in response to a previous Suspension of IRB approval:

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

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

5.8.4.3 Make a motion for the IRB's determination to either lift the suspension of IRB approval or that additional action items are required to protect subjects.

5.8.5 Obtain a second to the motion.

5.9 Open the floor for additional discussion.

5.10 Amend the original motion as indicated after board deliberation.

5.10.1 Obtain a second to the amended motion.

5.11 Call for a vote.

5.12 Only IRB members may vote.

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

5.12.1.1 Consultants may not vote.

5.12.1.2 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.)

5.12.1.3 The meeting coordinator will summarize the vote, including HRPP processes to facilitate the actions of the vote where reportable findings occur.

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

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

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

5.16 Upload meeting recording files to the shared drive.

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-308 - WORKSHEET - Pre-Review

6.5 HRP-314 - WORKSHEET - Criteria for Approval

6.6 HRP-315 - WORKSHEET - Advertisements

6.7 HRP-316 - WORKSHEET - Payments

6.8 HRP-317 - WORKSHEET - Short Form of Consent Documentation

6.9 HRP-318 - WORKSHEET - Additional Federal Agency Criteria

6.10 HRP-321 - WORKSHEET - Review of Information Items

6.11 HRP-323 - WORKSHEET - Criteria for Approval HUD

6.12 HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process

6.13 HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent

6.14 HRP-412 - CHECKLIST - Pregnant Women

6.15 HRP-413 - CHECKLIST - Non-Viable Neonates

6.16 HRP-414 - CHECKLIST - Neonates of Uncertain Viability

6.17 HRP-415 - CHECKLIST - Prisoners

6.18 HRP-416 - CHECKLIST - Children

6.19 HRP-417 - CHECKLIST - Cognitively Impaired Adults

6.20 HRP-418 - CHECKLIST - Non-Significant Risk Device

6.21 HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research

6.22 HRP-441 - CHECKLIST - HIPAA Waiver of Authorization

7 REFERENCES

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

7.2 45 CFR §46.109, §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

VCU Research and Innovation

HRP-042 | 03/01/2024 | Author: T. Bechert | Approver: S. Brooks

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

VCU Research and Innovation

HRP-043 | 10/09/2024 | Author: T. Bechert | Approver: J. Opalesky

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 of record.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Clarified meeting motion and voting process; 10/6/23.

2.2 Minor update for system reference consistency; 2/1/24.

2.3 Removed unnecessary footer; 10/9/24.

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 officially approved on behalf of the IRB by the IRB chair or IRB manager.

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/ Deputy Institutional Organizational Official (IO/DIO).

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 Use the HRP-501 - TEMPLATE MINUTES to record observations at meetings.

5.2 Under “Attendance Table” 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.

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 are 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 Record a summary of each business item that was discussed.

5.8 For each protocol reviewed record:

5.8.1 Type(s) of review: Initial review, continuing review, review of modifications to previously approved research, or review of Unanticipated Problem Involving Risks to Subjects or Others, Serious Non-Compliance, Continuing Non-Compliance, Suspension of IRB Approval, Termination of IRB Approval.

5.8.2 Protocol Title

5.8.3 Investigator name

5.8.4 IRB identification number

5.8.5 Funding Agency (indicate “none” if none)

5.8.6 Grant Title (indicate “none” if none)

5.8.7 Grant ID (indicate “none” if none)

5.8.8 IND or IDE (indicate “none” if none)

5.8.9 Documents reviewed

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

5.8.11 Consultant report: Summarize the key information provided the consultant. Delete if there was no consultant.

5.8.12 Controverted issues and their resolution. 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.”

5.8.13 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. If the protocol was tabled, indicate this. The single motion is comprehensive of the IRB’s determination.

5.8.14 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. Record a single vote for each submission reviewed.

5.8.14.1 For: Voting for the motion.

5.8.14.2 Against: Voting against the motion.

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

5.8.14.4 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”

5.8.14.5 Recused: Listed under “Members Present” but not present for the discussion and vote on this protocol 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.”

5.8.14.6 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).”

5.8.15 Level of risk determined by the convened IRB: Minimal Risk or more than Minimal Risk.

5.8.16 Determinations and findings that require documentation: If the research involves waiver or alteration of consent, waiver of written documentation of consent, non-significant risk determination, children, pregnant women, neonates, Prisoners, or cognitively impaired adults, enter “See IRB records for this protocol” and ensure that the corresponding completed checklist is in the RAMS-IRB Admin Docs tab. Otherwise delete if not applicable.

5.8.17 Rationale for a significant/non-significant device determination: Describe the rationale for the determination. Otherwise delete.

5.8.18 Modifications required to secure approval: If this is the motion, complete the table with the required changes and corresponding reasons. Otherwise, delete.

5.8.19 Deferral/disapproval reasons and recommended changes: If this is the motion, complete the table with the recommendations and corresponding reasons. Otherwise, delete.

5.8.20 Suspension/termination reasons and recommended changes: If this is the motion, complete the table with the recommendations and corresponding reasons. Otherwise, delete.

5.8.21 Tabled reason: If the protocol was tabled, provide the reasons. Otherwise, delete.

5.8.22 For Veterans Administration (VA) research that involves an Unanticipated Problem Involving Risks to Subjects or Others, complete HRP-509 – TEMPLATE VA MINUTES SUPPLEMENT.

5.9 Record the meeting end time.

5.10 Execute the “Record Meeting Decision” activity in RAMS-IRB per the minutes documentation.

5.10.1 Upload any final special determination checklists to Admin Docs, layering or replacing incomplete reviewer documents as indicated.

5.10.2 Send all outright approval letters per HRP-052 - SOP - Post-Review within 2 business days of the meeting.

5.11 Within 3 business days revise minutes for accuracy and provide them to the IRB chair for review and approval in the RAMS-IRB meeting workspace.

5.11.1 IRB members are simultaneously notified that the minutes are available for review.

5.11.2 For minutes of Veterans Administration (VA) research, have the IRB chair or a qualified voting member of the IRB designated by the IRB chair sign the minutes.

5.12 The IRB chair will review and execute the “Close Meeting Minutes signature” activity within 2 business days. If applicable, email them 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 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, or

5.12.2.2 Provide VA with, or access to, redacted copies of meeting minutes in a timely manner that allows the R&D Committee to review the IRB’s deliberations on VA Protocols. Redacted copies of meeting minutes should include the parts of the minutes related to the IRB’s review of VA protocols.

5.13 The IRB will acknowledge receipt of prior meeting minutes at a subsequent meeting.

MATERIALS

5.14 HRP-052 - SOP - Post-Review

5.15 HRP-501 - TEMPLATE MINUTES

5.16 HRP-509 - TEMPLATE VA MINUTES SUPPLEMENT

6 REFERENCES

6.1 21 CFR §56.115(a)(2)

6.2 45 CFR §46.115(a)(2)

6.3 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

VCU Research and Innovation

HRP-044 | 03/01/2024 | Author: T. Bechert | Approver: S. Brooks

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, 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.

1.2 This process begins when the IRB determines that research involving children, pregnant women, or fetuses 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 Institutional Official/ Deputy Institutional Official (IO/DIO) or designee communicates a decision to the IRB.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 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.

3.2 The criteria used to make a determination are:

3.2.1 That the research in fact satisfies the conditions of IRB approvable research in HRP-413 - CHECKLIST - Non-Viable Neonates, HRP-414 - CHECKLIST - Neonates of Uncertain Viability, or HRP-416 - CHECKLIST - Children, or HRP-412 - CHECKLIST - Pregnant Women.

3.2.2 All of the following criteria are met:

3.2.2.1 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, fetuses or neonates. The research will be conducted in accordance with sound ethical principles;

3.2.2.2 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-413 - CHECKLIST - Non-Viable Neonates, HRP-414 - CHECKLIST - Neonates of Uncertain Viability, or HRP-416 - CHECKLIST - Children.

4 RESPONSIBILITIES

4.1 The IO/DIO or designee carries out these procedures.

5 PROCEDURE

5.1 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.

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

5.3 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.

5.4 Publish in a form accessible to the public:

5.4.1 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.

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

5.4.3 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.

5.4.4 Note that written comments on posted materials must be submitted at least 7 days before the day of the panel meeting to be considered by the panelists (which will allow the public 21 days to comment on posted materials);

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

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

5.5 Open the meeting to the public.

5.6 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.

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

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

5.8.1 The organization approves support of the research as submitted;

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

5.8.3 The organization disapproves support of the research.

5.9 Inform the IRB and the investigator.

5.10 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-413 - CHECKLIST - Non-Viable Neonates

6.4 HRP-414 - CHECKLIST - Neonates of Uncertain Viability

7 HRP-416 - CHECKLIST - Children

8 REFERENCES

8.1 45 CFR §46.207, 45 CFR §46.407

8.2 21 CFR §50.24(e), 21 CFR §50.54(b), 21 CFR §812.66

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

VCU Research and Innovation

HRP-050 | 03/01/2024 | Author: T. Bechert | Approver: S. Brooks

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).

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

VCU Research and Innovation

HRP-051 | 10/9/2024 | Author: T. Bechert | Approver: J. Opalesky

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 Updated Materials section to include HRP-032 and HRP-040; 10/9/24.

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 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:

- 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 and document the verbal consultation in the minutes.

5.6 For Non-Committee Review:

- 5.6.1 Directly obtain the written information 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-032 – SOP - Non-Committee Review Conduct

6.3 HRP-040 – SOP - IRB Meeting Preparation

6.4 HRP-301 - WORKSHEET - Review Materials

7 REFERENCES

7.1 21 CFR §56.107(f)

7.2 45 CFR §46.107(f)

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

VCU Research and Innovation

HRP-052 | 11/26/2024 | Author: T. Bechert | Approver: J. Opalesky

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 Clarification to procedure 5.3.1.2 to set an approval interval for exempt determinations and expedited studies reviewed under the 2018 Common Rule regulatory authority.

2.2 Clarified process steps in section 5.3 and 5.4 for notification when lifting a suspension and 5.5 for reportable findings.

2.3 Removed reference to HRP-526 and added process steps to remove a Suspension of IRB Approval; removed reference to direct reporting to the Chief Ethics and Compliance Officer via the University Integrity and Compliance Office reporting system as this process is managed within OVPRI; 2/1/24.

2.4 Updated to clarify grant review status update interval, processing turnaround expectations, NHSR and finalize and stamp document processes, prisoner certification record retention, and to clarify OHRP incident report submission types; 11/26/24.

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 2 business days of receipt of the completed Non-Committee Review materials or outright IRB meeting approvals, or within 5 business days of the IRB meeting.

3.5 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.

3.5.1 For Veterans Affairs (VA) research:

3.5.1.1 An Unanticipated Problem Involving Risks to Subjects or Others that is a local research death, notification to the VA facility Director, the Research Compliance Officer (RCO) and

the Associate Chief of Staff/R&D must occur within 5 business days of the convened IRB's determination(s).

3.5.1.2 Information determined by the IRB to constitute an Unanticipated Problem Involving Risks to Subjects or Others, Serious Non-Compliance or Continuing Non-Compliance, notification to the VA facility Director, the Research Compliance Officer (RCO) and the Associate Chief of Staff/R&D must occur within 5 business days of the convened IRB's determination(s).

3.5.1.2.1 If the IRB is unable to make a determination on the apparent Unanticipated Problem Involving Risks to Subjects or Others within 30 calendar days of the convened IRB's initial review due to insufficient information or due to a lack of sufficient time to complete its review, the IRB must notify the VA medical facility Director, the Research Compliance Officer (RCO), and the ACOS/R&D in writing no later than five (5) business days after the determination was due.

3.6 When a modification is reviewed to lift a suspension for a previous Suspension of IRB Approval, the state of the study will be changed from "Suspended" to "Approved" when the modification is approved.

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 Confirm final CHECKLISTS are uploaded in Administrative Documents.

5.3 For initial reviews, continuing review, or modification:

5.3.1 If the communication is an IRB determination of Approved (advance to step 5.3.1.3 for NHSR unless otherwise noted):

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

5.3.1.2 Execute the applicable "Set Amendment Approval Date" or "Set Approval and Expiration Date" activity.

5.3.1.2.1 For expedited studies reviewed under the 2018 Common Rule regulatory authority, enter an expedited anniversary date to facilitate an automated RAMS-IRB status update request.

5.3.1.2.2 For Center or Institute Administrative Grant Review submissions with NHSR determination, set a 1-year approval interval to facilitate the status update process.

5.3.1.3 Reference HRP-303 - WORKSHEET - Communication of Review Results to determine the appropriate letter template.

5.3.1.4 Execute the "Prepare Letter to Study Team" activity and modify the system or paper-based letter as needed.

5.3.1.5 Execute the "Send Correspondence Letter" activity.

5.3.1.5.1 If reviewed at a convened meeting, "Send Correspondence Letter for Review" to the Chair or Vice Chair to approve the correspondence letter. The Chair/Vice Chair will complete the "Edit or Approve Correspondence Letter" activity and execute the "Send to Study Team" activity.

5.3.1.5.2 If reviewed by non-committee review, "Send Correspondence Letter for Review" to the assigned IRB Coordinator to complete the "Edit or Approve Correspondence Letter" activity.

5.3.1.5.3 Execute the "Send Correspondence to Study Team" activity.

5.3.1.5.3.1 For NHSR, processing concludes with this step.

5.3.1.6 Execute the “Finalize Approved Documents” activity.

5.3.1.6.1 Click “Update” and mark as Approved all new or changed documents, where applicable.

5.3.1.6.2 “Stamp” relevant documents (“yes” for consent forms and information sheets; recruitment materials where stamping is requested by the study team). Stamps do not expire and are applied at the time of initial review or once a document is revised. Stamps must be applied to clean drafts free of previous stamps.

5.3.1.6.2.1 To update a document with a previously applied stamp, update the “Stamp” to “No,” select “OK;” update the “Stamp” to “Yes.”

5.3.1.6.3 Click “OK” to exit Update Document activity.

5.3.1.7 Complete the “Send to Approved” activity.

5.3.1.8 “Log Private Comment” to the parent submission for studies under Committee Review where the IRB determined the study is minimal risk and therefore eligible for expedited continuing review.

5.3.1.9 Execute the Lift Suspension activity on the parent submission to move the study status from Suspended to Approved, when applicable.

5.3.1.10 “Reassign Ownership” to the appropriate team lead if the submission received a different level of review than anticipated during HRP-020 - SOP - Incoming Items. (e.g., An expedited submission that received Committee Review, or a full board submission determined to be minimal risk and eligible for expedited continuing review.)

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

5.3.2.1 Execute the “Send Correspondence Letter” activity and modify the letter as needed.

5.3.2.1.1 If reviewed at a convened meeting, send to Chair or Vice Chair to approve the correspondence letter. The Chair/Vice Chair will complete the “Edit or Approve Correspondence Letter” activity and execute the “Send to Study Team” activity.

5.3.2.2 Execute the “Send to Study Team” activity.

5.4 Refer to HRP-303 - WORKSHEET - Communication of Review Results to determine if any additional paper-based letters need to be sent and send all applicable letters within 30 business days.

5.4.1 Refer to HRP-303 - WORKSHEET - Communication of Review Results and send applicable letter to the Principal Investigator or other recipients within 5 business days.

5.4.1.1 Have letter signed by the signatory in the template letter.

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

5.4.1.2.1 For prisoner research funded, conducted or supported by DHHS: upload signed HRP-522 - LETTER - Cert Prisoner Research and copy of submitted online Subpart C Certification Form to submission under Admin Docs tab.

5.4.1.2.2 Save copy of submitted online Subpart C Certification Form, finalized HRP-522 - LETTER - Cert Prisoner Research, and submitted attachments to the VPR-IRB drive in the applicable OHRP Prisoner certifications sub-folder.

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 Execute the “Prepare Correspondence Letter” activity and modify HRP-519 - LETTER - Information Item.

5.5.2 Send to the Chair or Vice Chair to approve the correspondence letter. The Chair/Vice Chair will complete the “Edit or Approve Correspondence Letter” activity and execute the “Send to Study Team” activity.

5.5.3 Add to the Federal Reporting Tracking Log.

5.5.4 The following steps are performed by the IRB Meeting Coordinator, or designee, in consultation with the HRPP Director or designee:

5.5.4.1 When reporting to OHRP only, complete the *OHRP Incident Report Form*[1] within 30 business days from the determination of a reportable problem.

5.5.4.1.1 Select Full Report unless further actions will be taken in which case Initial Report submission type should be selected.

5.5.4.1.1.1 OHRP will require a Follow-up Report within 3 months of an Initial Report.

5.5.4.2 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 and send within 30 business days from the determination of a reportable problem.

5.5.4.3 Modify HRP-520a - LETTER - External Report - OHRP and Other Agencies for VCU internal communication of the reportable problem; attach the OHRP Incident Report Form email confirmation, and when applicable, a copy of the HRP-520a letter sent to any other outside agency.

5.5.4.4 Save all materials to the VPR-IRB drive in the applicable Federal Correspondence sub-folder.

6 MATERIALS

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

6.2 HRP-302 - WORKSHEET - Approval Intervals

6.3 HRP-303 - WORKSHEET - Communication of Review Results

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

7 REFERENCES

7.1 45 CFR §46.103(b)(4)(i), 45 CFR §46.207, 45 CFR §46.306(2)(C), 45 CFR §46.306(2)(D), 45 CFR §46.407, 45 CFR §46 Waiver of Informed Consent Requirements in Certain Emergency Research (November 1, 1996)

7.2 21 CFR §56.108(a)(1), 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

[1] https://oash.force.com/ohrpwebforms/s/incident-web-form

VCU Research and Innovation

HRP-060 | 03/01/2024 | Author: T. Bechert | Approver: S. Brooks

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.

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 IRB staff ensure completion of these procedures.

5 PROCEDURE

5.1 Have the Institutional Official/ Deputy Institutional Official (IO/DIO) 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 Institutional Official/ Deputy Institutional Official (IO/DIO) or designee evaluate the HRPP's emergency preparedness plan and make changes when appropriate.

- 5.2.1 When updates to the HRPP emergency preparedness plan are made, the IRB Director will designate appropriate IRB staff to make changes to associated educational materials for the HRPP research community.

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

- 5.3.1 Provide a copy of the evaluation to the IO/DIO or designee.
- 5.3.2 If the number of IRBs is not appropriate to the volume and types of research reviewed, work with the IO/DIO or designee to modify the IRB structure.

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

- 5.4.1 Communicate the results of the evaluation to each IRB chair and the IO/DIO or designee.

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

5.5 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.

5.5.1 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/DIO or designee.

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

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

5.6 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.

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

5.6.2 Provide a copy of the evaluation to the IO/DIO or designee.

5.6.3 Provide each IRB staff with a copy of his or her evaluation.

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

5.7 Use HRP-304 - WORKSHEET - IRB Composition to evaluate whether the composition of the IRB meets regulatory and organizational requirements.

5.7.1 Provide a copy of the evaluation to the IO/DIO or designee.

5.7.2 If the composition of an IRB does not meet regulatory and organizational requirements, work with the IO/DIO or designee to modify the IRB composition.

5.8 Evaluate the subject outreach plan.

5.8.1 Consider the following areas when evaluating the outreach plan:

5.8.1.1 Whether the existing scope and content of HRPP outreach materials, including HRP-104 – BROCHURE – Should I Take Part in Research, continue to be adequate;

5.8.1.2 Whether modifications to existing outreach materials are necessary;

5.8.1.3 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;

5.8.1.4 Whether there are new opportunities to provide outreach activities to the community, and;

5.8.1.5 Whether additional information is needed from the research community to assess the extent to which outreach materials are used and outreach activities take place.

5.8.2 Provide a copy of the evaluation to the IO/DIO or designee.

5.8.3 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:

5.8.3.1 Modifying existing outreach materials;

5.8.3.2 Developing new materials;

5.8.3.3 Surveying the research community to identify and participate in additional outreach opportunities, and;

5.8.3.4 Working directly with community organizations to identify and participate in additional outreach opportunities.

5.9 Check whether each member of a Veterans Administration (VA) IRB or Veterans Administration (VA) representative has been a member longer than 2 years, and if so, send the member HRP-560 - LETTER - IRB Member Appointment.

5.10 Review HRP-080 - SOP - IRB Formation and Registration to determine if IRB registration requires updating.[1]

5.11 Check when the last time the federalwide assurance (FWA) was updated or renewed. If more than 2 years, update/renew the federalwide assurance (FWA).[2]

6 MATERIALS

6.1 HRP-080 - SOP - IRB Formation and Registration

6.2 HRP-104 - BROCHURE - Should I Take Part in Research

6.3 HRP-304 - WORKSHEET - IRB Composition

6.4 HRP-326 - WORKSHEET- Performance Evaluation for IRB Chairs

6.5 HRP-327 - WORKSHEET - Performance Evaluation for IRB Members

6.6 HRP-328 - WORKSHEET - Performance Evaluation Criteria for IRB Staff

6.7 HRP-560 - LETTER - IRB Member Appointment

6.8 HRP-562 - LETTER - IRB Member Appreciation

7 REFERENCES

7.1 AAHRPP elements I.1.A, I-2, I.4.B, II.1.A-D

[1] See http://www.hhs.gov/ohrp/assurances/. Use the Web site: http://ohrp.cit.nih.gov/efile/.

[2] See http://www.hhs.gov/ohrp/assurances/. Use the Web site: http://ohrp.cit.nih.gov/efile/.

VCU Research and Innovation

HRP-061 | 03/01/2024 | Author: T. Bechert | Approver: S. Brooks

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.

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 achieving 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 IRB staff ensure 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 10 investigators.

5.2 Review the results of HRP-430 - CHECKLIST - Investigator Quality Improvement Assessment sent out the previous quarter, track the results, and examine for significant trends.

5.3 Conduct HRPP Quality Improvement Assessment:

- 5.3.1 Review the results of all Investigator QI Assessments sent out the previous quarter and examine for significant trends.

5.4 Complete HRP-431 - CHECKLIST - Minutes Quality Improvement Assessment on the minutes of the previous quarter. Track compliance and the days required to complete minutes and examine for significant trends.

5.5 Send the results to the HRPP Director and Institutional Official/ Deputy Institutional Official (IO/DIO) or designee.

- 5.5.1 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 HRPP Director and IO/DIO to implement an intervention.

5.5.2 Interventions may include policy and procedure modifications, education and training efforts, system modifications, or other corrective actions.

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

7 REFERENCES

7.1 AAHRPP elements I.5.A, I.5.B, I.5.D, I-9

VCU Research and Innovation

HRP-062 | 02/01/2024 | Author: T. Bechert | Approver: S. Brooks

SOP: Periodic Tasks

1 PURPOSE

1.1 This procedure establishes the process to complete daily tasks required to monitor the research review process.

1.2 The process begins each day.

1.3 The process ends when the tasks have been completed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Added review of Federal Reporting Tracking Log and review of modifications for Suspension of IRB Approval; revised title from Daily Tasks to Periodic Tasks; 2/1/24.

3 POLICY

3.1 None

4 RESPONSIBILITIES

4.1 IRB staff members are responsible for carrying out this procedure.

5 PROCEDURE

5.1 Check for emergency uses on the Full Board Tracking Log where the IRB has not received a report, within 5 days:

5.1.1 Complete and send HRP-551 - LETTER - Failure to Submit EU Report.

5.1.2 Process the failure to submit as a Finding of Non-Compliance under HRP-024 - SOP - New Information.

5.2 Check for reporting actions on the Federal Reporting Tracking Log and complete follow-up as indicated.

5.3 Determine whether a modification submission has been received within 90 days for any Suspension of IRB Approval.

5.3.1 If a modification has not been submitted, and the investigator is non-responsive to remediation attempts, refer the study to the convened IRB with recommendation to terminate IRB approval.

6 MATERIALS

6.1 HRP-024 - SOP - New Information

6.2 HRP-551 - LETTER - Failure to Submit EU Report

7 REFERENCES

7.1 AAHRPP elements I.1.A, I.7.C, II.2.E-II.2.E.2, II.2.F-II.2.F.3

VCU Research and Innovation

HRP-063 | 10/9/2024 | Author: T. Bechert | Approver: J. Opalesky

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 Removal of unnecessary footer; 10/9/24.

3 POLICY

3.1 Investigators are granted 30 calendar days to respond to an issued “Modifications Required to Secure Approval.”

3.2 RAMS-IRB will auto-withdraw any submission if the response to an issued “Modifications Required to Secure Approval” has not been returned within 30 calendar days.

3.3 If research is granted “Modifications Required to Secure Approval” and expires before response 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 In the case of Veterans Administration (VA) research, have the IRB chair determine within 2 business days whether participants may continue participating in the research interventions or interactions.

5.5 Communicate with the investigator using HRP-532 - LETTER - Conti Subj Expired Research.

6 MATERIALS

6.1 HRP-532 - LETTER - Conti Subj Expired Research

7 REFERENCES

7.1 AAHRPP elements II.2.E-II.2.E.2, II.2.F-II.2.F.3

VCU Research and Innovation

HRP-064 | 03/01/2024 | Author: T. Bechert | Approver: S. Brooks

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/ Deputy Institutional Official (IO/DIO) 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 HRPP Director or designee verifies for the IO/DIO 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 (e.g., in RAMS-IRB Admin Docs and Google Drive NIH GDS Certifications folder).

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

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 Points to Consider for IRBs and Institutions in their Review of Data Submission Plans for Institutional Certifications Under NIH's Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS) (https://osp.od.nih.gov/wp-content/uploads/PTC_for_IRBs_and_Institutions.pdf)

7.3 NIH Institutional Certification Forms (https://osp.od.nih.gov/scientific-sharing/institutional-certifications/)

7.4 Provisional Institutional Certification (https://osp.od.nih.gov/wp-content/uploads/GDS_Extramural_Certification.pdf)

VCU Research and Innovation

HRP-065 | 03/01/2024 | Author: T. Bechert | Approver: S. Brooks

SOP: Response Plan for Emergencies-Disasters Impacting the HRPP

1 PURPOSE

1.1 This SOP establishes the process for initiating a response to an emergency/disaster situation impacting the HRPP or 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.

1.2 The process starts when an emergency/disaster situation impacting the HRPP has occurred, or in preparation for scenarios where a potential emergency situation is imminent (e.g., natural disaster, man-made disaster, infectious disease pandemic, etc.) 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 disaster and emergency response planning and limits HRPP-specific disaster and 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

5.1 If an emergency/disaster has occurred, or there is an imminent possibility of an upcoming emergency/disaster, 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/DIO and or designated institutional personnel responsible for institutional level emergency preparedness, and determine whether there are new or revised 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 contact or notification of the human research community is necessary.

5.2 Assess whether the emergency/disaster could impact HRPP operations:

5.2.1 If the current or anticipated emergency/disaster 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.

5.2.1.2 If a virtual meeting is also not feasible under the circumstances caused by the emergency/disaster, 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/disaster, 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 protocol processing, pre-review, and review of continuing review submissions.

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/DIO to notify the research community of the IRB Office's limited capacity to process and review submissions.

5.2.2.4 When the emergency/disaster no longer presents a limitation to IRB Office functions, work with the IO/DIO to notify the IRB members and staff and research community that normal business operations have resumed.

5.2.3 If impact to local HRPP 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/DIO to identify appropriate candidates for external IRB reliance and follow HRP-801 - SOP - Establishing Authorization Agreements.

5.2.4 If data or records (paper or electronic) are unavailable during the current or anticipated emergency/disaster, consult with RAMS-IRB support and any applicable electronic system vendors to implement alternative procedures to access data/backup data.

5.3 Assess whether the emergency/disaster could necessitate additional flexibility in IRB review processes. If yes:

5.3.1 Review HRP-352 - WORKSHEET - Additional Emergency-Disaster 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 assure research subject safety during the emergency/disaster.

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/disaster and notify the community as appropriate.

5.4 Assess whether the emergency/disaster 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/disaster risk mitigation planning. Use HRP-542 - LETTER - Implementation of HRPP Emergency-Disaster Response Plan.

5.4.2 Provide investigators with copies of (or links to) HRP-108 - FLOWCHART - Study-Specific Emergency-Disaster Risk Mitigation Planning.

5.4.3 Provide investigators with copies of (or links to) HRP-351 - WORKSHEET - Protocol-Specific Emergency-Disaster Risk Mitigation Planning.

5.4.4 If the emergency/disaster could impact clinical care standards which could in turn impact research, develop guidance for researchers that clarify 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/disaster no longer presents a limitation to Human Research activities, work with the IO/DIO to notify the research community that normal business operations have resumed.

5.5 Evaluate whether the nature of the emergency/disaster may pose additional threats or risk to specific aspects of the institution's research activities or facilities. (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.)

5.5.1 If yes, and if broader institution-level emergency/disaster preparedness measures do not already address these specific activities or facilities, work with the IO/DIO and appropriate institutional leadership to escalate and address any additional threats or risks.

6 MATERIALS

6.1 HRP-060 - SOP - Annual Evaluations of the HRPP

6.2 HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN

6.3 HRP-108 - FLOWCHART - Study-Specific Emergency-Disaster Risk Mitigation Planning

6.4 HRP-351 - WORKSHEET - Protocol-Specific Emergency-Disaster Risk Mitigation Planning

6.5 HRP-352 - WORKSHEET - Additional Emergency-Disaster Review

6.6 HRP-542 - LETTER - Implementation of HRPP Emergency-Disaster Response Plan

6.7 HRP-801 - SOP - Establishing Authorization Agreement

7 REFERENCES

7.1 AAHRPP Element I.1.H

VCU Research and Innovation

HRP-070 | 03/01/2024 | Author: T. Bechert | Approver: S. Brooks

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.
- 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 Prisoners.

3.2.19.4 Research involving children.

3.2.19.5 Research involving adults unable to consent.

3.2.19.6 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

3.2.22 For Veterans Administration (VA) research:

3.2.22.1 Correspondence between the IRB and the Veterans Administration (VA) Research and Development Committee.

3.2.22.2 Internal or local serious adverse events.

3.2.22.3 Documentation of protocol deviations.

3.2.22.4 Reports of complaints from subjects

3.2.22.5 Records of expedited review activities

3.2.22.6 HIPAA Authorization documents

3.2.22.7 Audit results and documentation of compliance with remediation requirements

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

4.1 IRB staff members are responsible to carry out these procedures.

5 PROCEDURE

5.1 Minutes of IRB meetings: save to VPR-IRB shared file on Google Drive and upload into the RAMS-IRB meeting workspace.

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 a file related to that person or topic.

5.4 IRB member rosters: retain in VPR-IRB shared file on Google Drive.

5.5 IRB membership records (e.g., curricula vita and resumes): file in VPR-IRB shared file on Google Drive.

5.6 Policies and procedures:

5.6.1 File current policies and procedures in VPR-IRB shared file on Google Drive.

5.6.2 File replaced policies and procedures in an archived policies and procedures history file in a VPR-IRB shared file on Google Drive.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 AAHRPP elements I.1.A, I-9, II.5.A

VCU Research and Innovation

HRP-071 | 10/9/2024| Author: T. Bechert | Approver: J. Opalesky

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 HRPP Director or Institutional Official/ Deputy Institutional Official (IO/DIO) or designee determines that a Toolkit document 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 Expanded on procedures for the Toolkit evaluation and revision process; 2/1/24.

2.2 Removed unnecessary footer and image; 10/1/24.

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.

3.2 Substantive HRPP Toolkit revisions are reviewed and approved by the HRPP Director, or designee.

4 RESPONSIBILITIES

4.1 The HRPP Director or designee 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 Toolkit documents will be created following HRP-505 - TEMPLATE SOP for a new SOP, or through creation of an associated document.

5.1.3.1 The proposed draft version will be filed in the "*Toolkit Change Control_Tracked Changes Submitted*" subfolder of the *HRPP Toolkit (Change Control)* folder on the VPR_IRB shared Google drive.

5.1.4 Have the approver review and approve the document.

5.1.5 Once approved by the approver:

5.1.5.1 Update the approval/effective date within the proposed document maintained in the "*Toolkit Change Control_Tracked Changes Submitted*" subfolder.

5.1.5.2 Create a copy of the newly approved document.

5.1.5.3 File and maintain this approved version of the document in the Clean Document Archive sub-folder on the HRPP Toolkit (Change Control) folder on the VPR-IRB shared Google drive.

5.1.5.4 Create a duplicate of the approved document referenced in 5.2.5.2.

5.1.5.5 File and maintain this final approved version of the document in the "*Section D*" subfolder in the VPR-HRPP Toolkit shared Google drive.

5.1.5.6 Documents in Section D of the VPR-HRPP Toolkit shared drive are the final approved documents.

5.1.5.7 Move and retain the track changes document into the "*Tracked Change Archive*" subfolder.

5.2 For a revised Toolkit document:

5.2.1 Toolkit documents will be revised from the most recent version on the VPR-HRPP Toolkit shared drive.

5.2.2 Create a track changes version which is used to document the proposed changes

5.2.2.1 If a track changes version was provided with the proposed change, confirm the currently approved document was used as the basis for the track changes.

5.2.2.2 If a track changes version was not provided, create a new document by copying the currently approved document from the VPR-HRPP Toolkit shared drive, then track the proposed changes.

5.2.3 For revisions to SOPs, update Section 2 (Revisions from Previous Version) and include:

5.2.3.1 A short summary of changes,

5.2.3.2 The date of the most recent previous approval.

5.2.4 The proposed track changes version will be filed in the "*Toolkit Change Control_Tracked Changes Submitted*" subfolder of the HRPP Toolkit (Change Control) folder in the VPR_IRB shared folder on Google Drive while pending approval.

5.2.5 Have the approver review and approve the document.

5.2.6 Once approved by the approver:

5.2.6.1 Update the approval/effective date on the track changes version in the "Toolkit Change Control_Tracked Changes Submitted" subfolder.

5.2.6.2 Create a "clean" version from the newly approved track changes document.

5.2.6.2.1 File and maintain the clean approved version in the *Clean Document Archive* subfolder on the *HRPP Toolkit (Change Control)* folder on the VPR-IRB shared Google drive.

5.2.6.3 Create a duplicate of the clean approved version referenced in 5.3.4.2.

5.2.6.3.1 File and maintain this final approved version of the document in the "*Section D*" subfolder in the VPR-HRPP Toolkit shared Google drive.

5.2.6.3.2 Documents in *Section D* of the VPR-HRPP Toolkit shared drive are the final approved documents.

5.2.6.4 Move and retain the track changes document into the "*Tracked Change Archive*" subfolder.

5.3 Website Update:

5.3.1 Post or replace the approved toolkit document on the Human Research Protection Program Web site through submission of a VITALS ticket.

5.3.1.1 Update the version date (rev. date) on the HRPP Toolkit page.

5.4 Communicate changes and necessary training to affected individuals.

5.5 Update status on HRPP Toolkit Change Control Tracking Log.

6 MATERIALS

6.1 HRP-505 - TEMPLATE SOP

7 REFERENCES

7.1 AAHRPP elements I-9, II.5.A

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HRP-072 | 03/01/2024 | Author: T. Bechert | Approver: S. Brooks

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 The HRPP will comply with institutional policy issued by VCU Technology Services which establishes the general responsibilities for management, retention, and disposition of Virginia Commonwealth University records as mandated by the Virginia Public Records Act (VPRA) as related to IRB records retention procedures.

3.1.1 Electronic or paper records maintained by the HRPP will be accessed, handled, and disposed of (where applicable) consistent with institutional policy for Category I, II, and III information/data.

3.2 The HRPP will work with the OVPRI designated department records coordinator on matters related to staff training and program procedures to ensure compliance with institutional policy.

3.3 Protocol files are maintained electronically and are retained indefinitely.

3.4 All records not in protocol files are retained indefinitely.

3.5 Records may be maintained in printed form or electronically.

3.6 Protocols in which there was no subject enrollment or no research was conducted are to be retained the same as protocols where research was conducted.

3.7 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.

3.8 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.

3.9 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.

3.10 All records are to be accessible for inspection and copying by the Veterans Administration (VA) Research and Development Committee at reasonable times and in a reasonable manner.

3.11 Veterans Administration (VA) IRB records are retained in accordance with VHA's Records Control Schedule.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 Destroy protocol files for Veterans Administration (VA) research per Records Control Schedule 10-1 (VHA RCS 10-1).

5.2 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.

5.3 All other protocol files must be retained indefinitely or at least until the protocol has been closed, withdrawn, or terminated more than indefinitely, or at least 6 years after project completion for projects involving human subjects and 3 years after project completion for projects not involving human subjects, [1] unless otherwise required by law as outlined in institutional policy issued by VCU Technology Services.

5.3.1 In the case of multi-center research "completion" is referenced to the organization's involvement in the research, not the entire study.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 VHA Directive 1200.05 dated January 7, 2019

7.2 AAHRPP elements I.1.A, I-9, II.5.A, 11.5B

7.3 Code of Virginia § 42.1-76–§ 42.1-91

7.4 DoDI 3216.02

[1] Library of Virginia publishes GS-111 General Schedule

VCU Research and Innovation

HRP-080 | 02/01/2024| Author: T. Bechert | Approver: S. Brooks

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/ Deputy Institutional Official (IO/DIO) 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 and external IRBs 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 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.

3.5 A revised FWA Addendum will be submitted to the Veterans Administration (VA) for any modifications to a FWA (other than telephone, address, or email changes).

3.6 A membership roster for all IRB(s) to be designated on a VA medical facility's FWA must be submitted to ORO FWA staff at the time of the IRB's designation as an IRB of Record on the FWA.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

4.2 The IO/DIO 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/DIO 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 Director when all individuals have completed training.

5.1.1.5 Using the "Create Committee" SmartForm, a Site Manager role creates 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.

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

5.4 Submit a new/revised FWA and VA FWA Addendum to ORO FWA staff who will submit the FWA to HHS-OHRP (through ORO FWA staff).

5.5 Notify the IO/D-IO or their designee with a summary of changes.

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 VHA Directive 1058.03 September 17, 2020

7.4 AAHRPP elements I.1.A, II.1.A-C

VCU Research and Innovation

HRP-081 | 03/01/2024 | Author: T. Bechert | Approver: S. Brooks

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/ Deputy Institutional Official (IO/DIO) 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.

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/DIO or designee and send to the former IRB members.

5.1.2 Unregister the IRB with OHRP.[1]

5.1.3 Remove the IRB from the FWA.[2]

5.1.4 Remove members from HRP-601 - DATABASE - IRB Roster.

5.1.5 Remove the individual's Committee Member role in the system.

5.1.6 File:

5.1.6.1 DATABASE: IRB Roster (HRP-601)

5.1.6.2 FWA

5.1.6.3 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

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[1] See http://www.hhs.gov/ohrp/assurances/. Use the Web site: http://ohrp.cit.nih.gov/efile/.

[2] See http://www.hhs.gov/ohrp/assurances/. Use the Web site: http://ohrp.cit.nih.gov/efile/.

VCU Research and Innovation

HRP-082 | 02/01/2024| Author: T. Bechert | Approver: S. Brooks

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/ Deputy Institutional Official (IO/DIO) (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 Added online IRB nomination process; 2/1/24.

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 Nominations to serve as an IRB member may be submitted directly to the HRPP or via the IRB Nomination Form hosted on the VCU HRPP website.

4 RESPONSIBILITIES

4.1 4.1 IRB staff members carry out these procedures.

4.2 4.2 The IO/DIO or designee appoints/re-appoints IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs).

5 PROCEDURE

5.1 Communicate nominations received via the online IRB Nomination Form to OVPRI for further evaluation.

5.2 Have the individual complete HRP-202 - FORM - IRB Member Information.

5.3 Obtain a copy of the individual's résumé or curriculum vita.

5.4 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.

5.5 Interview the individual to assess suitability and availability.

5.5.1 Determine from the IO/DIO or designee whether the individual will be a regular IRB member, alternate IRB member, or IRB chair.

5.5.2 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.

5.5.3 For Veterans Administration (VA) representatives, communicate with the Veterans Administration (VA) Medical Center Director in writing to obtain confirmation of the appointment.

5.6 Schedule a time for the applicant to attend and observe an IRB meeting, as applicable.

5.7 Upon mutual agreement, add the individual to HRP-601 - DATABASE - IRB Roster.

5.8 Complete HRP-304 - WORKSHEET - IRB Composition and revise the membership as needed to ensure that the IRB is appropriately constituted.

5.9 Prepare HRP-560 - LETTER - IRB Member Appointment for the individual.

5.10 Provide to the IO/DIO or designee for review and approval:

5.10.1 HRP-202 - FORM - IRB Member Information.

5.10.2 Résumé or curriculum vita.

5.10.3 Completed HRP-560 - LETTER - IRB Member Appointment.

5.11 If not approved, select another individual and restart at 5.2.

5.12 Once the appointment letter is signed:

5.12.1 Send the signed HRP-560 - LETTER - IRB Member Appointment to the individual.

5.12.2 If the individual requires training, schedule the individual for training.

5.12.3 Update the registration of all affected IRBs.[1]

5.13 File:

5.13.1 HRP-601 - DATABASE - IRB Roster.

5.13.2 Signed IRB appointment/re-appointment letter.

5.13.3 HRP-202 - FORM - IRB Member Information.

5.13.4 Résumé or curriculum vita.

5.13.5 Any other signed agreements.

5.14 Notify the IRB manager when the individual has completed training.

5.14.1 Add the individual to the appropriate IRB panel in the Committee workspace under the Meeting tab using the “Edit Members” 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

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

[1] See http://www.hhs.gov/ohrp/assurances/. Use Web site: http://ohrp.cit.nih.gov/efile/.

VCU Research and Innovation

HRP-083 | 03/01/2024 | Author: T. Bechert | Approver: S. Brooks

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/ Deputy Institutional Official (IO/DIO) 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/DIO or designee and send to the individual.

5.4 Update the registration of all affected IRBs.[1]

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.

5.6.1 If applicable, update the "Update Eligible Designated Reviewers" activity.

6 MATERIALS

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

[1] See http://www.hhs.gov/ohrp/assurances/. Use the Web site: http://ohrp.cit.nih.gov/efile/.

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

VCU Research and Innovation

HRP-084 | 03/01/2024 | Author: T. Bechert | Approver: S. Brooks

SOP: IRB Meeting Scheduling and Notification

1 PURPOSE

1.1 This procedure establishes the process to schedule and notify individuals of convened meetings.

1.2 The process begins when there are approximately fewer than 180 days of meetings on the current schedule.

1.3 The process ends when meetings are scheduled at least six months in advance and individuals in the organization are notified of the schedule.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Whenever possible the IRB schedules meetings at least 7 days in advance, less for ad hoc meetings for urgent issues.

3.2 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.

3.3 Additional meetings may be scheduled on an ad hoc basis.

4 RESPONSIBILITIES

4.1 IRB staff carry 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 VCU HRPP 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 / Deputy Institutional Official (IO/DIO) or designee.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 ICH-GCP E6 3.3.2

7.2 AAHRPP elements I-9, II.2.D

VCU Research and Innovation

HRP-090 | 11/7/2024| Author: T. Bechert | Approver: J. Opalesky

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 Revision to who may serve as a witness; addition of FDA informed consent guidance footnote; 2/1/24.

2.2 Revision to indicate that the witness and interpreter may be the same person; 11/7/24.

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, 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.

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 subjects able to speak the language that the subject understands.

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 Obtain the current IRB approved consent form.

5.1.2 Verify that you are using the most current IRB-approved version of the study specific consent form and that the consent form is in a language understandable to the subject/representative.

5.1.3 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.

5.1.4 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.

5.1.5 If the subject/representative cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the subject/representative. The interpreter may be a member of the research team, a family member, or friend of the subject/representative.

5.1.5.1 Where medical and technical information is discussed, use of a qualified medical interpreter is encouraged and may be available through VCUHS Language Services.

5.1.5.2 The CyraCom interpreter system may be used in the in-patient clinical setting at VCUHS. CyraCom is a language service that allows hospitals and physicians to utilize a three-phone system to provide interpretation, when appropriate.

5.1.6 Read the consent document (or have an interpreter read the translated consent document) with the subject/representative. Begin with a concise and focused presentation of 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.

5.2 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.

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 interpreter fluent in both English and the language understood by the subject/representative. The interpreter may be a member of the research team, family member, or friend of the subject/representative.

5.2.4.1 Where medical and technical information is discussed, use of a qualified medical interpreter is encouraged and may be available through VCUHS Language Services.

5.2.4.2 The CyraCom interpreter system may be used in the in-patient clinical setting at VCUHS. CyraCom is a language service that allows hospitals and physicians to utilize a three-phone system to provide interpretation, when appropriate.

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.[1] 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 understands 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:

5.3.1 Obtain the current IRB approved script.

5.3.2 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.

5.3.3 When possible provide a copy of the script to the subject/representative.

5.3.4 If the subject/representative cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the subject/representative. The interpreter may be a member of the research team, a family member, or friend of the subject/representative.

5.3.5 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.

5.4 Invite and answer the subject/representative's questions.

5.5 Give the subject/representative time to discuss taking part in the research study with family members, friends and other care providers as appropriate.

[1] FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023) https://www.fda.gov/media/88915/download

5.6 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.

5.7 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:

5.7.1 The subject/representative understands the information provided.

5.7.2 The subject/representative does not feel pressured by time or other factors to make a decision.

5.7.3 The subject/representative understands that there is a voluntary choice to make.

5.7.4 The subject/representative is capable of making and communicating an informed choice.

5.8 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.

5.9 Once a subject/representative indicates that he or she does not want to take part in the research study, this process stops.

5.10 If the subject/representative agrees to take part in the research study:

5.10.1 If the subject is a child:

5.10.1.1 Whenever possible explain the research to the extent compatible with the child's understanding.

5.10.1.2 Request the assent (affirmative agreement) of the child unless:

5.10.1.2.1 The capability of the child is so limited that the child cannot reasonably be consulted.

5.10.1.2.2 The IRB determined that assent was not a requirement.

5.10.1.3 Once a child indicates that he or she does not want to take part in the research study, this process stops.

5.10.2 If the subject is an adult unable to consent:

5.10.2.1 Whenever possible explain the research to the extent compatible with the adult's understanding.

5.10.2.2 Request the assent (affirmative agreement) of the adult unless:

5.10.2.2.1 The capability of the adult is so limited that the adult cannot reasonably be consulted.

5.10.2.2.2 The IRB determined that assent was not a requirement.

5.10.2.3 Once an adult unable to consent indicates that he or she does not want to take part in the research study, this process stops.

5.10.3 Obtain written documentation of the consent process according to HRP-091 - SOP - Written Documentation of Consent.

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

VCU Research and Innovation

HRP-091 | 02/01/2024| Author: T. Bechert | Approver: S. Brooks

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 Added considerations for making a mark and subjects physically unable to sign the consent form; added FDA guidance reference; 2/1/24.

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.

3.3 The Legally Authorized Representative (LAR) when the subject is an adult unable to give consent. One or both biological 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 Print the name of the following individuals on the consent document:

5.1.2.1 Subject/Representative

5.1.2.2 Person obtaining consent

5.1.3 Have the following individuals personally sign and date (or otherwise "make their mark” on) the consent document:

5.1.3.1 Subject/Representative

5.1.3.1.1 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.[i]

5.1.3.1.2 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.[ii]

5.1.3.2 Person obtaining consent

5.1.4 If the IRB required written documentation of assent, note on the signature block one of the following:

5.1.4.1 Assent of the child was obtained.

5.1.4.2 Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

5.1.5 If an impartial witness was part of the consent process:

5.1.5.1 Print the name of the impartial witness on the consent document.

5.1.5.2 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 explained to, and apparently understood by, the subject, and that consent was freely given.

5.1.6 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.

5.3 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.

5.3.1 If the subject/representative declines, take no further action.

5.3.2 If the subject/representative accepts, follow the process to document consent in writing with the long or short form of consent documentation.

5.4 Place the signed and dated documents in the subject's binder.

6 MATERIALS

6.1 If the consent process will be documented in writing with the long form of consent documentation:

6.1.1 Consent form

6.2 If the consent process will be documented in writing with the 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)

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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[i] FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023) https://www.fda.gov/media/88915/download

[ii] FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023) https://www.fda.gov/media/88915/download