



**HEALTH
SCIENCES**

OFFICE OF RESEARCH

Human Research Protections Program

Investigator Manual¹

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Scope

Throughout this document, “Institution” refers to The University of New Mexico Health Sciences Center (UNM HSC). The UNM Health Sciences Center is made up of the following academic and clinical entities:

Academic Components

- School of Medicine
- College of Nursing
- College of Pharmacy
- College of Population Health

Clinical Components

- UNM Comprehensive Cancer Center
- UNM Clinical and Translational Sciences Center
- UNM Medical Group
- UNM Sandoval Regional Medical Center
- University of New Mexico Hospital
- UNM Children’s Hospital
- UNM Adult Psychiatric Center
- UNM Children’s Psychiatric Hospital
- The Carrie Tingley Hospital

The Human Research Review Committee (HRRC) is the name given to the organization’s Institutional Review Boards. Each board or “committee” is registered with the Department of Health and Human Services under this Institution’s federal wide assurance (FWA). Collectively, the HRRCs are responsible for the oversight of all human subject research at the UNM HSC.

“HRPO” refers to the Human Research Protections Office at the UNM HSC. The HRPO is responsible for the administration of human research compliance oversight including regulatory compliance, education and training, quality improvement and quality assurance.

What is the purpose of this manual?

This document, “INVESTIGATOR MANUAL (HRP-103)”, is designed to guide you through policies and procedures related to the conduct of Human Research that are specific to this Institution. General information regarding Human Research protections and relevant federal regulations and guidance is incorporated into the required human protections training. For additional information see below: “What training do my staff and I need in order to conduct Human Research?”

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Where can I find additional information?

Human Research Protections Program (HRPP) Standard Operating Procedures, guidance documents, training materials, templates, checklists and worksheets referenced in this Investigator Manual are available in the Huron IRB Library and on the Human Research Protections Office (HRPO) website (<https://hsc.unm.edu/research/hrpo/>).

Templates: Templates are available in the Huron IRB Library to assist researchers in creating a UNM study protocol or informed consent form.

Worksheets: Worksheets are documents that the Human Research Review Committees (HRRCs) use to make determinations. These are guidance documents that are not always completed or kept with the study file, but are used to assist with making complex regulatory decisions. Researchers may use these documents as a reference to ensure they are providing the information necessary for the HRRC to make appropriate determinations. Worksheets should not be included in submissions made in Huron IRB.

Checklists: Checklists are documents that the HRRC uses to document regulatory determinations. These documents may be completed as applicable by the HRRC/HRPO Staff and are kept in Huron IRB for each study. Researchers may use these documents as a reference to ensure they are providing the information necessary for the HRRC to make appropriate determination. Checklists should not be included in submissions made in Huron IRB.

What is Human Research?

The “HUMAN RESEARCH PROTECTION PROGRAM PLAN (HRP-101)” defines the activities that this Institution considers to be “Human Research.” An algorithm for determining whether an activity is Human Research can be found in the “WORKSHEET: Human Research (HRP-310),” located in the Huron IRB Library and the HRPO Website. Use this document for guidance as to whether an activity meets either the DHHS or FDA definition of Human Research, keeping in mind that the HRRC makes the ultimate determination in questionable cases as to whether an activity constitutes Human Research that may be subject to HRRC oversight.

The following activities are not considered research:

- 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.
- 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

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public health signals, onsets of disease outbreaks, or conditions of public health importance, including:

- the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
- trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products.
- 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).
- 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.
- Authorized operational activities (as determined by the relevant federal agency) in support of intelligence, homeland security, defense, or other national security missions.

Before conducting any Human Research activities, it is your responsibility to obtain HRRC review and approval for the research activity (or an HRRC review and determination of exempt human research). If you have questions about whether an activity is Human Research, contact the HRPO. To obtain a written determination of Not Human Research, make a New Study submission in Huron IRB.

What is the Human Research Protection Program?

The document “HUMAN RESEARCH PROTECTION PROGRAM PLAN (HRP-101)” describes this Institution’s overall plan to protect participants in Human Research.

- The mission of the Human Research Protection Program.
- The ethical principles that the Institution follows governing the conduct of Human Research.
- The applicable laws that govern Human Research.
- When the Institution becomes “engaged in Human Research” and when someone is acting as an agent of the Institution conducting Human Research.
- The types of Human Research that may not be conducted.
- The roles and responsibilities of individuals within the Institution.
- UNM HSC does not conduct limited review.

Who can be a Principal Investigator?

To serve as a Principal Investigator (PI) on a human research study submitted to the Human Research Review Committee (HRRC), you must be a contract (paid) UNM HSC faculty member who is:

- .50 FTE or greater
- Tenure track or non-tenure track
- Researcher, clinical educator or lecturer

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Examples of positions not eligible to serve as Principal Investigator at UNM HSC:

- Adjunct Faculty
- Visiting Faculty
- Volunteer Faculty
- Postdoctoral Fellows
- Students
- Staff without Letter of Academic Title

In special instances (not indicated above) and with support from the Dean or Department Chair, other members of the HSC community may request approval to serve as Principal Investigator.

The PI must complete the [PI Eligibility Request Form](#) (located on the Huron IRB website). The completed request should be sent to HSC-HRPO@salud.unm.edu and will be reviewed by the Vice President for Research.

The HRRC recognizes one Principal Investigator of each project. The Principal Investigator bears the ultimate responsibility for assuring that the conduct of the study complies with all of UNM HSC HRPP policies and procedures for the protection of human participants.

When the Principal Investigator for clinical studies involving medical/clinical interventions or investigational agents does not have a medical degree, there must be at least one co-investigator on the project who is a qualified licensed healthcare provider.

What training do my staff and I need to conduct Human Research?

This section describes the training requirements imposed by the HRRC. You may have additional training imposed by other federal, state, or Institutional policies.

Investigators and staff conducting research involving human participants must complete the Collaborative Institutional Training Initiative (CITI) human subjects research online training program or the National Institute of Health (NIH) Protection Human Research Participants Course (PHRP).

Training is valid for a three-year period, after which time the training must be repeated. All members of the research team involved in the design, conduct, or reporting of the research must complete training. Members of the research team who have not completed human research protections training may not take part in aspects of the research that involve human participants.

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For each new research submission received, verification will be made during the HRRC Administrative & Pre-Review that the applicable training requirements have been met and are current for all members of the research study team. If the training requirements are incomplete or not current for any member of the study staff, the submission will be returned to the PI and can only be re-submitted once the requirements are met.

HRRC approval may not be granted for proposed research in which investigators have not completed human research protections training.

The CITI site can be accessed at <http://www.citiprogram.org/>.

What financial interests do my staff and I need to disclose to conduct Human Research?

Per UNM Faculty Handbook [Policy E110](#) Conflicts of Interest in Research, investigators, including non-UNM investigators participating in UNM research have a responsibility to disclose any situation that could conceivably be viewed as a conflict of interest or a reportable financial interest. [Additional HSC COI Reporting Requirements Due to 2011 Revised Federal Regulation](#) may be found on the [UNM HSC Conflicts of Interest website](#).

Individuals involved in the design, conduct, or reporting of research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards are considered to have an institutional responsibility.

All individuals involved in the design, conduct, or reporting of research are required to submit the disclosure of the financial interests in the Click COI/ERA System:

- On submission of a New Study for initial review or a determination of Not Human Research
- On submission for the addition of a new investigator
- Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest

All personnel named as an investigator in an HRRC (IRB) submission have a responsibility to ensure that their financial conflicts of interest disclosure are current at the time of submission. Study personnel must disclose whether they, their spouse, domestic partner, or dependent children have any financial interests that reasonably appear to be related to the discloser's institutional responsibilities.

Individuals with 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

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hospital, or medical center are required to disclose the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration of the travel.

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

- Joining the institution
- Financial conflicts policies are revised in a manner that changes the investigator requirements
- Non-compliant with financial conflicts policies and procedures

The UNM HSC disclosure is completed by HSC & Main campus employees, students, and research fellows. The Non-UNM disclosure is completed by collaborators and consultants that are not employed by UNM, but their affiliated institution has a COI office. Non-UNM study team members not affiliated with an institution with a COI office must complete the FCOI and COI/ERA courses in MOODLE (link to MOODLE can be found on the HSC HRPO website and the HSC COI website).

Additional details can be found in “SOP: Financial Conflicts of Interests (HRP-055).”

The Conflicts of Interest (COI) Committee will assess whether an actual or potential conflict exists and work with the investigator to determine how it should be resolved or managed. HRRC approval will not be granted until all conflicts of interest reviews for a study are completed and the management plan(s), if any, has (have) been reviewed by the HRRC. The HRRC may add additional conditions to a management plan but cannot reduce or remove any conditions placed by the COI Committee.

For more information on COI policies:

Faculty Handbook:

[Policy E110](#) Conflicts of Interest in Research

[Policy E70](#) Intellectual Property Policy

[Policy E80](#) Conflict of Interest Waiver Policy for Technology Transfer

[Policy C130](#) Policy Concerning Outside Employment and Conflicts of Commitment

Other HSC COI-related Policies and Requirements:

[Guidance Document for HSC Investigators with Outside Business Interests](#)

[Additional HSC COI Reporting Requirements Due to 2011 Revised Federal Regulation](#)

[Policy for HSC Faculty Outside Professional Activities](#)

[Policy for Managing Private Healthcare Industry \(PCHI\) Interactions at the UNM HSC Clinical Care and Educational Missions](#)

[HSC Supplemental Policy to UNM COI Policy E110](#)

[HSC Conflicts of Interest in Research Policy on Participation in Vendor-Sponsored Events](#)

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Does the HRRC charge to review research?

The HRPO charges fees to review research unless the PI is a UNM HSC faculty member AND any of the following apply:

1. The project is receiving no monetary support from any external entity
2. The project is supported by a federal or state grant or contract awarded directly to UNM HSC and the grant or contract includes facilities and administration (F&A) costs.
3. The project is a sub-award to UNM HSC and the sub-award includes flow-through of facilities and administration (F&A) costs from a federal or state agency.
4. The project is receiving monetary support from a non-profit agency, such as a foundation, and is receiving no other form of industry support.
5. The project is receiving support from an industry sponsor that is limited to supplying a drug or device (no monetary support).

A complete schedule of IRB fees may be found on the HRPO website at (<https://hsc.unm.edu/research/hrpo/investigators/fees.html>).

How do I submit new Human Research to the HRRC?

The HRRC must review and approve all Human Research activities prior to the initiation of any research activities. The PI should complete a New Study submission in the Huron IRB system and submit it to the HRRC along with all required documents.

Information regarding how-to create submissions in Huron IRB including checklists for required supporting documents can be found in the Investigator Submission Guide (located in the Huron IRB Library).

The Huron IRB system will prompt the user to upload documents throughout the submission, including protocols, consent forms, recruitment materials, etc. In addition, any other study-specific documents should be uploaded to the relevant SmartForm pages. The PI submits the New Study for processing by executing the “Submit” function. Maintain electronic copies of all information submitted to the HRRC in case revisions are required. Before submitting the research for initial review, you must ensure the following:

- All study team members are aware of their roles in the research.
- All study team members have completed required training.

Document Upload Tips:

- Add version dates to the body and file names of the protocol, consent, HIPAA, and recruitment documents. The HRPO prefers that you use a date for the version and not just a number. This facilitates tracking revisions of the document(s) in the future.

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- The name you give the file when it is uploaded is the name that will appear on your HIRC determination letter.
- The protocol, consent, HIPAA, and recruitment forms must be submitted as MS WORD documents. All others can be separate PDF documents. Please note that documents in formats such as JPEG or MS Publisher are not accepted.
- All documents must be unprotected; we cannot accept password protected items.

Can I use an external IRB to review my research study?

In order to help facilitate human research and to avoid duplicative IRB review while at the same time protecting the rights and welfare of human subjects, the UNM HSC is willing to rely on external IRBs. The UNM HSC has negotiated reliance agreements with the following external IRBs that may be applicable when UNM HSC researchers are involved in certain clinical trials.

1. The UNM HSC has an IRB agreement in place with the Central Institutional Review Board (CIRB) of the National Cancer Institute (NCI) for the review of adult and pediatric national multi-centered cooperative oncology group cancer treatment trials.
2. The UNM HSC has IRB authorization agreements with Western IRB for only the following types of research:
 - a. Non-cancer related pharmaceutically sponsored or pharmaceutically initiated clinical trials utilizing the Participant Clinical Interactions Core of the UNM Clinical and Translational Science Center (CTSC). To determine how to qualify for WIRB submission through the CTSC visit the CTSC’s WIRB Partnership web page.
 - b. Cancer-related, pharmaceutically sponsored or pharmaceutically initiated clinical trials conducted under the auspices of the New Mexico Cancer Care Alliance.

All research conducted at UNM HSC or by UNM HSC faculty must be reviewed by the UNM HSC HIRC unless authorized by the Executive Vice President for Research in his/her role as Institutional Official's Designee. The Vice President for Research is vested with the authority to make the decision whether or not to rely on another IRB.

How do I request to rely on an external IRB or have the HIRC serve as the IRB of record for a multi-site study?

Please contact the HRPO single IRB Reliance Coordinator (HRPO-sIRB@salud.unm.edu) to initiate this process. The single IRB Reliance Coordinator will provide guidance on this process and will help facilitate execution of the IRB Authorization Agreement. Lastly the single IRB Reliance Coordinator will help complete the New Study SmartForm in Huron IRB.

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How do I write an Investigator Protocol?

Utilize the appropriate template protocol from the Huron IRB library. Each template protocol has been developed to be a comprehensive guide for drafting a new Investigator Protocol. Each section of the protocol template includes detailed guidance information and instructions and should be removed as the template is completed. The protocol templates and any/all referenced worksheets and checklists can be located in the Huron IRB Library. Consult the HRPO staff for more information about these resources.

The HRP-509 local protocol addendum must be completed even if you have a sponsor protocol. The HRP-509 local protocol addendum provides the HRRC an overview of how the study will be conducted at UNM. If you have a sponsor protocol document, you may reference protocol document sections when filling out the HRP-509 protocol by clearly indicating the page and paragraph number where the reviewer can locate the information from the protocol document. The data management section should clearly define how confidentiality and privacy are addressed at the UNM site and, in most cases, should not reference the sponsor protocol sections.

Include all study sponsor documents for HRRC review in your submission, including but not limited to: Sponsor Consent Form templates, Investigator Brochure(s), Device Manuals, approved drug and/or device labeling, Pharmacy Manuals, Laboratory Manuals, Manual of Operations, and all study instruments (e.g., SF-36, Becks Depression Inventory, etc.).

If you are including non-English speaking study participants, include all translated documents and identify each as Spanish (or appropriate language) in the file name. Please upload a copy of the Translation Certification document to the “Local Site Documents” page. It is recommended to wait until English documents that contain UNM specific information have been approved by the HRRC before translating and submitting them for HRRC review.

Depending on the nature of the proposed research activities, some sections in templates may not be applicable. If so, mark as “NA” and briefly state why it does not apply; **do not delete the template sections.**

Include a version number and/or version date in the body, footer and file name. These should be updated each time the document is revised.

As a reminder, please delete the italicized template instructions in your final protocol document, as applicable.

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How do I create a consent document?

Utilize the appropriate consent template document from the Huron IRB library. Each template consent has been developed to be a comprehensive guide for drafting a consent form.

Note that all long form consent documents and short form consent documents must contain all of the required and all additional appropriate elements of informed consent disclosure. Review the “Long Form of Consent Documentation” section in the HRRC’s “WORKSHEET: Criteria for Approval (HRP-314),” to ensure that these elements are addressed.

Sections 46.102(b) and 46.116(h) of the revised Common Rule requires clinical trials post one IRB-approved consent form for each clinical trial conducted or supported by a Federal department or agency on a website, ClinicalTrials.gov, as required by the US Federal government. The Principal Investigator or their designee is responsible for posting the consent form to the website following the Protocol Registration and Results System (PRS) instructions for document uploads. The consent form must be posted on the website after the clinical trial is closed to recruitment, but no later than 60 days after the last study visit by any participant, as required by the protocol. The Principal Investigator or their designee is responsible for requesting from the Federal funding agency an exception to the requirement to post the consent document, and responsible for redacting names, addresses, and other personally identifiable information as well as confidential commercial information from the consent form.

Include a version number and/or version date in the body, footer and file name. These should be updated each time the document is revised

How do I document consent?

Consent to participate in research is documented by the use of an informed consent document that has been signed by the participant or the participant’s legally authorized representative (LAR), unless the HRRC has waived the requirement to obtain written documentation of consent. Use the signature block approved by the HRRC. Complete all items in the signature block, including dates and applicable checklists. Refer to “SOP HRP-090: Informed Consent Process for Research” and “SOP HRP-091: Written Documentation of Consent”.

The following are the requirements for long form consent documents:

- The participant or participant’s LAR signs and dates the consent document.
- The individual obtaining consent signs and dates the consent document.
- Whenever the HRRC or the sponsor require a witness to the oral presentation, the witness signs and dates the consent document.
- For participants or LARs who cannot read, and whenever required by the HRRC or the sponsor, a witness to the oral presentation signs and dates the consent document.
- A copy of the signed and dated consent document is to be provided to the participant.

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When appropriate, the consent process may be altered to allow for non-verbal or other alternative methods for obtaining and documenting consent. Proposed alterations to the consent process and its documentation are submitted for HRRC review and approval.

How do I document assent from children or cognitively impaired adults?

Assent is defined as “a child’s affirmative agreement to participate in research.” Passive resignation to submit to an intervention or procedure is not considered assent. Federal regulations do not specify any of the elements of informed assent and do not provide an age at which assent is to be sought. In determining whether children are capable of assenting, the HRRC takes into account the ages,

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maturity, and psychological state of the children involved. The HRRC determines whether all or some of the children are capable of assenting. In general, capacity to assent is assumed to begin at about age seven.

As a general rule, all adults, regardless of their diagnosis or condition are presumed competent to consent to participate in research unless there is evidence of a serious disability that would impair reasoning or judgment. When investigators propose to include individuals with questionable capacity, the investigators must provide a plan for assessing the participants' decision-making capacity. Assessment is done on an individual basis and should determine the potential participant's ability to understand and express a reasoned choice based on:

- The voluntary nature of research participation and the information relevant to his/her participation (research procedures);
- Consequences of participation for the participant's own situation, especially with regard to the participant's health condition;
- Consequences of the alternatives to participation;
- Potential risks and benefits involved in the study; and
- Procedures to follow if he/she experience discomfort or wishes to withdraw.

If the assessment shows evidence that the participant is competent to consent, the investigators obtain valid informed consent directly from the participant. If the assessment determines that the potential participant does not have sufficient capacity to consent, the investigator must do the following:

- Document the participant is incapable of understanding the information presented regarding the research in the participant's research record;
- Document the information provided to the participant's LAR regarding the cognitive and health status of the participant, the risks and benefits of the research, and the role of the LAR in the research record;
- Obtain the consent and signature of the participant's LAR; and
- Obtain and document the participant's assent if the person with decisional impairment is capable of exercising some judgment concerning the nature of the research.

The verbal objection of an adult with decisional impairment is binding. If the participant, at any time, objects to continuing in the research study, he/she may not participate in the research study. Situations may arise in which the investigator could legitimately return to the participant at a later point to ascertain whether the previous objection still stands, but this must be detailed in the Protocol and approved by the HRRC. The only exception will be research providing direct benefit only available in the context of the research, in which case the investigator must submit a request to the HRRC to

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enroll the participant or continue their participation, and provide written documentation of the agreement of the participant’s LAR. In this instance, the HRRRC may solicit advice of experts.

Do I need to obtain informed consent in order to screen, recruit, or determine the eligibility of prospective subjects?

The HRRRC may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject’s LAR, if either of the following conditions are met:

- (1) The investigator will obtain information through oral or written communication with the prospective subject or LAR,

or

- (2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

The research protocol should include information about how potential subjects will be identified and recruited in order for the IRB to be able to determine whether informed consent for these activities is required.

Contact the HRPO with additional questions or for further guidance regarding the requirement to obtain HIPAA authorization or a waiver to obtain HIPAA authorization for recruitment purposes.

What are the different regulatory classifications that research activities mayfall under?

Submitted activities may fall under one of the following four regulatory classifications:

- **“Not Human Research”**: Activities must meet the Institutional definition of “Human Research” to fall under HRRRC oversight. Activities that do not meet this definition are not subject to HRRRC oversight or review. Refer to “WORKSHEET: Human Research (HRP-310)” for guidance. Contact the HRPO in cases where it is unclear whether an activity is Human Research or if you need documentation of a determination of “Not Human Research.”
- **Exempt**: Certain categories of Human Research may be exempt from regulation but require HRRRC review. it is the responsibility of the Institution (HRRRC), not the investigator, to determine whether Human Research is exempt from HRRRC review. Refer to “WORKSHEET: Exemption (HRP-312)” for guidance on the categories of research that may be exempt.

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- **NOTE:** Changes that affect an initial determination of exemption will require a new application to be submitted so that the HRRC review can occur at the expedited or convened review level. When these types of changes are made to research that was previously determined to be exempt, researchers should consult with the HRPO staff to discuss if the changes invalidate the exemption determination. Changes that may affect the determination of exemption include but are not limited to:
 - Addition of vulnerable populations, such as prisoners, children, adults with decisional impairment, etc.;
 - New knowledge that increases the risk level;
 - Federally-funded research that adds survey or interview procedures with children that do not meet exempt category 2;
 - Federally-funded research that adds observational research of children involving participation by the researcher;
 - Addition of an element that is subject to FDA regulations;
 - The use of any methods described in the Expedited review categories that do not meet the exempt criteria (e.g., blood draws). For information about Expedited review categories, please refer to this link:
<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html>
 - Change in the way identifiers are recorded (directly or indirectly) from existing data, documents, records, pathological specimens, or diagnostic specimens so that participants can be identified;
 - Addition of an instrument, survey, etc. from which information obtained is recorded in such a manner that (i) human participants can be identified, directly or through identifiers linked to the participants; and (ii) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation;
- Changes that do not affect the determination of exemption but do affect the funding, conflict of interest or contact information of those responsible for the research should be reported to the HRRC through a Modification submission to the study in Huron IRB.
 - Changes that affect the contacts for the research include:
 - A change in the Principal Investigator of the research
 - A change in the institutional affiliation of the Principal Investigator
 - Changes that affect the status of federal funding for the research include:
 - The addition of a federal funding source
 - The removal of a federal funding source

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- Review Using the Expedited Procedure: Certain categories of non-exempt Human Research may qualify for review using the expedited procedure, meaning that the project may be approved by a single designated HRRC reviewer, rather than the convened board. Review “WORKSHEET: Eligibility for Review Using the Expedited Procedure (HRP-313)” for reference on the categories of research that may be reviewed using the expedited procedure.
- Review by the Convened HRRC: Non-Exempt Human Research that does not qualify for review using an expedited procedure must be reviewed by the convened HRRC.

What are the determinations the HRRC can make when reviewing proposed research?

The HRRC may approve research, require modifications to the research to secure approval, table research, defer research or disapprove research:

- Approval: Made when all criteria for approval are met. See “How does the HRRC decide whether to approve Human Research?” below.
- Modifications Required to Secure Approval: Made when HRRC members require specific modifications to the research before approval can be finalized.
- Tabled: Made when the HRRC cannot approve the research at a meeting for reasons unrelated to the research, such as loss of quorum. When taking this action, the HRRC automatically schedules the research for review at the next meeting.
- Deferred: Made when the HRRC determines that the board is unable to approve research as presented. When making this determination, the HRRC describes its reasons for this decision, describes modifications that might make the research approvable, and gives the investigator an opportunity to respond to the HRRC in person or in writing.
- Disapproval: Made when the HRRC determines that it is unable to approve research and the HRRC cannot identify modifications that might make the research approvable. When making this determination, the HRRC describes its reasons for this decision and gives the investigator an opportunity to respond to the HRRC in person or in writing.

How does the HRRC decide whether to approve Human Research?

The criteria for HRRC approval can be found in the “WORKSHEET: Exemption (HRP-312)” for exempt Human Research and the “WORKSHEET: Criteria for Approval (HRP-314)” for non-exempt Human Research. The latter worksheet references other checklists that might be relevant. All checklists and worksheets can be found in the Huron IRB Library.

These checklists and worksheets may be used as applicable for initial review, continuing review, and review of modifications to previously approved Human Research.

You are encouraged to refer to the checklists and worksheets to write your Investigator Protocol in a way that addresses the criteria for approval. Please do not submit the checklists or worksheets as part of your submission.

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What will happen after HRRC review?

The HRPO will provide you with a written decision indicating that the HRRC has approved the research, requires modifications to secure approval, has tabled or deferred the research, or has disapproved the research.

- If the HRRC has approved the submission: The Human Research may commence once all other Institutional requirements have been met. HRRC approval is valid for a limited period of time, usually 365 days. The end of the approval period is noted in the approval letter.
- If the HRRC requires modifications to secure approval: Make the requested modifications and submit them to the HRRC. If all requested modifications are made, the HRRC will issue a final approval. If you do not make some or all of the required modifications, explain in writing why the modifications were not made and submit it to the HRRC. The HRRC will review your explanation and decide whether or not the research can be approved without these modifications. Research cannot commence until final approval is received. If the HRRC defers the submission: The HRRC will provide a statement of the reasons for deferral and suggestions to make the study approvable, and give you an opportunity to respond in writing. You may revise your submission according to the HRRC's guidance, which makes it approvable in most cases.
- If the HRRC disapproves the submission: The HRRC will provide a statement of the reasons for disapproval and give you an opportunity to respond in writing.

In all cases, you have the right to address your concerns to the HRRC directly at an HRRC meeting. Please contact the HRPO to request this.

What are my obligations after HRRC approval?

- 1) Do not start Human Research activities until you have the final HRRC approval letter.
- 2) Do not start Human Research activities until you have obtained all other required institutional approvals, including approvals of departments or divisions that require approval prior to commencing research that involves their resources.
- 3) Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.
 - a) Delegate responsibility to the research staff in accordance with the staff's training and qualifications.
 - b) Ensure that all procedures associated with the research are performed, with the appropriate level of supervision, only by individuals who are licensed or otherwise qualified to perform them under the laws of New Mexico and policies of The University of New Mexico Health Sciences Center.
 - c) Monitor the conduct of the research and perform quality management activities to ensure the safety of participants and the quality and integrity of the research data.

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- 4) Unless waivers or alterations are approved by the HRRC, obtain the legally effective informed consent from human participants or their representatives, using only the currently approved informed consent documents, and provide a signed copy to the participant, if applicable.
- 5) Ensure that only HRRC-approved investigators obtain informed consent from potential participants.
- 6) If unavailable to conduct the research personally, as when on sabbatical leave or vacation, arrange for another HRRC-approved investigator on the study to assume direct responsibility or notify the HRRC of alternate arrangements.
- 7) Maintain accurate and complete research records, including but not limited to, original signed informed consent and authorization documents, and retain these records according to HRRC policy and the applicable regulatory retention terms.
- 8) Fully inform the HRRC of all locations in which human participants will be recruited for this project and obtain and maintain current HRRC approvals/letters of support when applicable.
- 9) Ensure that Research Staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.
- 10) Update the study record in Huron IRB with any changes to the study personnel.
- 11) Personally conduct or supervise the Human Research.
 - a) Conduct the Human Research in accordance with the relevant current protocol as approved by the HRRC and in accordance with applicable federal regulations and local laws.
 - b) When required by the HRRC, ensure that consent or permission is obtained in accordance with the relevant current protocol as approved by the HRRC.
 - c) Do not modify the Human Research without prior HRRC review and approval unless necessary to eliminate apparent immediate hazards to participants. Please immediately submit a Reportable New Information (RNI) report in Huron IRB.
 - d) Protect the rights, safety, and welfare of participants involved in the research.
- 12) Submit to the HRRC:
 - a) Proposed modifications to the approved research as described in this manual. (See “How do I submit a modification?”)
 - i Single subject protocol exceptions should be submitted via the modification process.
 - b) A continuing review application as requested in the approval letter. (See “How do I submit continuing review?”)
 - c) A continuing review application when the Human Research is closed. (See “How Do I Close Out a Study?”)
- 13) Complete the Report New Information SmartForm within 5 business days for any of the following information items (Appendix A-1):
 - a) Information that indicates a new or increased risk, or a new safety issue. For example:
 - i New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.

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- ii An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or to describe a new risk
 - iii Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol
 - iv Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm
 - v Complaint of a subject that indicates that the complaining subject or other subjects might be at increased risk of harm or at risk of a new harm
 - vi Any changes significantly affecting the conduct of the research
- b) Harm experienced by a subject or other individual, which in the opinion of the investigator are **unexpected** and **probably related** to the research procedures.
- i A harm is “unexpected” when its specificity or severity are inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.
 - ii A harm is “probably related” to the research procedures if in the opinion of the investigator, the research procedures more likely than not caused the harm.
- c) Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.
- d) Audit, inspection, or inquiry by a federal agency and any resulting reports (e.g. FDA Form 483.)
- e) Written reports of study monitors.
- f) Failure to follow the protocol due to the action or inaction of the investigator or research staff.
- g) Breach of confidentiality.
- h) Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
- i) Incarceration of a subject in a study not approved by the IRB to involve prisoners.
- j) Complaint of a subject that cannot be resolved by the research team.
- k) Premature suspension or termination of the protocol by the sponsor, investigator, or institution.
- l) Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application, including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects).
- 14) Submit an updated disclosure of financial interests to the UNM HSC Conflicts of Interest Office within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.

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- 15) Do not accept or provide payments to professionals in exchange for referrals of potential participants (“finder’s fees.”)
- 16) Do not accept or provide payments designed to accelerate recruitment that were tied to the rate or timing of enrollment (“bonus payments.”)
- 17) See additional requirements of various federal agencies in Appendix A-2 through A-9. These represent additional requirements and do not override the baseline requirements of this section.
- 18) If the HRRC requests or your study is selected for an onsite post-approval review, cooperate with HRPO Quality Improvement program staff to ensure the completion of the audit.
- 19) If the study is a clinical trial and supported by a Common Rule agency, one IRB-approved version of a consent form that has been used to enroll participants must be posted on a public federal website designated for posting such consent forms. The form must be posted after recruitment closes, and no later than 60 days after the last study visit. Please contact the study sponsor with any questions.

What are my obligations as the overall study PI for an sIRB study?

- 1) Coordinating with HRPP personnel to determine whether this institution’s IRB can act as the single IRB for all or some institutions participating in the study or if an external IRB will assume oversight.
- 2) Identifying all sites that will be engaged in the human research and requiring oversight by the IRB.
- 3) Ensuring that all sites receive a request to rely on the reviewing IRB and that all institutional requirements are satisfied before a study is activated at a relying site.
- 4) Collaborating with the reviewing IRB to document roles and responsibilities for communicating and coordinating key information from study teams and the IRB or HRPP at relying sites in a ‘Communication Plan’
- 5) Responding to questions or information requests from study teams or the IRB or HRPP staff at relying sites.
- 6) Providing relying site investigators with the policies of the reviewing IRB.
- 7) Providing relying site investigators with the IRB-approved versions of all study documents.
- 8) Preparing and submitting IRB applications on behalf of all sites. This includes initial review, modifications, personnel updates, reportable new information and continuing review information for all sites.
- 9) Establishing a process for obtaining and collating information from all sites and submitting this information to the reviewing IRB. This includes site-specific variations in study conduct, such as the local consent process and language, subject identification and recruitment processes and local variations in study conduct. These variations should be documented in a Local protocol Addendum for each site.
- 10) Ensuring that consent forms used by relying sites follow the consent template approved by the reviewing IRB and include required language as specified by the relying sites.
- 11) Providing site investigators with all determinations and communications from the reviewing IRB.

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- 12) Submitting reportable new information from relying sites to the reviewing IRB in accordance with the terms outlined in the authorization agreement or communication plan.
- 13) Reporting the absence of continuing review information from relying sites if they do not provide the required information prior to submission of the continuing review materials to the reviewing IRB. Notifying the relying site of their lapse in approval and applicable corrective actions.
- 14) Providing study records to the relying institution, reviewing IRB or regulatory agencies upon request.

What are my obligations as investigator when relying on an external IRB?

- 1) Obtaining appropriate approvals from this institution prior to seeking review by another IRB.
- 2) Complying with determinations and requirements of the reviewing IRB.
- 3) Providing the reviewing IRB with requested information about local requirements or local research context issues relevant to the IRB’s determination prior to IRB review.
- 4) Notifying the reviewing IRB when local policies that impact IRB review are updated.
- 5) Cooperating in the reviewing IRB’s responsibility for initial and continuing review, record keeping and reporting and providing all information requested by the reviewing IRB in a timely manner.
- 6) Disclosing conflicts of interest as required by the reviewing IRB and complying with management plans that may result.
- 7) Promptly reporting to the reviewing IRB any proposed changes to the research and not implementing those changes to the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the participants.
- 8) When enrolling participants, obtaining, documenting and maintaining records of consent for each participant or each participant’s legally authorized representative.
- 9) Promptly reporting to the reviewing IRB any unanticipated problems involving risks to participants or others according to the requirements specified in the reliance agreement.
- 10) Providing the reviewing IRB with data safety monitoring reports in accordance with the reviewing IRB’s reporting policy.
- 11) Reporting non-compliance, participant complaints, protocol deviations or other events according to the requirements specified in the reliance agreement.
- 12) Specifying the contact person and providing contact information for researchers and research staff to obtain answers to questions, express concerns, and convey suggestions regarding the use of the reviewing IRB.

How do I submit a Modification?

You must report planned changes in a study and receive approval from the HRRC prior to implementing these changes, except where necessary to eliminate apparent immediate hazards to the participants. In the case of changes implemented to eliminate immediate hazards to the participants, the emergency protocol changes must be reported to the HRRC using a Reportable New Information

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submission. See “What new information needs to be reported to the HRRC during the course of the study and prior to the next continuing review?” below.

To request approval for modifications to an approved study, click “Create Modification / CR” in the Huron IRB system, answer the questions on each SmartForm page, upload all requested supporting documents and execute the “Submit” function in the workspace to send it to the HRPO for processing. When revising previously approved documents, such as protocols, consent forms, recruitment materials, etc., use the “track changes” feature in MS Word and mark all revisions being made as part of the submission and update all version dates. Maintain electronic copies of all documents submitted to the HRRC in case revisions are required. Please note that research must continue to be conducted as previously approved, or halted, until HRRC approval of the Modification is received.

Modifications may require the consent form/process be revised to reflect study changes. For research given an Exempt determination, please refer to “What are the different regulatory classifications of research?” above for modifications to Exempt research that are accepted by the HRRC.

To submit a Modification for a pSite in an sIRB study, you must use the “Create Modification/CR” function in the SITE workspace. Otherwise, the process is identical to the one described above for the Modification of a single site submission.

How do I submit a Continuing Review?

The UNM HSC HRRC requires continuing review for all studies approved using the expedited procedure. The following points justify why continuing review enhances protection of research participants:

- Risk Assessment and Monitoring of Potential Non-Compliance
 - The continuing review process serves as a mechanism to maintain annual oversight in order to ensure the risk/benefit assessment remains unchanged.
 - Additionally, the annual continuing review is an opportunity for the HRRC to discover non-compliance that may affect participant safety. At time of continuing review, the Principal Investigator eligibility requirements are re-checked, as is compliance with human subjects protection training and the financial conflicts of interest (FCOI) training.
- The HRRC prefers to adopt a more stringent approach, at this time, and require continuing reviews annually for all studies approved using the expedited procedure. The submission of a continuing review in Huron IRB is very streamlined and includes the completion of a single SmartForm, and thereby, does not unduly burden investigators while giving the HRRC an annual update.

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A continuing review submission must be submitted prior to the expiration date of HRRC approval. To submit a continuing review submission, click “Create Modification / CR” in the Huron IRB system, answer the questions in each SmartForm, attach all requested supporting documents and execute the “Submit” activity in the workspace to send it to the HRPO for review.

If the continuing review application is not received **45 days prior** to expiration, the HRRC may not be able to conduct a review, prior to expiration. You may be restricted from submitting new human research until the completed application has been received, and this may be considered serious or continuing non-compliance.

If the HRRC approval expires, all Human Research procedures related to the protocol under review must cease including recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection or analysis of private identifiable information. In addition, any data analyses of previously collected research data must cease. Continuing Human Research procedures without HRRC approval is a violation of Institutional policy. If current participants will be harmed by stopping Human Research procedures that are available outside the Human Research context, provide these on a clinical basis as needed to protect current participants. If current participants will be harmed by stopping Human Research procedures that are not available outside the Human Research context, immediately contact the HRRC and provide a written list of the currently enrolled participants and why they will be harmed by stopping procedures. Remember that research data cannot be collected during study expiration.

A pSite in a sIRB study submits documentation of the sIRB’s Continuing Review approval by submitting a Modification (of “other parts”) on the SITE page. The modification summary must include the action of “uploading the External IRB letter of continuing review approval” to the “Other Attachments” section of the Local Site Documents page. The End of Approval date must be updated on the STUDY page to reflect the date on the current Continuing Review approval letter.

What new information needs to be reported to the HRRC during the course of the study and prior to the next continuing review?

Information items that fall into one or more of the categories listed in “Appendix A-1 Reportable New Information” must be reported to the HRRC within 5 business days of the investigator becoming aware of the information. These information items will be reviewed by the HRRC to determine if they represent non-compliance, unanticipated problems involving risks to participants or others, and/or result in suspension of HRRC approval or termination of HRRC approval. To submit an information item, click “Create Reportable New Information” in the Huron IRB system, answer the questions in the SmartForm, attach all requested supporting documents and click the “Submit” activity in the

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workspace to send it to the HRRC Office for review. Maintain electronic copies of all information submitted to the HRRC.

How do I close out a study?

To be eligible for closure, the research study must meet all of the following criteria:

- The research is permanently closed to enrollment at this institution;
- All participants enrolled at this institution have completed all protocol-related interventions and interactions, including interventions and interactions related to collection of long-term follow-up data;
- No additional identifiable private information about the participants is being obtained by this institution’s investigator; and
- Analysis of private identifiable information at this institution is completed.

In order to close a study that stored identifiable data and/or specimens the data/specimens must be handled per the approved protocol data/specimen management plan. If identifiable data/specimens will be used for future research, they must be placed in an HRRC-approved repository.

In order to close a study, create and submit a Continuing Review submission following the instructions above. By selecting the first 4 options in the Research Milestones section of the “Continuing Review Information / Study Closure Information” page, the study will automatically be routed for closure. Provide all other information and applicable documentation as for a Continuing Review.

If you fail to submit a continuing review submission to close out Human Research, you will be restricted from submitting new Human Research until the completed application has been received.

If the continuing review submission for closing out a Human Research study is not received by the date requested in the approval letter, you will be restricted from submitting new Human Research until the completed application is received.

To close a pSite in a sIRB study, create and submit a Modification of other parts on the SITE page. The modification summary must include the action of “uploading the External IRB letter of closure” to the Local Site Documents page, by clicking “other attachments”.

How long do I keep research-related records?

Maintain your Human Research records, including signed and dated consent documents, for at least three years after closure of the research. Maintain signed and dated HIPAA authorizations and consent documents that include HIPAA authorizations for at least six years after completion of the research. Study records with minors must be retained until the minor becomes 22 years old ([Policy HSC-R-801 PR.1](#)).

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If your Human Research is sponsored, contact the sponsor before disposing of Human Research records. If your research is regulated by the FDA, refer to Appendix A-3.

What if I need to use an unapproved drug, biologic, or device in an emergency and there is no time for HRRC review?

Contact the HRPO immediately to discuss the situation. If there is no time to make this contact, reference the “WORKSHEET: Emergency Use (HRP-322)” for the regulatory criteria allowing such a use and adhere to them in your use of the emergency article. Use the “TEMPLATE EMERGENCY USE CONSENT DOCUMENT (HRP-506)” to prepare your consent document. You must submit a report of the emergency use to the HRRC within five days of the use. If additional use of the emergency article is anticipated, you must submit a New Study application in Huron IRB for HRRC review within 30 days.

If you fail to submit the report within five days or the HRRC application for initial review within 30 days, you will be restricted from submitting new Human Research until the report and HRRC application for initial review have been received.

Emergency use of an unapproved drug or biologic in a life-threatening situation without prior HRRC review is “research” as defined by FDA, the individual getting the test article is a “subject” as defined by FDA, and therefore is governed by FDA regulations for HRRC review and informed consent.

Emergency use of an unapproved device without prior HRRC review is not “research” as defined by FDA and the individual getting the test article is not a “subject” as defined by FDA. However, FDA guidance recommends following similar rules as for emergency use of an unapproved drug or biologic. Individuals getting an unapproved drug, biologic, or device without prior HRRC review cannot be considered a “subject” as defined by DHHS and their results cannot be included in prospective “research” as that term is defined by DHHS.

How do I get additional information and answers to questions?

This document and the policies and procedures for the Human Research Protection Program are available on the Huron IRB website at <https://irb.health.unm.edu> .

If you have any questions or concerns about the Human Research Protection Program, contact the HRPO Office at:

HRPP Director
 University of New Mexico Health Sciences Center
 Reginald Heber Fitz Hall, B71

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Albuquerque, New Mexico 87131
 Email: HSC-hrpo@salud.unm.edu
 Phone: (505) 272-1129

If you have questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the Human Research Protection Program that cannot be addressed by contacting the HRPO, follow the directions in the “HUMAN RESEARCH PROTECTION PROGRAM PLAN (HRP-101)” under “Reporting and Management of Concerns.”

Appendix A-1 ***Reportable New Information***

Report information items that fall into one or more of the following categories to the HRRC within 5 business days. Reference SOP: New Information (HRP-024).

- 1) Information that indicates a new or increased risk, or a new safety issue, for example:
 - a. New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.
 - b. Protocol violation that harmed participants or others or that indicates participants or others might be at increased risk of harm
 - c. Complaint of a participant that indicates participants or others might be at increased risk of harm or at risk of a new harm
 - d. An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or describe a new risk
 - e. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol
 - f. Changes significantly affecting the conduct of the clinical trial or increasing the risk to participants
- 2) Harm experienced by a participant or other individual, which in the opinion of the investigator is unexpected and *related or possibly related* to the research procedures.
 - a. A harm is "unexpected" when its specificity or severity are inconsistent with risk information previously reviewed and approved by the HRRC in terms of nature, severity, frequency, and characteristics of the study population.
 - b. A harm is "related or possibly related" to the research procedures if, in the opinion of the investigator, the research procedures more likely than not caused the harm.

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- 3) Non-compliance with the federal regulations governing human research or with the requirements or determinations of the HRRC, or an allegation of such non-compliance.
- 4) Failure to follow the protocol due to the action or inaction of the investigator or research staff.
- 5) Change to the protocol made without prior HRRC review to eliminate an apparent immediate hazard to a participant.
- 6) Breach of confidentiality.
- 7) Complaint of a participant that cannot be resolved by the research team.
- 8) Premature suspension or termination by the sponsor, investigator, or institution.
- 9) Incarceration of a participant in a study not approved by the HRRC to involve prisoners.
- 10) Audit, inspection, or inquiry by a federal agency and any resulting reports (e.g., FDA Form 483).
- 11) Written reports of study monitors.
- 12) Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application, including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of participants).
- 13) Unanticipated Problems Involving Risks to Subjects or Others, including any event or problem that is serious, unexpected, and related to the research, where “related” means the event or problem might reasonably be regarded as caused by, or probably caused by, the research.
- 14) Disciplinary action against the investigator or research staff by federal, state, and local regulatory agencies.

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Appendix A-2 *Additional Requirements for DHHS-Regulated Research*²

1. When a participant decides to withdraw from a clinical trial, the investigator conducting the clinical trial should ask the participant to clarify whether the participant wishes to withdraw from all components of the trial or only from the primary interventional component of the trial. In the latter case, research activities involving other components of the clinical trial, such as follow-up data collection activities, for which the participant previously gave consent may continue. The investigator should explain to the participant who wishes to withdraw the importance of obtaining follow-up safety data about the participant.
2. Investigators are allowed to retain and analyze already collected data relating to any participant who chooses to withdraw from a research study or whose participation is terminated by an investigator without regard to the participant's consent, provided such analysis falls within the scope of the analysis described in the HRRC-approved protocol. This is the case even if that data includes identifiable private information about the participant.
3. For research not subject to regulation and review by FDA, investigators, in consultation with the funding agency, can choose to honor a research participant's request that the investigator destroy the participant's data or that the investigator exclude the participant's data from any analysis.
4. When seeking the informed consent of participants, investigators should explain whether already collected data about the participants will be retained and analyzed even if the participants choose to withdraw from the research.
5. When research is covered by a certificate of confidentiality, researchers:
 - a. May not disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
 - b. May not disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.
 - c. May disclose information only when:
 - i. Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding.

² <http://www.hhs.gov/ohrp/policy/subjectwithdrawal.html>

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- ii. Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
 - iii. Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
 - iv. Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human participants in research.
- d. Researchers must inform participants of the protections and limitations of certificates of confidentiality (see language in HRP-502 - TEMPLATE CONSENT DOCUMENT).
 - i. For studies that were previously issued a Certificate and notified participants of the protections provided by that Certificate, NIH does not expect participants to be notified that the protections afforded by the Certificate have changed, although IRBs may determine whether it is appropriate to inform participants.
 - ii. If part of the study cohort was recruited prior to issuance of the Certificate, but are no longer actively participating in the study, NIH does not expect participants consented prior to the change in authority, or prior to the issuance of a Certificate, to be notified that the protections afforded by the Certificate have changed, or that participants who were previously consented to be re-contacted to be informed of the Certificate, although the IRB may determine whether it is appropriate to inform participants.
- e. Researchers conducting research covered by a certificate of confidentiality, even if the research is not federally funded, must ensure that if identifiable, sensitive information is provided to other researchers or organizations, the other researcher or organization must comply with applicable requirements when research is covered by a certificate of confidentiality.

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Appendix A-3 *Additional Requirements for FDA-Regulated Research*

When a participant withdraws from a study:³

- a. The data collected from the participant to the point of withdrawal remains part of the study database and may not be removed.
- b. An investigator may ask a participant who is withdrawing whether the participant wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the participant would distinguish between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review, and address the maintenance of privacy and confidentiality of the participant's information.
- c. If a participant withdraws from the interventional portion of the study, but agrees to continued follow-up of associated clinical outcome information as described in the previous bullet, the investigator must obtain the participant's informed consent for this limited participation in the study (assuming such a situation was not described in the original informed consent form). HRRC approval of informed consent documents is required.
- d. If a participant withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposes related to the study the participant's medical record or other confidential records requiring the participant's consent.
- e. An investigator may review study data related to the participant collected prior to the participant's withdrawal from the study, and may consult public records, such as those establishing survival status.

For FDA-regulated research involving investigational drugs:

- a. Investigators must abide by FDA restrictions on promotion of investigational drugs:⁴
 - i. An investigator, or any person acting on behalf of an investigator, must not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug.
 - ii. This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in

³ <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126489.pdf>

⁴ <http://www.accessdata.fda.gov/SCRIPTS/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.7>

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scientific or lay media. Rather, its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialization of the drug before it is approved for commercial distribution.

- iii. An investigator must not commercially distribute or test market an investigational new drug.
- b. Follow FDA requirements for general responsibilities of investigators⁵
 - i. An investigator is responsible for ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of participants under the investigator's care; and for the control of drugs under investigation.
 - ii. An investigator must, in accordance with the provisions of 21 CFR §50, obtain the informed consent of each human participant to whom the drug is administered, except as provided in 21 CFR §50.23 or §50.24 of this chapter.
 - iii. Additional specific responsibilities of clinical investigators are set forth in this part and in 21 CFR §50 and 21 CFR §56.
- c. Follow FDA requirements for control of the investigational drug⁶
 - i. An investigator must administer the drug only to participants under the investigator's personal supervision or under the supervision of a sub-investigator responsible to the investigator.
 - ii. The investigator must not supply the investigational drug to any person not authorized under this part to receive it.
- d. Follow FDA requirements for investigator recordkeeping and record retention⁷
 - i. Disposition of drug:
 - 1. An investigator is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by participants.
 - 2. If the investigation is terminated, suspended, discontinued, or completed, the investigator must return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug under 21 CFR §312.59.
 - ii. Case histories.

⁵ <http://www.accessdata.fda.gov/SCRIPTS/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.60>

⁶ <http://www.accessdata.fda.gov/SCRIPTS/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.61>

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1. An investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation.
 2. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital charts, and the nurses' notes. The case history for each individual must document that informed consent was obtained prior to participation in the study.
- iii. Record retention:
1. An investigator must retain required records for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.
- e. Follow FDA requirements for investigator reports⁸
- i. Progress reports: The investigator must furnish all reports to the sponsor of the drug who is responsible for collecting and evaluating the results obtained.
 - ii. Safety reports: An investigator must promptly report to the sponsor any adverse effect that may reasonably be regarded as caused by, or probably caused by, the drug. If the adverse effect is alarming, the investigator must report the adverse effect immediately.
 - iii. Final report: An investigator must provide the sponsor with an adequate report shortly after completion of the investigator's participation in the investigation.
 - iv. Financial disclosure reports:
 1. The clinical investigator must provide the sponsor with sufficient accurate financial information to allow an applicant to submit complete and accurate certification or disclosure statements as required under 21 CFR §54.
 2. The clinical investigator must promptly update this information if any relevant changes occur during the course of the investigation and for 1 year following the completion of the study.

⁸ <http://www.accessdata.fda.gov/SCRIPTS/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.64>

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- f. Follow FDA requirements for assurance of HRRC review⁹
 - i. An investigator must assure that the HRRC complies with the requirements set forth in 21 CFR §56 and will be responsible for the initial and continuing review and approval of the proposed clinical study.
 - ii. The investigator must also assure that he or she will promptly report to the HRRC all changes in the research activity and all unanticipated problems involving risk to human participants or others, and that he or she will not make any changes in the research without HRRC approval, except where necessary to eliminate apparent immediate hazards to human participants.
- g. Follow FDA requirements for inspection of investigator's records and reports¹⁰
 - i. An investigator must, upon request from any properly authorized officer or employee of FDA, at reasonable times, permit such officer or employee to have access to, make copies of and verify any records or reports made by the investigator pursuant to 312.62.
 - ii. The investigator is not required to divulge participant names unless the records of particular individuals require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual case studies, or do not represent actual results obtained.
- h. Follow FDA requirements for handling of controlled substances¹¹
 - i. If the investigational drug is subject to the Controlled Substances Act, the investigator must take adequate precautions, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.

For FDA-regulated research involving investigational devices:

- a. General responsibilities of investigators.¹¹
 - i. An investigator is responsible for ensuring that an investigation is conducted according to the signed agreement, the investigational plan and applicable FDA regulations, for protecting the rights, safety, and welfare of participants under the investigator's care, and for the control of devices under investigation. An investigator also is responsible for ensuring that informed consent is obtained in accordance with 21 CFR §50.

⁹ <http://www.accessdata.fda.gov/SCRIPTS/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.66>

¹⁰ <http://www.accessdata.fda.gov/SCRIPTS/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.68>

¹¹ <http://www.accessdata.fda.gov/SCRIPTS/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.69>

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- b. Specific responsibilities of investigators¹²
- i. Awaiting approval: An investigator may determine whether potential participants would be interested in participating in an investigation, but must not request the written informed consent of any participant to participate, and must not allow any participant to participate before obtaining HRRC and FDA approval.
 - ii. Compliance: An investigator must conduct an investigation in accordance with the signed agreement with the sponsor, the investigational plan, and other applicable FDA regulations, and any conditions of approval imposed by an HRRC or FDA.
 - iii. Supervising device use: An investigator must permit an investigational device to be used only with participants under the investigator's supervision. An investigator must not supply an investigational device to any person not authorized to receive it.
 - iv. Financial disclosure:
 1. A clinical investigator must disclose to the sponsor sufficient accurate financial information to allow the applicant to submit complete and accurate certification or disclosure statements required under 21 CFR §54.
 2. The investigator must promptly update this information if any relevant changes occur during the course of the investigation and for 1 year following completion of the study.
 - v. Disposing of device: Upon completion or termination of a clinical investigation or the investigator's part of an investigation, or at the sponsor's request, an investigator must return to the sponsor any remaining supply of the device or otherwise dispose of the device as the sponsor directs.
- c. Maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation:¹³
- i. All correspondence with another investigator, the HRRC, the sponsor, a monitor, or FDA, including required reports.
 - ii. Records of receipt, use or disposition of a device that relate to:
 1. The type and quantity of the device, the dates of its receipt, and the batch number or code mark.
 2. The names of all persons who received, used, or disposed of each device.

¹² <http://www.accessdata.fda.gov/SCRIPTS/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.110>

¹³ <http://www.accessdata.fda.gov/SCRIPTS/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.140>

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3. Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of.
- iii. Records of each participant's case history and exposure to the device. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital charts, and the nurses' notes. Such records must include:
 1. Documents evidencing informed consent and, for any use of a device by the investigator without informed consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent.
 2. Documentation that informed consent was obtained prior to participation in the study.
 3. All relevant observations, including records concerning adverse device effects (whether anticipated or unanticipated), information and data on the condition of each participant upon entering, and during the course of, the investigation, including information about relevant previous medical history and the results of all diagnostic tests.
 4. A record of the exposure of each participant to the investigational device, including the date and time of each use, and any other therapy.
 - iv. The protocol, with documents showing the dates of and reasons for each deviation from the protocol.
 - v. Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigations or a particular investigation.
- d Inspections¹⁴
- i. Entry and inspection: A sponsor or an investigator who has authority to grant access must permit authorized FDA employees, at reasonable times and in a reasonable manner, to enter and inspect any establishment where devices are held (including any establishment where devices are manufactured, processed, packed, installed, used, or implanted or where records of results from use of devices are kept).
 - ii. Records inspection: A sponsor, HRRc, or investigator, or any other person acting on behalf of such a person with respect to an investigation, must permit authorized FDA employees, at reasonable times and in a reasonable manner, to inspect and copy all records relating to an investigation.

¹⁴ <http://www.accessdata.fda.gov/SCRIPTS/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.145>

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- iii. Records identifying participants: An investigator must permit authorized FDA employees to inspect and copy records that identify participants, upon notice that FDA has reason to suspect that adequate informed consent was not obtained, or that reports required to be submitted by the investigator to the sponsor or HRRC have not been submitted or are incomplete, inaccurate, false, or misleading.
- e. Prepare and submit the following complete, accurate, and timely reports¹⁵
 - i. Unanticipated adverse device effects. An investigator must submit to the sponsor and to the reviewing IRB a report of any unanticipated adverse device effect occurring during an investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect.
 - ii. Withdrawal of HRRC approval. An investigator must report to the sponsor, within 5 working days, a withdrawal of approval by the reviewing IRB of the investigator's part of an investigation.
 - iii. Progress. An investigator must submit progress reports on the investigation to the sponsor, the monitor, and the reviewing IRB at regular intervals, but in no event less often than yearly.
 - iv. Deviations from the investigational plan:
 - 1. An investigator must notify the sponsor and the reviewing IRB of any deviation from the investigational plan to protect the life or physical wellbeing of a participant in an emergency.
 - 2. Such notice must be given as soon as possible, but in no event later than 5 working days after the emergency occurred.
 - 3. Except in such an emergency, prior approval by the sponsor is required for changes in or deviations from a plan, and if these changes or deviations may affect the scientific soundness of the plan or the rights, safety, or welfare of human participants, FDA and HRRC approval is also required.
 - v. Informed consent. If an investigator uses a device without obtaining informed consent, the investigator must report such use to the sponsor and the reviewing IRB within 5 working days after the use occurs.
 - vi. Final report. An investigator must, within 3 months after termination or completion of the investigation or the investigator's part of the investigation, submit a final report to the sponsor and the reviewing IRB.

¹⁵ <http://www.accessdata.fda.gov/SCRIPTS/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.150>

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- vii. Other. An investigator must, upon request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.

Appendix A-4 ***Additional Requirements for Clinical Trials (ICH-GCP)***

Investigator's Qualifications and Agreements

- a. The clinical trial should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with good clinical practice and the applicable regulatory requirements.
- b. The investigator should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirements, and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the HRRC, and/or the regulatory authorities.
- c. The investigator should be thoroughly familiar with the appropriate use of the investigational product, as described in the protocol, in the current Investigator's Brochure, in the product information and in other information sources provided by the sponsor.
- d. The investigator should be aware of, and should comply with, GCP and the applicable regulatory requirements.
- e. The investigator/institution should permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authorities.
- f. The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.

Adequate Resources

- a. The investigator should be able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable participants within the agreed recruitment period.
- b. The investigator should have sufficient time to properly conduct and complete the trial within the agreed trial period.
- c. The investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.
- d. The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product, and their trial-related duties and functions.

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Medical Care of Trial Participants

- a. A qualified physician (or dentist, when appropriate), who is an investigator or a sub investigator for the trial, should be responsible for all trial-related medical (or dental) decisions.
- b. During and following an individual's participation in a trial, the investigator/institution should ensure that adequate medical care is provided to a participant for any adverse events, including clinically significant laboratory values, related to the trial. The investigator/institution should inform a participant when medical care is needed for intercurrent illnesses of which the investigator becomes aware.
- c. It is recommended that the investigator inform the participant's primary physician about the individual's participation in the trial if the participant has a primary physician and if the participant agrees to the primary physician being informed.
- d. Although a participant is not obliged to give his/her reasons for withdrawing prematurely from a trial, the investigator should make a reasonable effort to ascertain the reasons, while fully respecting the participant's rights.

Communication with the HRRC

- a. Before initiating a trial, the investigator/institution should have written and dated approval opinion from the HRRC for the trial protocol, written informed consent form, consent form updates, participant recruitment procedures (e.g., advertisements), and any other written information to be provided to participants.
- b. As part of the investigator's/institution's written application to the HRRC, the investigator/institution should provide the HRRC with a current copy of the Investigator's Brochure. If the Investigator's Brochure is updated during the trial, the investigator/institution should supply a copy of the updated Investigator's Brochure to the HRRC.
- c. During the trial, the investigator/institution should provide to the HRRC all documents subject to review.

Compliance with Protocol

- a. The investigator/institution should conduct the trial in compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authorities and which was given approval opinion by the HRRC. The investigator/institution and the sponsor should sign the protocol, or an alternative contract, to confirm agreement.
- b. The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval opinion from the HRRC of an amendment, except where necessary to eliminate any immediate hazards to trial participants, or when the changes involve only logistical or

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administrative aspects of the trial (e.g., change in monitors, change of telephone numbers).

- c. The investigator, or person designated by the investigator, should document and explain any deviation from the approved protocol.
- d. The investigator may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard to trial participants without prior HRRC approval opinion. As soon as possible, the implemented deviation or change, the reasons for it, and, if appropriate, the proposed protocol amendments should be submitted: a) to the HRRC for review and approval opinion, b) to the sponsor for agreement and, if required, c) to the regulatory authorities.

Investigational Product

- a. Responsibility for investigational product accountability at the trial site rests with the investigator/institution.
- b. Where allowed/required, the investigator/institution may/should assign some or all of the investigator's/institution's duties for investigational product accountability at the trial site to an appropriate pharmacist or another appropriate individual who is under the supervision of the investigator/institution.
- c. The investigator/institution and/or a pharmacist or other appropriate individual, who is designated by the investigator/institution, should maintain records of the product's delivery to the trial site, the inventory at the site, the use by each participant, and the return to the sponsor or alternative disposition of unused product. These records should include dates, quantities, batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the investigational product and trial participants. Investigators should maintain records that document adequately that the participants were provided the doses specified by the protocol and reconcile all investigational product received from the sponsor.
- d. The investigational product should be stored as specified by the sponsor and in accordance with applicable regulatory requirements.
- e. The investigator should ensure that the investigational product is used only in accordance with the approved protocol.
- f. The investigator, or a person designated by the investigator/institution, should explain the correct use of the investigational product to each participant and should check, at intervals appropriate for the trial, that each participant is following the instructions properly.
- g. Randomization Procedures and Unblinding: The investigator should follow the trial's randomization procedures, if any, and should ensure that the code is broken only in accordance with the protocol. If the trial is blinded, the investigator should promptly

document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the investigational product.

Informed Consent of Trial Participants

- a. In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirements, and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki. Prior to the beginning of the trial, the investigator should have the HRRC's written approval opinion of the written informed consent form and any other written information to be provided to participants.
- b. The written informed consent form and any other written information to be provided to participants should be revised whenever important new information becomes available that may be relevant to the participant's consent. Any revised written informed consent form, and written information should receive the HRRC's approval opinion in advance of use. The participant or the participant's legally acceptable representative should be informed in a timely manner if new information becomes available that may be relevant to the participant's willingness to continue participation in the trial. The communication of this information should be documented.
- c. Neither the investigator, nor the trial staff, should coerce or unduly influence a participant to participate or to continue to participate in a trial.
- d. None of the oral and written information concerning the trial, including the written informed consent form, should contain any language that causes the participant or the participant's legally acceptable representative to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their agents from liability for negligence.
- e. The investigator, or a person designated by the investigator, should fully inform the participant or, if the participant is unable to provide informed consent, the participant's legally acceptable representative, of all pertinent aspects of the trial including the written information and the approval opinion by the HRRC.
- f. The language used in the oral and written information about the trial, including the written informed consent form, should be as non-technical as practical and should be understandable to the participant or the participant's legally acceptable representative and the impartial witness, where applicable.
- g. Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the participant or the participant's legally acceptable representative ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be

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answered to the satisfaction of the participant or the participant's legally acceptable representative.

- h. Prior to an individual's participation in the trial, the written informed consent form should be signed and personally dated by the participant or by the participant's legally acceptable representative, and by the person who conducted the informed consent discussion.
- i. If a participant is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion. After the written informed consent form and any other written information to be provided to participants, is read and explained to the participant or the participant's legally acceptable representative, and after the participant or the participant's legally acceptable representative has orally consented to the participant's participation in the trial and, if capable of doing so, has signed and personally dated the informed consent form, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the participant or the participant's legally acceptable representative, and that informed consent was freely given by the participant or the participant's legally acceptable representative.
- j. Both the informed consent discussion and the written informed consent form and any other written information to be provided to participants should include explanations of the following:
 - i. That the trial involves research.
 - ii. The purpose of the trial.
 - iii. The trial treatments and the probability for random assignment to each treatment.
 - iv. The trial procedures to be followed, including all invasive procedures.
 - v. The participant's responsibilities.
 - vi. Those aspects of the trial that are experimental.
 - vii. The reasonably foreseeable risks or inconveniences to the participant and, when applicable, to an embryo, fetus, or nursing infant.
 - viii. The reasonably expected benefits. When there is no intended clinical benefit to the participant, the participant should be made aware of this.
 - ix. The alternative procedures or courses of treatment that may be available to the participant, and their important potential benefits and risks.
 - x. The compensation and/or treatment available to the participant in the event of trial related injury.

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- xi. The anticipated prorated payment, if any, to the participant for participating in the trial.
 - xii. The anticipated expenses, if any, to the participant for participating in the trial.
 - xiii. That the participant's participation in the trial is voluntary and that the participant may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the participant is otherwise entitled.
 - xiv. That the monitors, the auditors, the HRRC, and the regulatory authorities will be granted direct access to the participant's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the participant or the participant's legally acceptable representative is authorizing such access.
 - xv. That records identifying the participant will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the participant's identity will remain confidential.
 - xvi. That the participant or the participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the participant's willingness to continue participation in the trial.
 - xvii. The persons to contact for further information regarding the trial and the rights of trial participants, and whom to contact in the event of trial-related injury.
 - xviii. The foreseeable circumstances and/or reasons under which the participant's participation in the trial may be terminated.
 - xix. The expected duration of the participant's participation in the trial.
 - xx. The approximate number of participants involved in the trial.
- k. Prior to participation in the trial, the participant or the participant's legally acceptable representative should receive a copy of the signed and dated written informed consent form and any other written information provided to the participants. During a participant's participation in the trial, the participant or the participant's legally acceptable representative should receive a copy of the signed and dated consent form updates and a copy of any amendments to the written information provided to participants.
- l. When a clinical trial (therapeutic or non-therapeutic) includes participants who can only be enrolled in the trial with the consent of the participant's legally acceptable representative (e.g., minors, or patients with severe dementia), the participant should be informed about the trial to the extent compatible with the participant's

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understanding and, if capable, the participant should sign and personally date the written informed consent.

- m. Except as described above, a non-therapeutic trial (i.e. a trial in which there is no anticipated direct clinical benefit to the participant), should be conducted in participants who personally give consent and who sign and date the written informed consent form.
- n. Non-therapeutic trials may be conducted on participants with consent of a legally acceptable representative provided the following conditions are fulfilled: a) The objectives of the trial cannot be met by means of a trial in participants who can give informed consent personally. b) The foreseeable risks to the participants are low. c) The negative impact on the participant's well-being is minimized and low. d) The trial is not prohibited by law. e) The approval opinion of the HRRC is expressly sought on the inclusion of such participants, and the written approval opinion covers this aspect. Such trials, unless an exception is justified, should be conducted in patients having a disease or condition for which the investigational product is intended. Participants in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.
- o. In emergency situations, when prior consent of the participant is not possible, the consent of the participant's legally acceptable representative, if present, should be requested. When prior consent of the participant is not possible, and the participant's legally acceptable representative is not available, enrolment of the participant should require measures described in the protocol and/or elsewhere, with documented approval opinion by the HRRC, to protect the rights, safety and well-being of the participant and to ensure compliance with applicable regulatory requirements. The participant or the participant's legally acceptable representative should be informed about the trial as soon as possible and consent to continue and other consent as appropriate should be requested.

Records and Reports

- a. The investigator should ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRFs and in all required reports.
- b. Data reported on the CRF, that are derived from source documents, should be consistent with the source documents or the discrepancies should be explained.
- c. Any change or correction to a CRF should be dated, initialed, and explained (if necessary) and should not obscure the original entry (i.e. an audit trail should be maintained); this applies to either written and electronic changes or corrections. Sponsors should provide guidance to investigators and/or the investigators' designated representatives on making such corrections. Sponsors should have written procedures to assure that changes or corrections in CRFs made by sponsor's designated

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representatives are documented, are necessary, and are endorsed by the investigator. The investigator should retain records of the changes and corrections.

- d. The investigator/institution should maintain the trial documents as specified in Essential Documents for the Conduct of a Clinical Trial and as required by the applicable regulatory requirements. The investigator/institution should take measures to prevent accidental or premature destruction of these documents.
- e. Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period however if required by the applicable regulatory requirements or by an agreement with the sponsor. It is the responsibility of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained.
- f. The financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/institution.
- g. Upon request of the monitor, auditor, HRRC, or regulatory authority, the investigator/institution should make available for direct access all requested trial-related records.

Progress Reports

- a. The investigator should submit written summaries of the trial status to the HRRC annually, or more frequently, if requested by the HRRC.
- b. The investigator should promptly provide written reports to the sponsor, the HRRC and, where applicable, the institution on any changes significantly affecting the conduct of the trial, and/or increasing the risk to participants.

Safety Reporting

- a. All serious adverse events (SAEs) should be reported immediately to the sponsor except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports. The immediate and follow-up reports should identify participants by unique code numbers assigned to the trial participants rather than by the participants' names, personal identification numbers, and/or addresses. The investigator should also comply with the applicable regulatory requirements related to the reporting of unexpected serious adverse drug reactions to the regulatory authorities and the HRRC.

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- b. Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol.
- c. For reported deaths, the investigator should supply the sponsor and the HRRC with any additional requested information (e.g., autopsy reports and terminal medical reports).
- d. Premature Termination or Suspension of a Trial If the trial is prematurely terminated or suspended for any reason, the investigator/institution should promptly inform the trial participants, should assure appropriate therapy and follow-up for the participants, and, where required by the applicable regulatory requirements, should inform the regulatory authorities. In addition:
 - i. If the investigator terminates or suspends a trial without prior agreement of the sponsor, the investigator should inform the institution where applicable, and the investigator/institution should promptly inform the sponsor and the HRRC, and should provide the sponsor and the HRRC a detailed written explanation of the termination or suspension.
 - ii. If the sponsor terminates or suspends a trial, the investigator should promptly inform the institution where applicable and the investigator/institution should promptly inform the HRRC and provide the HRRC a detailed written explanation of the termination or suspension.
 - iii. If the HRRC terminates or suspends its approval opinion of a trial, the investigator should inform the institution where applicable and the investigator/institution should promptly notify the sponsor and provide the sponsor with a detailed written explanation of the termination or suspension.

Final Reports by Investigator:

Upon completion of the trial, the investigator, where applicable, should inform the institution; the investigator/institution should provide the HRRC with a summary of the trial's outcome, and the regulatory authorities with any reports required.

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Appendix A-5 *Additional Requirements for Department of Defense (DOD) research*

1. When appropriate, research protocols must be reviewed and approved by the HRRC prior to the Department of Defense approval. Consult with the Department of Defense funding component to see whether this is a requirement.
2. Civilian researchers attempting to access military volunteers should seek collaboration with a military researcher familiar with the service-specific requirements.
3. Employees of the Department of Defense (including temporary, part-time, and intermittent appointments) may not be able to legally accept payments to participate in research and should check with their supervisor before accepting such payments. Employees of the Department of Defense cannot be paid for conducting research while on active duty.
4. Service members must follow their command policies regarding the requirement to obtain command permission to participate in research involving human participants while on-duty or off-duty.
5. Components of the Department of Defense might have stricter requirements for research-related injury than the DHHS regulations.
6. There may be specific educational requirements or certification required.
7. When assessing whether to support or collaborate with this institution for research involving human participants, the Department of Defense may evaluate this institution’s education and training policies to ensure the personnel are qualified to perform the research.
8. When research involves U.S. military personnel, policies and procedures require limitations on dual compensation:
 - a. Prohibit an individual from receiving pay of compensation for research during duty hours.
 - b. An individual may be compensated for research if the participant is involved in the research when not on duty.
 - c. Federal employees while on duty and non-Federal persons may be compensated for blood draws for research up to \$50 for each blood draw.
 - d. Non-Federal persons may be compensated for research participating other than blood draws in a reasonable amount as approved by the HRRC according to local prevailing rates and the nature of the research.
9. When conducting multi-site research, a formal agreement between institutions is required to specify the roles and responsibilities of each party.
10. When following DoD regulations, when serving as the reviewing IRB for a DoD-covered research study, policies and procedures or a written agreement must define the responsibilities of the DoD organization and non-DoD reviewing IRB, including but not limited to:
 - a. DoD institutions collaborating with non-DoD institutions may rely on a collaborating non-DoD institution’s IRB if the following conditions are met:
 - i. Each institution engaged in non-exempt human participant research must have a current federal assurance of compliance.

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- ii The non-DoD institution’s IRB is registered in accordance with Subpart E of 45 CFR 46.
- iii The DoD institution reviews the protocol to ensure all applicable local and DoD requirements are addressed in the protocol.
- iv The DoD institution, non-DoD institution, and the non-DoD institution’s IRB have a written agreement defining the responsibilities and authorities of each institution in complying with all legal requirements. This agreement must specify that the non-DoD IRB will apply the DoD requirements specified in DoDI 3216.02, including but not limited to non-DoD institutional responsibilities defined under DoDI 3216.02 section 3.6(b).
- v If the research constitutes classified human participant research, the COHRP must approve the agreement to rely on the non-DoD institution’s IRB.

11. Other specific requirements of the Department of Defense research can be found in the “Additional Requirements for Department of Defense (DOD) Research” section in the HRRC’s “WORKSHEET: Additional Federal Criteria (HRP-318).”

Appendix A-6 *Additional Requirements for Department of Energy (DOE) Research*

1. When following DOE requirements:
 - a. The HRP Program Manager at DOE or NNSA must be notified:
 - b. Immediately upon learning of a serious adverse event. The HSP Program Manager(s) shall also be informed of any corrective actions taken and consulted regarding the plan for any remaining corrective actions.
 - c. Within 48 hours, with a description of corrective actions taken, of:
 - i Unanticipated problems
 - ii Significant adverse events
 - iii Complaints about the research
 - iv Any suspension or termination of HRRC approval of research
 - v Any significant non-compliance with HRPP procedures or other requirements.

2. When following DOE requirements:
 - a. Personally identifiable information collected and/or used during human participant research projects must be protected in accordance with the requirements of DOE Order 206.1, Department of Energy Privacy Program.
 - b. Any breach involving Personally Identifiable Information must be reported:
 - i Immediately upon a finding of a suspected or confirmed data breach involving Personally Identifiable Information (PII) in printed or electronic form, the incident must be reported to the DOE-Cyber Incident Response Capability in

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accordance with the requirements of DOE O 206.1. The time frame for “immediately” is defined as upon discovery.

ii Within 48 hours the DOE or NNSA HSP Program Manager must also be notified of any corrective actions taken and consulted regarding the plan for any remaining corrective actions.

3. Research that involves one or more of the following is considered by DOE to be human subjects research and requires HRRC review:
 - a. Intentional modification of the human environment
 - b. Study of human environments that use tracer chemicals, particles or other materials to characterize airflow.
 - c. Study in occupied homes or offices that:
 - i. Manipulate the environment to achieve research aims.
 - ii. Test new materials.
 - iii. Involve collecting information on occupants’ views of appliances, materials, or devices installed in their homes or their energy-saving behaviors through surveys and focus groups.
4. You must complete and submit to the HRRC the DOE “DOE Institutional Review Board Template for Reviewing Human Subjects Research Protocols that Utilize Personally Identifiable Information (PII)” if your research includes Personally Identifiable Information.
5. Requirements for human participant protections for classified research apply to all research conducted or supported by the DOE, including contracts, and including Human Terrain Mapping research.
6. Requirements for human participant protections and their accompanying Contractor Requirements Documents (CRDs) apply to all research conducted at DOE institutions regardless of funding source, or by DOE employees/contractor personnel regardless of funding source or location conducted, and whether done domestically or in an international environment, and including Human Terrain Mapping research. DOE workers are considered vulnerable subjects and shall be afforded additional protections as determined by the HRRC.
7. When following DOE requirements:
 - a. Research involving human participants involving multiple DOE sites (e.g., members of the research team from more than one DOE site and/or data or human subjects from more than one DOE site) must be reviewed and approved by one of the Central DOE IRBs prior to initiation, unless review by another appropriate IRB of record is authorized by the DOE and/or NNSA HSP Program Manager.
 - b. If authorized by the DOE and/or NNSA HSP Program Manager, research may be reviewed by other appropriate IRB of record. In all cases, an IRB Authorization Agreement (IAA) or Memorandum of Understanding (MOU) must be in place between the organization(s) conducting the HSR and the organization responsible for IRB review.

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8. Other specific requirements of the Department of Energy (DOE) research can be found in the “Additional Requirements for Department of Energy (DOE) Research” section in the HRRC’s “WORKSHEET: Additional Federal Criteria (HRP-318).”

Appendix A-7 *Additional Requirements for Department of Justice (DOJ) Research*

Additional Requirements for DOJ Research conducted in the Federal Bureau of Prisons

1. Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.
2. The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
3. The research design must be compatible with both the operation of prison facilities and protection of human participants.
4. Investigators must observe the rules of the institution or office in which the research is conducted.
5. Any investigator who is a non-employee of the Bureau of Prisoners must sign a statement in which the investigator agrees to adhere to the requirements of 28 CFR §512.
6. The research must be reviewed and approved by the Bureau Research Review Board.
7. Incentives cannot be offered to help persuade inmate participants to participate. However, soft drinks and snacks to be consumed at the test setting may be offered. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research participants who are both (1) no longer in Bureau of Prisons custody and (2) participating in authorized research being conducted by Bureau employees or contractors.
8. A non-employee of the Bureau may receive records in a form not individually identifiable when advance adequate written assurance that the record will be used solely as statistical research or reporting record is provided to the agency.
9. Except as noted in the consent statement to the participant, you must not provide research information that identifies a participant to any person without that participant’s prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertain.
10. Except for computerized data records maintained at an official Department of Justice site, records that contain non disclosable information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system.
11. If you are conducting a study of special interest to the Office of Research and Evaluation but the study is not a joint project involving Office of Research and Evaluation, you may be asked to

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provide Office of Research and Evaluation with the computerized research data, not identifiable to individual participants, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.

12. Required elements of disclosure additionally include:
 - a. Identification of the investigators.
 - b. Anticipated uses of the results of the research.
 - c. A statement that participation is completely voluntary and that the participant may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable).
 - d. A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, an investigator may not guarantee confidentiality when the participant indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the participant is an inmate, indicates intent to leave the facility without authorization.
 - e. A statement that participation in the research project will have no effect on the inmate participant's release date or parole eligibility.
13. You must have academic preparation or experience in the area of study of the proposed research.
14. The HRRC application must include a summary statement, which includes:
 - a. Names and current affiliations of the investigators.
 - b. Title of the study.
 - c. Purpose of the study.
 - d. Location of the study.
 - e. Methods to be employed.
 - f. Anticipated results.
 - g. Duration of the study.
 - h. Number of participants (staff or inmates) required and amount of time required from each.
 - i. Indication of risk or discomfort involved as a result of participation.
15. The HRRC application must include a comprehensive statement, which includes:
 - a. Review of related literature.
 - b. Detailed description of the research method.
 - c. Significance of anticipated results and their contribution to the advancement of knowledge.
 - d. Specific resources required from the Bureau of Prisons.

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- e. Description of all possible risks, discomforts, and benefits to individual participants or a class of participants, and a discussion of the likelihood that the risks and discomforts will actually occur.
 - f. Description of steps taken to minimize any risks.
 - g. Description of physical or administrative procedures to be followed to ensure the security of any individually identifiable data that are being collected for the study.
 - h. Destroy research records or remove individual identifiers from those records when the research has been completed.
 - i. Description of any anticipated effects of the research study on Institutional programs and operations.
 - j. Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.
16. The HRRC application must include a statement regarding assurances and certification required by federal regulations, if applicable.
 17. You must assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor.
 18. At least once a year, you must provide the Chief, Office of Research and Evaluation, with a report on the progress of the research.
 19. At least 12 working days before any report of findings is to be released, you must distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board, the regional director, and the warden of each institution that provided data or assistance.
 20. You must include an abstract in the report of findings.
 21. In any publication of results, you must acknowledge the Bureau's participation in the research project.
 22. You must expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
 23. Prior to submitting for publication the results of a research project conducted under this subpart, you must provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.
 24. Other specific requirements of the Department of Justice (DOJ) Research Conducted within the Federal Bureau of Prisons (BOP) can be found in the "Additional Requirements for Department of Justice (DOJ) Research Conducted within the Federal Bureau of Prisons (BOP)" section in the HRRC's "WORKSHEET: Additional Federal Criteria (HRP-318)."

Additional Requirements for DOJ Research Funded by the National Institute of Justice

1. The project must have a privacy certificate approved by the National Institute of Justice Human Subjects Protection Officer.

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2. All investigators and research staff are required to sign employee confidentiality statements, which are maintained by the responsible investigator.
3. The confidentiality statement on the consent document must state that confidentiality can only be broken if the participant reports immediate harm to participants or others.
4. Under a privacy certificate, investigators and research staff do not have to report child abuse unless the participant signs another consent document to allow child abuse reporting.
5. A copy of all data must be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials.
6. Other specific requirements of the Department of Justice (DOJ) Research Funded by the National Institute of Justice can be found in the “Additional Requirements for Department of Justice (DOJ) Research” section in the HRRC’s “WORKSHEET: Additional Federal Criteria (HRP-318).”

Appendix A-8 *Additional Requirements for Department of Education (ED) Research*

1. Each school at which the research is conducted must provide an assurance that they comply with the Family Educational Rights and Privacy Act (FERPA) and the Protection of Pupil Rights Amendment (PPRA).
2. Provide a copy of all surveys and instructional material used in the research. Upon request parents of children¹⁶ involved in the research¹⁷ must be able to inspect these materials.
3. The school in which the research is being conducted must have policies regarding the administration of physical examinations or screenings that the school may administer to students.
4. Other specific requirements of the Department of Education (ED) Research can be found in the “Additional Requirements for Department of Education (ED) Research” section in the HRRC’s “WORKSHEET: Additional Federal Criteria (HRP-318).”

¹⁶ Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age or majority as determined under state law.

¹⁷ Research or experimentation program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques.

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Appendix A-9 *Additional Requirements for Environmental Protection Agency (EPA) Research*

1. Research conducted, supported, or intended to be submitted to EPA is subject to Environmental Protection Agency Regulations.
2. Intentional exposure of pregnant women or children to any substance is prohibited.
3. Observational research involving pregnant women and fetuses are subject to additional DHHS requirements for research involving pregnant women (45 CFR §46 Subpart B) and additional DHHS requirements for research involving children (45 CFR §46 Subpart D.)
4. Research involving children must meet category #1 or #2.
5. Other specific requirements of the Environmental Protection Agency (EPA) Research can be found in the “Additional Requirements for Environmental Protection Agency (EPA) Research and Research Intended to be Submitted to the Environmental Protection Agency” section in the HRRC’s “WORKSHEET: Additional Federal Criteria (HRP-318).”

Appendix A-10 *National Institutes of Health Single IRB Studies*

1. The National Institutes of Health (NIH) expects that all sites participating in multi-site studies involving non-exempt human subjects research funded by the NIH will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46.
 - a. This policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. It does not apply to career development, research training or fellowship awards.
 - b. This policy applies to domestic awardees and participating domestic sites. Foreign sites participating in NIH-funded, multi-site studies will not be expected to follow this policy.
 - c. Exceptions to the NIH policy will be made where review by the proposed sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy. Requests for exceptions that are not based on a legal, regulatory, or policy requirement will be considered if there is a compelling justification for the exception. The NIH will determine whether to grant an exception following an assessment of the need.

Appendix A-11 *Protecting the rights and welfare of research participants during an emergency*

1. The organization plans for emergencies, educates those in the HRPP, and responds effectively to ensure the sustainability of the HRPP.

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2. The HRPP has an emergency preparedness and response plan, appropriate to the size and complexity of the HRPP, that addresses how continuity of operations will be maintained to ensure human participant protections during an emergency.
3. The emergency preparedness and response plan is periodically evaluated and, when necessary, adjusted to ensure continuity of operations.
4. Organizations provide education about the organization's emergency response and preparedness plan for IRB members and staff, researchers and research staff, and other persons in the HRPP.
5. Persons in the HRPP are knowledgeable about the organization's expectations during emergencies.