

**Investigator Manual**

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## Scope

Throughout this document “institution” refers to University of Central Florida (UCF).

## 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 does my staff and I need in order to conduct Human Research?”](#_What_training_does)

## What is Human Research?

UCF’s “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 IRB Policies & Procedures section of the IRB Web site. 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 IRB makes the ultimate determination in questionable cases as to whether an activity constitutes Human Research subject to IRB oversight.

You are responsible not to conduct Human Research without prior IRB review and approval (or an institutional review and determination of exempt Human Research). If you have questions about whether an activity is Human Research, contact the IRB Office who will provide you with a determination. If you wish to have a written determination, provide a written request to the IRB Office using the electronic IRB system.

## What is the Human Research Protection Program?

The document “HUMAN RESEARCH PROTECTION PROGRAM PLAN (HRP-101)” describes this institution’s overall plan to protect subjects 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.

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

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

Investigators and staff conducting human subjects research must complete the Collaborative Institutional Training Initiative (CITI) human subjects online training program. Investigators and staff conducting social/behavioral/education research should complete Human Subjects Research-Group 2 Social/Behavioral Research Investigators and Key Personnel. Investigators and staff conducting biomedical research must complete Human Subjects Research-Group 1 Biomedical Research Investigators and Key Personnel. In addition, investigators and staff conducting research with the Department of the Navy (DON) must affiliate with DON in the CITI site and complete DON-Supported Extramural Performers

The CITI site can be accessed by clicking the CITI link at the top of the IRB home page or at <http://www.citiprogram.org/>.

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. External study team members engaged in research activities including contact or communication with participants, access to identifiable data or specimens, or involved in the consent process must affiliate with UCF in CITI and complete the appropriate UCF CITI 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 subjects.

## Who can be listed as a Principal Investigator?

The Principal Investigator is the person ultimately responsible for the research and the protection of human subjects. UCF staff and core faculty members may be listed Principal Investigator (PI) in the research protocol and IRB application.

Graduate level students (Doctoral, Master’s, and Resident) may be listed as the PI under the supervision of a faculty advisor. The advisor’s name is required in the IRB application and both the advisor’s name and contact information is to be included in the informed consent document.

Undergraduate students, non-core faculty, and volunteer faculty conducting research are not eligible to be listed as PI. Instead, a faculty advisor must be listed as the PI, and the student(s) as co-investigator(s). Non-core or volunteer faculty should seek an eligible UCF affiliate to serve as the PI.

## What financial interests do my staff and I need to disclose prior to conducting Human Research?

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 institution responsibility.

All individuals involved in the design, conduct, or reporting of research are required to disclose personal financial interests in the New Study SmartForm in the electronic IRB system.

* On submission of an initial review.
* At least annually as part of continuing review.
* Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.

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 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 upon:

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

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

## How do I submit new Human Research to the IRB?

Complete the New Study SmartForm in the electronic IRB system and attach all requested supplements, have the SmartForm submitted by the PI by clicking the “Submit” activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required. Before submitting the research for initial review, you must:

• Obtain the financial interest status (“yes” or “no”) of each research staff.

• Obtain the agreement of research staff to his/her role in the research.

## What are the components of an IRB submission?

A human research protocol and a completed Application are two key components of all new IRB submissions. In addition, the following materials must be submitted when applicable:

* Data collection instruments (spreadsheets, logs, etc.)
* All written material to be provided to, or meant to be seen or heard by, participants, including:
  + Recruitment materials and scripts (examples-flyers, email, social media post, recruitment scripts)
  + Informed Consent or Summary Explanation of Research documents
  + Debriefing statements
  + Interview/focus group questions, surveys, questionnaires, evaluation instruments
  + Pictures, audio, or video used during Human Research
* Documentation of CITI training and a signed “FORM: Individual Investigator Agreement (HRP-252)” for external study team members engaged in research activities including contact or communication with participants, access to identifiable data or specimens, or involved in the consent process

## How do I request to rely on an external IRB?

Complete the New Study SmartForm in the electronic IRB system, indicate that an External IRB will serve as the IRB of Record and attach all requested supplements. Once the study information is complete, select the “Site” link and select the “Edit Site” activity. Complete the Site SmartForm and attach all available supplements. Have the SmartForm submitted by the PI by clicking the “Submit” activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

## How do I request that this IRB serve as the IRB of record (sIRB) for my collaborative or multi-site research study?

On the New Study SmartForm in the electronic IRB system, indicate if the study is a multi-site or collaborative research study, then select “Yes” to the question “Will your IRB act as the single IRB of record for other participating sites?” Complete the rest of the New Study SmartForm and attach all available supplements. Have the SmartForm submitted by the PI by clicking the “Submit” activity.

* + Evaluation instruments and surveys
  + Advertisements (printed, audio, and video)
  + Recruitment materials and scripts
  + Pictures, audio, or video used during Human Research
* Consent documents
  + If consent will not be presented in writing, a script of information to be provided orally to participants is required
* Completed grant application (if applicable)
* Complete sponsor protocol including DHHS-approved protocol
* DHHS-approved sample consent document
* Current investigator brochure for each investigational drug
* Current package insert for each marketed drug
* Current product information for each investigational device
* Principal Investigator CV and/or other documentation evidencing qualifications (if not already on file)
* Foreign language version of any written material to be provided to, or meant to be seen or heard by, participants.
* Translation verification statement (can be an email) from an objective person (not part of research) who is fluent in English and the foreign language.

## How do I write an Investigator Protocol?

Use the “TEMPLATE PROTOCOL (HRP-503)” as a starting point for drafting a new Investigator Protocol, and reference the instructions in italic text for the information the IRB looks for when reviewing research. Here are some key points to remember when developing an Investigator Protocol:

* The italicized bullet points in the “TEMPLATE PROTOCOL (HRP-503)” serve as guidance to investigators when developing an Investigator Protocol for submission to the IRB. **All italicized comments are meant to be deleted prior to submission.**
* Note that, depending on the nature of your research, certain sections of the template may not be applicable to your Investigator Protocol. Indicate this as appropriate. In this situation, **do not delete the section**, but remove the italicized comments and replace with “N/A” or ‘Not Applicable”.
* For any items described in the sponsor’s protocol or other documents submitted with the application, investigators may simply reference the page numbers of these documents within the Investigator Protocol rather than repeat information.
* When writing an Investigator Protocol, always keep an electronic copy. You will need to modify this copy when making changes to the Investigator Protocol.
* If you believe your activity may not be Human Research, contact the IRB Office prior to developing your Investigator Protocol.
* You may not involve any individuals who are members of the following populations as subjects in your research unless you indicate this in your inclusion criteria as the inclusion of subjects in these populations has regulatory implications.
  + Adults unable to provide legally effective consent
  + Individuals who are not yet adults (infants, children, teenagers)
  + Pregnant women
  + Prisoners
* If you are conducting community-based participatory research, you may contact the IRB Office for information about:
  + Research studies using a community-based participatory research design
  + Use of community advisory boards
  + Use of participant advocates
  + Partnerships with community-based institutions or organizations

## How do I complete a New Application in the IRB System?

The main sections of the IRB System application form that investigators must complete are listed below. To start a new application in the IRB System, click “Create a New Study” and complete the New Study SmartForm. Depending on how questions are answered, some sections listed below will not appear in New Study SmartForm application when not applicable.

**Basic Information**

* **Study Title**: This is the complete title of the research as it is written in the study protocol or grant).
* **Short Title**: Select a short title for your study. You can use the sponsor's short title or any other unique name.
  + As a guideline, the short title (50 characters or less) identifies the study throughout the IRB system, such as in your inbox and in the IRB's list of submissions to review.
* **Brief Description**- In a few words, summarize: the central question the research is intended to answer, the primary objectives, and the methods used
* **Principal Investigator**-the person starting the application will automatically be listed as the PI. Update the PI information if necessary.
* **Financial interest related to research**
* **External IRB**
* What kind of study—Multi-site, collaborative, or single site.
  + A multi-site study is one where study activities outlined in a single protocol are carried out at multiple institutions. For example, a clinical trial conducted in three different clinics.
  + A collaborative study is one where two or more institutions coordinate to complete a portion of the research outlined in a specific protocol.
  + A single-site study is one where all research activities occur at one institution. Note, this may include different locations for conducting interviews or online surveys.
* **Attach the completed Investigator Protocol** (“TEMPLATE: Protocol (HRP-503)”, “FORM: Request for Human Subjects Determination (HRP-250),” or “FORM: Request for Exempt Determination Form (HRP-255)”). The protocol uploaded should be the final version with all template language removed, no track changes or highlights and in a Microsoft Word format
* **Funding Sources**- Identify all external funding sources, such as industry sponsors and government agencies.
  + The main purpose is to help the IRB identify all studies associated with particular grants.
  + If funding comes from a specific internal funding program, also identify that funding source.

**Study Team Members**

* **Local Study Team Member Information**---Add information about each UCF affiliated person involved in the design, conduct, or reporting of the research.
  + You do not need to add the principal investigator here.
  + Do not add the study's primary contact person for IRB communications here unless the person is also engaged in the research. The person who creates the study in the IRB system is assigned as the primary contact by default and can be changed later as described in "Changing the Primary Contact" in the Study Submission Guide.
  + If you have difficulty finding the person in the list, try typing the beginning of the first or last name. Contact the IRB staff for assistance if a person is not listed in the system.
  + For multi-site studies, only include information in this section about UCF affiliated team members.
* **External Team Member Information**— Attach information about members of your research team who were not listed for selection in the previous question.
  + Unlisted people are likely to be outside your institution, or perhaps students or other groups your institution doesn't include in the system. Use the “FORM: External Team Member Information (HRP-252).”

**Study Scope**

* Identify factors involved in the study that may require review of additional details. Your answers determine whether you must provide additional information on following smart form pages.
* **Other Research Locations**-Research locations are locations both inside and outside the institution where research activities will be conducted by members of the study team listed on this application. Research locations include locations at which a PI or study team member **would not ordinarily have privileges to conduct or oversee research**. They can include physical locations owned or managed by your institution, or external locations used by arrangement.
* **Drug or Biologic Use**: Check this item if the Human Research protocol involves the use of investigational drugs. If checked, you will be asked to provide additional information about the investigational drug(s) to be used in the Human Research.
  + For Human Research involving the use of drugs, provide the information requested in the smart form. List all drugs being used in the Human Research (approved and unapproved). For each, indicate whether it has an Investigational New Drug (IND) number.
  + For each drug with an IND number, ensure that the application includes one of the following:
    - Sponsor protocol with the IND number;
    - Communication from the sponsor with the IND number; or
    - Communication from the FDA with the IND number.
* **Device Use**- Check this item if the Human Research protocol involves the use of investigational medical devices. If checked, you will be asked to provide additional information about the investigational medical device(s) used in the Human Research.
  + List all devices being evaluated for safety or effectiveness (both approved and unapproved).
* Contact the IRB in advance with any questions about whether your research activity involves the use of an investigational device (note that, under certain circumstances, even video games, computer software, or smart phone apps used to diagnose, cure, treat, prevent, or mitigate disease may be determined by the FDA to be investigational devices).
* For each, indicate whether it has an Investigational Device Exemption (IDE) number. Indicate whether the device is being submitted under the “Abbreviated IDE requirements” in 21 CFR 812.2(b)(FDA regulations).
* For each device with an IDE number, ensure that the application includes one of the following:
* Sponsor protocol with the IDE number;
* Communication from the sponsor with the IDE number; or
* Communication from the FDA with the IDE number.
* Humanitarian Use Device (HUD) -Check this item if your activity involves standard use of a Humanitarian Use Device. Do not check this box if you are evaluating the safety or effectiveness of a HUD.

**Local Site Documents (these include documents that are specific to UCF)**

* **Consent Forms**:
  + If you are submitting a study for Full Board or Expedited Review where a consent process is required, create and attach Informed Consent Document Template(s) using HRP-502 (adults) or HRP-502b (parent for child) templates. Note, for most minimal risk studies not involving children or cognitively impaired adults, you may request a Waiver of Written Documentation of Consent and signature blocks can be deleted. See HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent to see if your study may qualify for this waiver.
  + If you are submitting a study for Exempt Determination where a consent process is required, create and attach a document used as part of the consent process using “FORM: HRP-254 Summary Explanation of Research.”
  + If your study design justifies withholding certain information about the study in the Informed Consent, upload a copy “TEMPLATE: HRP-510 Debriefing Statement.”
  + If languages other than English are included in the study, the IRB will notify you when to upload the translated versions of the documents along with “FORM: Translation Verification (HRP-256).”
  + Ensure that all consent document language is consistent with the study protocol.

**Recruitment Materials (submission of all relevant materials is required):**

* Email scripts.
* Web postings.
* Flyers, handouts, and posters.
* Advertisements (printed, audio, and video).
* Other materials not listed here.
* See HRP-315 - WORKSHEET – Advertisements for elements required in written recruitment materials.
* If languages other than English are included in the study, the IRB will notify you when to upload the translated versions of the documents along with “FORM: Translation Verification (HRP-256).”

**Other Attachments (submission of all relevant attachments not included elsewhere in the application are required):**

* Data collection instruments (spreadsheets, logs, etc.).
* Evaluation instruments and surveys.
* Interview and focus group protocols.
* Pictures, audio or video files or screen capture for materials used during Human Research.
* Current investigatory brochure for each investigational drug.
* Current package inserts for each marketed drug.
* Individual Investigator Agreements.
* Letters of support.
* Other materials not listed here.

**Additional Information:**

* Select appropriate PI description See the previous section in this document titled “Who can be listed as a Principal Investigator?”
* Student researchers will be asked for the name of a faculty advisor and to upload a completed copy of “FORM: Faculty Advisor Review (HRP-251)”
* Indicate whether or not any portion the participants research activities will take place online
* Select applicable vulnerable or special consideration population
* Individuals who are under legal age:

Does the Human Research involve children, adolescents, minors, or other individuals not old enough to consent to the Human Research procedures for themselves? Unless the process of consent is waived, permission by one or both parents or a guardian will be needed to allow such individuals to participate in the research.

* Cognitively Impaired Adults

Does the Human Research involve adults who may not have the ability (or may have limited ability) to consent to the Human Research procedures for themselves? Unless the process of consent is waived, permission by a legally authorized representative (LAR) will be needed to allow such individuals to participate in the research.

* Pregnant women

Will the Human Research involve pregnant women at any time from the period of implantation until delivery? NOTE: In general, this item should only be checked when the study recruitment will target pregnant women and/or pregnancy is an inclusion criterion.

* Prisoners

Does the Human Research involve prisoners (any individual involuntarily confined or detained in a penal institution? The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing), regardless of whether the Human Research is focused on prisoners.

* + Indicate whether the study is affiliated with the Department of Navy (DON)
    - If yes, you will be prompted to attach CITI DON-Extramural performers training certificates for each study team member.
  + Indicate whether the study protocol will require access to medical records or otherwise collect Private Health Information (PHI)?
    - If yes, you will be prompted to upload documentation of the provider’s HIPAA privacy officer approval, HIPAA Authorization, or Review Preparatory to Research.
  + Indicate whether any of the study procedures will be carried out internationally.
    - If yes, upload the approval forms from the local review board.
  + Indicate whether the study is protected by International Traffic in Arms Regulations (ITAR), a United States regulatory regime to restrict and control the export of defense and military related technologies to safeguard U.S. national security and further U.S. foreign policy objectives.

## How do I finalize and submit my application?

After creating your study in the IRB system, click “Finish” on the “Final Page” of the SmartForm.

Under Manage Ancillary Reviews, identify each person who should provide additional review by clicking “Add”, then “Person” and searching for the appropriate reviewer. Most studies only require review from the departmental sign-off and faculty advisor (where applicable)

* Select “department” review type for departmental routing.
* Select “faculty” for faculty advisor review.
* Select other review types, as applicable.

Depending on the nature of the research, certain additional UCF reviews and approvals may be required. These additional approvals may include:

* Scientific or Expert Opinion
* Institutional Biosafety Committee
  + Required if the Human Research protocol requires the use of biohazardous agents. See the UCF Biological Safety Manual for a list of applicable biohazardous agents.
* Radiation Safety Committee
  + Required if Radiation is being used for reasons other than clinical care, include this review is if the Human Research protocol requires the use of approved or unapproved diagnostic or therapeutic radioactive materials or radiation-producing devices outside routine clinical practice.
* Institutional Animal Care and Use Committee
* Conflict of Interest Committee
* HIPAA Privacy Officer
* FERPA Review
* General Counsel/Legal

IMPORTANT: After completing the study application and clicking “Finish”, the study workflow will be in the “Pre-Submission” state and will not have been officially received by the IRB. To submit the study for IRB review, click “Submit”, then “ok” to verify submission requirements have been met. Only then will the study workflow be updated to “Pre-Review” indicating that the study is now with the IRB.

## How do I create a consent document?

Use the “TEMPLATE CONSENT DOCUMENT (HRP-502 or HRP-502b for studies involving children)” to create a consent document.

Note that all long form consent documents and all summaries for 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 IRB’s “WORKSHEET: Criteria for Approval (HRP-314),” to ensure that these elements are addressed. When using the short form of consent documentation the appropriate signature block from “TEMPLATE CONSENT DOCUMENT (HRP-502)” should be used on the short form.

We recommend that you date the revisions of your consent documents to ensure that you use the most recent version approved by the IRB.

## What are the different regulatory classifications that research activities may fall 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 IRB oversight. Activities that do not meet this definition of are not subject to IRB oversight or review. Review the IRB Office’s “WORKSHEET: Human Research (HRP-310)” for reference. Contact the IRB Office in cases where it is unclear whether an activity is Human Research. Request a determination of Not Human Research by completing the “FORM: Request for Human Subjects Request (HRP- 250)” and attaching in place of the protocol in the IRB system
* Exempt: Certain categories of Human Research may be exempt from regulation but require IRB review. It is the responsibility of the institution, not the investigator, to determine whether Human Research is exempt from IRB review. Review the IRB Office’s “WORKSHEET: Exemption (HRP-312)” for reference on the categories of research that may be exempt. Request a determination of an exempt category by completing the “FORM: Request for Exempt Determination (HRP- 255)” and attaching in place of the protocol in the IRB system
* 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 IRB reviewer, rather than the convened board. Review the IRB Administration’s “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 IRB: Non-Exempt Human Research that does not qualify for review using the expedited procedure must be reviewed by the convened IRB.

## What are the decisions the IRB can make when reviewing proposed research?

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

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

## How does the IRB decide whether to approve Human Research?

The criteria for IRB 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 on the IRB Web site.

These checklists are used for initial review, continuing review, and review of modifications to previously approved Human Research.

You are encouraged to use the checklists to write your Investigator Protocol in a way that addresses the criteria for approval.

## What will happen after IRB review?

The IRB will provide you with a written decision indicating that the IRB has approved the Human Research, requires modifications to secure approval, or has disapproved the Human Research.

* If the IRB has approved the Human Research: The Human Research may commence once all other institutional approvals have been met. IRB approval is usually good for a limited period of time which is noted in the approval letter.
* If the IRB requires modifications to secure approval and you accept the modifications: Make the requested modifications and submit them to the IRB. If all requested modifications are made, the IRB will issue a final approval. Research cannot commence until this final approval is received. If you do not accept the modifications, write up your response and submit it to the IRB.
* If the IRB defers the Human Research: The IRB 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. In most cases if the IRB’s reasons for the deferral are addressed in a modification, the Human Research can be approved
* If the IRB disapproves the Human Research: The IRB 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 IRB directly at an IRB meeting.

## What are my obligations after IRB approval?

1. **Do not start Human Research activities until you have the final IRB approval or determination 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.
4. 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.
5. Update the IRB office with any changes to the list of study personnel.
6. Personally conduct or supervise the Human Research. Recognize that the investigator is accountable for the failures of any study team member.
   1. Conduct the Human Research in accordance with the relevant current protocol as approved by the IRB, and in accordance with applicable federal regulations and local laws.
   2. When required by the IRB ensure that consent or permission is obtained in accordance with the relevant current protocol as approved by the IRB.
   3. Do not modify the Human Research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
   4. Protect the rights, safety, and welfare of subjects involved in the research.
7. Submit to the IRB:
   1. Proposed modifications as described in this manual. (See “How do I submit a modification?”)
   2. A continuing review application as requested in the approval letter. (See “How do I submit continuing review?”
   3. A study closure request when the Human Research is closed. (See “How Do I Close Out a Study?”)
8. Report any of the information items in on the back of “FORM: Reportable New Information (HRP-214)” to the IRB within five business days of discovering the reportable event.
9. Submit an updated disclosure of financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.
10. Do not accept or provide payments to professionals in exchange for referrals of potential subjects (“finder’s fees.”)
11. Do not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment (“bonus payments.”)
12. See additional requirements of various federal agencies in Appendix A. These represent additional requirements and do no override the baseline requirements of this section.

## What kinds of “reportable events” must be reported to the IRB during the conduct of research?

Any of the following events must be reported to the IRB within five business days of their occurrence using the “Reportable New Information” form in the IRB System:

1. Information that indicates a new or increased risk, or a new safety issue. For example:
   1. 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.
   2. 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
   3. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol
   4. Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm
   5. Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm
   6. Any changes significantly affecting the conduct of the research
2. Harm experienced by a subject or other individual, which in the opinion of the investigator are **unexpected** and **probably related** to the research procedures.
   1. A harm is “**unexpected**” when its specificity or severity is inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.
   2. 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.
3. 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.
4. Audit, inspection, or inquiry by a federal agency and any resulting reports (e.g. FDA Form 483.)
5. Written reports of study monitors.
6. Failure to follow the protocol due to the action or inaction of the investigator or research staff.
7. Breach of confidentiality.
8. Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
9. Incarceration of a subject in a study not approved by the IRB to involve prisoners.
10. Complaint of a subject that cannot be resolved by the research team.
11. Premature suspension or termination of the protocol by the sponsor, investigator, or institution.
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 subjects.)

Note: Events that are anticipated per the research plan or study protocol do not require reporting to the IRB *unless* occurring with unexpected severity or frequency.

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

1. Coordinating with HRPP personnel to determine whether the UCF’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. Ensure 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. Collaborate 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.
5. Respond to questions or information requests from study teams or the IRB or HRPP staff at relying sites.
6. Provide relying site investigators with the policies of the reviewing IRB.
7. Provide relying site investigators with the IRB-approved versions of all study documents.
8. Preparation and submission of 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.
10. Ensuing 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.
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. Obtain appropriate approvals from this institution prior to seeking review by another IRB.
2. Comply with determinations and requirements of the reviewing IRB.
3. Provide 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, obtain, document and maintain records of consent for each participant or each particpant’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. Proving 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 document consent?

Use the signature block approved by the IRB. Ensure all items are completed in the signature block, including dates and applicable checklists.

The following are the requirements for long form consent documents:

* The subject or representative signs and dates the consent document.
* The individual obtaining consent signs and dates the consent document.
* Whenever the IRB or the sponsor require a witness to be present at the oral presentation, the witness signs and dates the consent document.
* For subjects who cannot read and whenever required by the IRB or the sponsor, a witness who can read that is present at the oral presentation signs and dates the consent document.
* A copy of the signed and dated consent document is to be provided to the subject.

The following are the requirements for short form consent documents:

* The subject or representative signs and dates the short form consent document.
* The individual obtaining consent signs and dates the summary.
* If present, the witness to the oral presentation signs and dates the short form consent document and the summary.
* Copies of the signed and dated consent document and summary are provided to the person(s) signing those documents.

## How do I submit a modification?

Changes to research after initial approval require approval by the IRB prior to implementation. This includes changes to the protocol or research plan, informed consent documents, study personnel, recruitment materials, research locations, or other study related materials.

Minor modifications can be accomplished through a study modification request through the IRB system. Minor modifications are proposed changes to an existing study which include no substantive alterations in: the research design or methodology; the participant population (for example, adding a vulnerable population); the level of risk to the participants; the facilities available to support the safe conduct of the research; or any other factor that would warrant review of the proposed changes by the convened IRB. It is important to note that modifications that involve substantive changes to the previously approved research may require a new study application or the same level of review as a new application.

In the IRB System, find the study that needs modification by clicking the “IRB” tab, then the “Active” tab and searching for the study. Open the study link and click “Create Modification/CR” and select “Modification” only if a Continuing Review is not due. Click the appropriate toggle buttons to indicate if study team members, other parts of the study, or both will be modified. Making the appropriate selection will generate the appropriate SmartForm for updates.

Answer questions 1 and 2, and completely list all requested modifications in field 3. Click “Continue” to advance through the application or “Jump To” to advance to a specific page. Upload all modified documents in the appropriate area (see section previous section “How do I complete the a New Application in the IRB System?). Note, to facilitate review, documents need to be uploaded in MS Word format. Click “Finish” and then “Submit” to finalize the submission process. The workflow dashboard will update from Pre-Submission to “Pre-Review” when the modification request has been has been successfully submitted to the IRB through the IRB System.

Maintain electronic copies of all information submitted to the IRB in case revisions are required. Please note that research must continue to be conducted without inclusion of the modification until IRB approval is granted.

TIP-When modifying a study, do not delete information from a protocol that has already taken place. Instead, update the appropriate protocol section(s) to add the updates and note at what time the changes are made. For example, “Modification, Nov 2018, participants will no longer receive Survey A and will now receive Survey B. Survey B includes……as detailed in attached study document titled “Survey B.”

## How do I submit continuing review or a study closure request?

Continuing review is typically required every 12 months for expedited or convened board studies. Please note that if the continuing review application is not approved by the IRB prior to the protocol expiration date, you will be placed on the “Restricted list.” Any new human research submitted will not be reviewed until the completed Continuing Review Application (or a Study Closure Request) has been received..

Human Research must undergo continuing review until all four of the following conditions are true:

• The research is permanently closed to enrollment.

• All participants have completed all research-related interventions.

• Collection of private identifiable information is completed.

• Analysis of private identifiable information is completed.

If all of the above items are true, the research must be closed. Complete and submit a study closure request” in the IRB System, and upload any applicable additional documentation.

To submit a continuing review or closure request, open the study in the IRB System by clicking the “IRB” tab, then the “Active” tab and searching for the study. Open the study link and click “Create Modification/CR”

**For Continuing Review without Modification OR a Study Closure Request**

* Select “Continuing Review”
* Complete sections 1 – 4. In section 5, upload an explanation of any items left unchecked in section 4
* Click “Finish” and then “Submit” to verify that your submission has routed to the Pre-Review state.

**For Continuing Review with Modifications**

* Select ‘Modification and Continuing Review”
* Click the appropriate toggle buttons to indicate if study team members, other parts of the study, or both will be modified. Making the appropriate selection will generate the appropriate SmartForm for updates.
* On Page “Continuing Review/Study Closure Information”, complete sections 1 – 4. In section 5, upload an explanation of any items left unchecked in section 4.
* Follow directions listed in “How do I submit a modification?” above to complete any necessary modifications
* Click “Finish” and then “Submit” to verify that your submission has routed to the Pre-Review state.

## expires?

If the approval of Human Research 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. Continuing Human Research procedures is a violation of institutional policy. If current subjects 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 subjects. If current subjects will be harmed by stopping Human Research procedures that are not available outside the Human Research context, immediately contact the IRB chair and provide a written list of the currently enrolled subjects and why they will be harmed by stopping Human Research procedures.

## How long do I keep records?

Maintain your Human Research records, including signed and dated consent documents for at least five years after completion 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.

If your Human Research is sponsored, contact the sponsor before disposing of Human Research records.

## What if I would like to use lotteries, drawings, raffle prizes, or games of chance for research compensation?

In general, due to Florida's strict state laws regarding lotteries and the appearance of coercion in research studies, the IRB does not allow lotteries unless the study is investigating the lottery process or psychological effects of lotteries as the purpose of the study. The least coercive inducement is something given to every participant. We have had similar request as incentives for research participants and have encouraged PI's to avoid the use of drawings for prizes due to the provisions of Florida law.  
  
The UCF IRB has been advised to direct requests for Lotteries, Prizes and Games of Chance to our General Counsel's Office. Each scenario must be handled on a case by case basis because all the unique facts for each specific case are important for a proper legal evaluation every time.  
  
See the following pertinent sections of the Florida Statutes that address this issue.  
  
Chapter 849 of the Florida Statutes deals with "Gambling" in general.   
  
Section 849.09 Lottery prohibited; exception - states in its most pertinent part:  
  
"(1) It is unlawful for any person in this state to:  
(a) Set up, promote, or conduct any lottery for money or for anything of value;  
(b) Dispose of any money or other property of any kind whatsoever by means of any lottery;  
(c) Conduct any lottery drawing for the distribution of a prize or prizes by lot or chance, or advertise any such lottery scheme or device in any newspaper or by circulars, posters, pamphlets, radio, telegraph, telephone, or otherwise;"  
  
There are limited exceptions to this, but they most likely would not apply to our university scenarios.  
  
The Florida Statute Section 849.0935 is most likely applicable for the incentive that you wish to offer.. Drawings by chance are permitted, provided that we comply with all the legal requirements. Studies proposing request for drawings of chance will require ancillary review by the UCF General Counsels Office to make sure all of the statutory requirements are met:  
  
The most important language of that section is outlined below:  
  
"Section 849.0935 Charitable, nonprofit organizations; drawings by chance; required disclosures; unlawful acts and practices; penalties.—(1) As used in this section, the term:  
(a) “Drawing by chance” or “drawing” means an enterprise in which, from the entries submitted by the public to the organization conducting the drawing, one or more entries are selected by chance to win a prize. The term “drawing” does not include those enterprises, commonly known as “matching,” “instant winner,” or “preselected sweepstakes,” which involve the distribution of winning numbers, previously designated as such, to the public.  
(b) “Organization” means an organization which is exempt from federal income taxation pursuant to 26 U.S.C. s. 501(c)(3), (4), (7), (8), (10), or (19), and which has a current determination letter from the Internal Revenue Service, and its bona fide members or officers.  
(2) The provisions of s. 849.09 shall not be construed to prohibit an organization qualified under 26 U.S.C. s. 501(c)(3), (4), (7), (8), (10), or (19) from conducting drawings by chance pursuant to the authority granted by this section, provided the organization has complied with all applicable provisions of chapter 496.  
(3) All brochures, advertisements, notices, tickets, or entry blanks used in connection with a drawing by chance shall conspicuously disclose:   
(a) The rules governing the conduct and operation of the drawing.  
(b) The full name of the organization and its principal place of business.  
(c) The source of the funds used to award cash prizes or to purchase prizes.  
(d) The date, hour, and place where the winner will be chosen and the prizes will be awarded, unless the brochures, advertisements, notices, tickets, or entry blanks are not offered to the public more than 3 days prior to the drawing.  
(e) That no purchase or contribution is necessary."  
  
Please contact the IRB for more information.

## What if I plan to conduct research with external collaborators or at another site which has an IRB? Do I have to submit to both UCF IRB and the IRB where the research is being conducted?

Contact the IRB office to discuss the situation.

There are situations in which both IRBs may need to review the study. It is also possible that one institution can rely upon the other institution’s IRB.

The UCF IRB may rely upon the IRB of another institution if one of the following is true:

* The IRBs are part of an AAHRPP accredited institution.
* The UCF investigator is a collaborator on Human Research that is primarily conducted at another institution and the UCF investigator’s role does not include interaction or intervention with subjects.

Note: If UCF is the direct recipient of federal funding, the UCF IRB must review the Human Research.

The UCF IRB may rely upon a non-accredited institution provided an agreement is in place to ensure that the research is being reviewed appropriately.

If the UCF IRB relies upon another IRB for your research, you will not need to go through a review process here at UCF. However, you must make a submission in the IRB system strictly for record-keeping purposes, after you receive approval from the outside IRB. The submission must include the IRB system study application, the approved protocol that was submitted to the other institution, the approved Informed Consent, other study documents, as appropriate, and the institution’s IRB approval letter. When submitting in the IRB System, be sure to route the study to the faculty advisor (if applicable) and department chair/dean/director for electronic signature approval. The UCF IRB will review the submission, change the status in the IRB System to “Rely upon Other IRB,” and send the PI (and others) an IRB letter to that effect via the IRB System.

## What if I plan to conduct research at UCF Health? Do I have to submit to both UCF IRB and the HIPAA Privacy Officer for UCF Health?

The IRB office and the HIPAA Privacy Officer for UCF Health have important, but separate, roles to play before human subjects research -- which may include interactions with patients and/or access to and use of their personal medical records -- can be conducted at UCF Health.   
  
The PI must obtain approval from both the UCF IRB and the UCF Health Privacy Officer (as applicable) and is responsible for ensuring that appropriate documentation is uploaded to the study in the IRB System and provided to UCF Health.

Process:

* The PI must submit the IRB protocol, Informed Consent, and other study materials in the IRB System.  The UCF IRB will inform the PI whether HIPAA Privacy Officer review is required and will provide the PI with the UCF Health HIPAA Authorization form and/or the UCF Health Review Preparatory to Research form, as applicable.
* The PI will submit the completed UCF Health HIPAA Authorization form and the approved IRB Protocol to the HIPAA Privacy Officer for UCF Health for review and approval.  If the study involves review of medical records to identify potential research subjects or to develop a research protocol, then a completed UCF Health Review Preparatory to Research form must be submitted to the HIPAA Privacy Officer first.
* When the UCF Health HIPAA Authorization form and/or the UCF Health Review Preparatory to Research form are approved, the PI must upload the document(s) to the IRB approved study in the IRB System for documentation purposes only, using the IRB Miscellaneous Attachment Form

The study (including recruitment of study participants and/or review of their personal medical records) can begin only when the PI has obtained an IRB approval letter and approval from the HIPAA Privacy Officer for UCF Health.

## What if I plan to conduct research with or at Florida Hospital, Orlando Health, or Nemours? Do I have to submit to both UCF IRB and the IRB where the research is being conducted?

UCF has an agreement with Florida Hospital, Orlando Health, and Nemours. UCF faculty members, researchers, and students (College of Medicine students for the most part) who plan to conduct research at the hospital or with the hospital’s patients or employees must submit the appropriate application, protocol, and other study documents to the hospital IRB. When the study is submitted to the hospital’s IRB, their IRB office sends an e-mail to UCF IRB with information regarding UCF researcher involvement (this may be a new study or an addendum that is adding the UCF researcher to a previously approved study) and UCF IRB is given access to review the submission. If the UCF IRB reviewer has questions or revision suggestions, these are shared with the hospital IRB so that they can be addressed prior to approval by the hospital’s IRB.

After the hospital IRB approves the study and issues their IRB approval letter, the UCF PI must make a submission in the IRB system strictly for record-keeping purposes. The submission must include the IRB System study application, the approved protocol, the approved Informed Consent, other study documents, as appropriate, and the other institution’s IRB approval letter. When submitting in the IRB System, be sure to route the study to the faculty advisor (if applicable) and department chair/dean/director for electronic signature approval. The UCF IRB will review the submission, change the status in the IRB System to “Rely upon Other IRB” and send the PI (and others) an IRB letter to that effect via the IRB System.

## 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 IRB Web Site at <http://www.research.ucf.edu/Compliance/irb.html>.

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

* Phone: 407-823-2901,
* Fax: 407-823-3299
* E-Mail: [irb@ucf.edu](mailto:irb@ucf.edu)
* Address:

Office of Research

12201 Research Parkway

Suite 501

Orlando, FL 32826

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 contact the IRB Office, follow the directions in the “HUMAN RESEARCH PROTECTION PROGRAM PLAN (HRP-101)” under “Reporting and Management of Concerns.”

1. Additional Requirements for DHHS-Regulated Research[[1]](#footnote-1)
2. When a subject decides to withdraw from a clinical trial, the investigator conducting the clinical trial should ask the subject to clarify whether the subject wishes to withdraw from all components of the trial or only from the primary interventional component of the trial. If the latter, research activities involving other components of the clinical trial, such as follow-up data collection activities, for which the subject previously gave consent may continue. The investigator should explain to the subject who wishes to withdraw the importance of obtaining follow-up safety data about the subject.
3. Investigators are allowed to retain and analyze already collected data relating to any subject who chooses to withdraw from a research study or whose participation is terminated by an investigator without regard to the subject’s consent, provided such analysis falls within the scope of the analysis described in the IRB-approved protocol. This is the case even if that data includes identifiable private information about the subject.
4. For research not subject to regulation and review by FDA, investigators, in consultation with the funding agency, can choose to honor a research subject’s request that the investigator destroy the subject’s data or that the investigator exclude the subject’s data from any analysis.
5. When seeking the informed consent of subjects, investigators should explain whether already collected data about the subjects will be retained and analyzed even if the subjects choose to withdraw from the research.
6. Additional Requirements for FDA-Regulated Research
7. When a subject withdraws from a study:[[2]](#footnote-2)
   1. The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.
   2. An investigator may ask a subject who is withdrawing whether the subject 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 subject 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 subject’s information.
   3. If a subject 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 subject’s informed consent for this limited participation in the study (assuming such a situation was not described in the original informed consent form). IRB approval of informed consent documents is required.
   4. If a subject 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 subject’s medical record or other confidential records requiring the subject’s consent.
   5. An investigator may review study data related to the subject collected prior to the subject’s withdrawal from the study, and may consult public records, such as those establishing survival status.
8. For FDA-regulated research involving investigational drugs:
   1. Investigators must abide by FDA restrictions on promotion of investigational drugs:[[3]](#footnote-3)
      1. 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.
      2. This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in 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.
      3. An investigator must not commercially distribute or test market an investigational new drug.
   2. Follow FDA requirements for general responsibilities of investigators[[4]](#footnote-4)
      1. 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 subjects under the investigator's care; and for the control of drugs under investigation.
      2. An investigator must, in accordance with the provisions of 21 CFR §50, obtain the informed consent of each human subject to whom the drug is administered, except as provided in 21 CFR §50.23 or §50.24 of this chapter.
      3. Additional specific responsibilities of clinical investigators are set forth in this part and in 21 CFR §50 and 21 CFR §56.
   3. Follow FDA requirements for control of the investigational drug[[5]](#footnote-5)
      1. An investigator must administer the drug only to subjects under the investigator's personal supervision or under the supervision of a sub-investigator responsible to the investigator.
      2. The investigator must not supply the investigational drug to any person not authorized under this part to receive it.
   4. Follow FDA requirements for investigator recordkeeping and record retention[[6]](#footnote-6)
      1. Disposition of drug:
         1. An investigator is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects.
         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.
      2. Case histories.
         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.
      3. Record retention: 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.
   5. Follow FDA requirements for investigator reports[[7]](#footnote-7)
      1. Progress reports: The investigator must furnish all reports to the sponsor of the drug who is responsible for collecting and evaluating the results obtained.
      2. 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.
      3. Final report: An investigator must provide the sponsor with an adequate report shortly after completion of the investigator's participation in the investigation.
      4. 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.
   6. Follow FDA requirements for assurance of IRB review[[8]](#footnote-8)
      1. An investigator must assure that an IRB that complies with the requirements set forth in 21 CFR §56 will be responsible for the initial and continuing review and approval of the proposed clinical study.
      2. The investigator must also assure that he or she will promptly report to the IRB all changes in the research activity and all unanticipated problems involving risk to human subjects or others, and that he or she will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.
   7. Follow FDA requirements for inspection of investigator's records and reports[[9]](#footnote-9)
      1. 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, and copy and verify any records or reports made by the investigator pursuant to 312.62.
      2. The investigator is not required to divulge subject 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.
   8. Follow FDA requirements for handling of controlled substances[[10]](#footnote-10)
      1. 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.
9. For FDA-regulated research involving investigational devices:
   1. General responsibilities of investigators.[[11]](#footnote-11)
      1. 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 subjects 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.
   2. Specific responsibilities of investigators[[12]](#footnote-12)
      1. Awaiting approval: An investigator may determine whether potential subjects would be interested in participating in an investigation, but must not request the written informed consent of any subject to participate, and must not allow any subject to participate before obtaining IRB and FDA approval.
      2. 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 IRB or FDA.
      3. Supervising device use: An investigator must permit an investigational device to be used only with subjects under the investigator's supervision. An investigator must not supply an investigational device to any person not authorized to receive it.
      4. 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.
      5. 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.
   3. Maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation:[[13]](#footnote-13)
      1. All correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required reports.
      2. 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.
         3. Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of.
      3. Records of each subject'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 subject 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 subject to the investigational device, including the date and time of each use, and any other therapy.
      4. The protocol, with documents showing the dates of and reasons for each deviation from the protocol.
      5. Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigations or a particular investigation.
   4. Inspections[[14]](#footnote-14)
      1. 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).
      2. Records inspection: A sponsor, IRB, 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.
      3. Records identifying subjects: An investigator must permit authorized FDA employees to inspect and copy records that identify subjects, 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 IRB have not been submitted or are incomplete, inaccurate, false, or misleading.
   5. Prepare and submit the following complete, accurate, and timely reports[[15]](#footnote-15)
      1. 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.
      2. Withdrawal of IRB 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.
      3. 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.
      4. 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 well-being of a subject 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 subjects, FDA and IRB also is required.
      5. 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.
      6. 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.
      7. Other. An investigator must, upon request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.
10. Additional Requirements for Clinical Trials (ICH-GCP)
11. Investigator's Qualifications and Agreements
    1. 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.
    2. 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 IRB, and/or the regulatory authorities.
    3. 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.
    4. The investigator should be aware of, and should comply with, GCP and the applicable regulatory requirements.
    5. The investigator/institution should permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authorities.
    6. The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.
12. Adequate Resources
    1. The investigator should be able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.
    2. The investigator should have sufficient time to properly conduct and complete the trial within the agreed trial period.
    3. 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.
    4. 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.
13. Medical Care of Trial Subjects
    1. 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.
    2. During and following a subject's participation in a trial, the investigator/institution should ensure that adequate medical care is provided to a subject for any adverse events, including clinically significant laboratory values, related to the trial. The investigator/institution should inform a subject when medical care is needed for intercurrent illnesses of which the investigator becomes aware.
    3. It is recommended that the investigator inform the subject's primary physician about the subject's participation in the trial if the subject has a primary physician and if the subject agrees to the primary physician being informed.
    4. Although a subject 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 subject's rights.
14. Communication with IRB
    1. Before initiating a trial, the investigator/institution should have written and dated approval opinion from the IRB for the trial protocol, written informed consent form, consent form updates, subject recruitment procedures (e.g., advertisements), and any other written information to be provided to subjects.
    2. As part of the investigator's/institution’s written application to the IRB, the investigator/institution should provide the IRB 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 IRB.
    3. During the trial the investigator/institution should provide to the IRB all documents subject to review.
15. Compliance with Protocol
    1. 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 IRB. The investigator/institution and the sponsor should sign the protocol, or an alternative contract, to confirm agreement.
    2. 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 IRB of an amendment, except where necessary to eliminate an immediate hazards to trial subjects, or when the changes involves only logistical or administrative aspects of the trial (e.g., change in monitors, change of telephone numbers).
    3. The investigator, or person designated by the investigator, should document and explain any deviation from the approved protocol.
    4. The investigator may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard to trial subjects without prior IRB 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 IRB for review and approval opinion, b) to the sponsor for agreement and, if required, c) to the regulatory authorities.
16. Investigational Product
    1. Responsibility for investigational product accountability at the trial site rests with the investigator/institution.
    2. 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.
    3. 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 subject, 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 subjects. Investigators should maintain records that document adequately that the subjects were provided the doses specified by the protocol and reconcile all investigational product received from the sponsor.
    4. The investigational product should be stored as specified by the sponsor and in accordance with applicable regulatory requirements.
    5. The investigator should ensure that the investigational product are used only in accordance with the approved protocol.
    6. The investigator, or a person designated by the investigator/institution, should explain the correct use of the investigational product to each subject and should check, at intervals appropriate for the trial, that each subject is following the instructions properly.
    7. 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.
17. Informed Consent of Trial Subjects
    1. 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 IRB's written approval opinion of the written informed consent form and any other written information to be provided to subjects.
    2. The written informed consent form and any other written information to be provided to subjects should be revised whenever important new information becomes available that may be relevant to the subject’s consent. Any revised written informed consent form, and written information should receive the IRB's approval opinion in advance of use. The subject or the subject’s legally acceptable representative should be informed in a timely manner if new information becomes available that may be relevant to the subject’s willingness to continue participation in the trial. The communication of this information should be documented.
    3. Neither the investigator, nor the trial staff, should coerce or unduly influence a subject to participate or to continue to participate in a trial.
    4. None of the oral and written information concerning the trial, including the written informed consent form, should contain any language that causes the subject or the subject'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.
    5. The investigator, or a person designated by the investigator, should fully inform the subject or, if the subject is unable to provide informed consent, the subject's legally acceptable representative, of all pertinent aspects of the trial including the written information and the approval opinion by the IRB.
    6. 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 subject or the subject's legally acceptable representative and the impartial witness, where applicable.
    7. Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the subject or the subject'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 answered to the satisfaction of the subject or the subject's legally acceptable representative.
    8. Prior to a subject’s participation in the trial, the written informed consent form should be signed and personally dated by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion.
    9. If a subject 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 subjects, is read and explained to the subject or the subject’s legally acceptable representative, and after the subject or the subject’s legally acceptable representative has orally consented to the subject’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 subject or the subject's legally acceptable representative, and that informed consent was freely given by the subject or the subject’s legally acceptable representative.
    10. Both the informed consent discussion and the written informed consent form and any other written information to be provided to subjects should include explanations of the following:
        1. That the trial involves research.
        2. The purpose of the trial.
        3. The trial treatments and the probability for random assignment to each treatment.
        4. The trial procedures to be followed, including all invasive procedures.
        5. The subject's responsibilities.
        6. Those aspects of the trial that are experimental.
        7. The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant.
        8. The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.
        9. The alternative procedures or courses of treatment that may be available to the subject, and their important potential benefits and risks.
        10. The compensation and/or treatment available to the subject in the event of trial related injury.
        11. The anticipated prorated payment, if any, to the subject for participating in the trial.
        12. The anticipated expenses, if any, to the subject for participating in the trial.
        13. That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.
        14. That the monitors, the auditors, the IRB, and the regulatory authorities will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.
        15. That records identifying the subject 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 subject’s identity will remain confidential.
        16. That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.
        17. The persons to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury.
        18. The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.
        19. The expected duration of the subject's participation in the trial.
        20. The approximate number of subjects involved in the trial.
    11. Prior to participation in the trial, the subject or the subject'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 subjects. During a subject’s participation in the trial, the subject or the subject’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 subjects.
    12. When a clinical trial (therapeutic or non-therapeutic) includes subjects who can only be enrolled in the trial with the consent of the subject’s legally acceptable representative (e.g., minors, or patients with severe dementia), the subject should be informed about the trial to the extent compatible with the subject’s understanding and, if capable, the subject should sign and personally date the written informed consent.
    13. Except as described above, a non-therapeutic trial (i.e. a trial in which there is no anticipated direct clinical benefit to the subject), should be conducted in subjects who personally give consent and who sign and date the written informed consent form.
    14. Non-therapeutic trials may be conducted in subjects 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 subjects who can give informed consent personally. b) The foreseeable risks to the subjects are low. c) The negative impact on the subject’s well-being is minimized and low. d) The trial is not prohibited by law. e) The approval opinion of the IRB is expressly sought on the inclusion of such subjects, 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. Subjects in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.
    15. In emergency situations, when prior consent of the subject is not possible, the consent of the subject's legally acceptable representative, if present, should be requested. When prior consent of the subject is not possible, and the subject’s legally acceptable representative is not available, enrolment of the subject should require measures described in the protocol and/or elsewhere, with documented approval opinion by the IRB, to protect the rights, safety and well-being of the subject and to ensure compliance with applicable regulatory requirements. The subject or the subject'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.
18. Records and Reports
    1. 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.
    2. Data reported on the CRF, that are derived from source documents, should be consistent with the source documents or the discrepancies should be explained.
    3. 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 both 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 representatives are documented, are necessary, and are endorsed by the investigator. The investigator should retain records of the changes and corrections.
    4. 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.
    5. 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.
    6. The financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/institution.
    7. Upon request of the monitor, auditor, IRB, or regulatory authority, the investigator/institution should make available for direct access all requested trial-related records.
19. Progress Reports
    1. The investigator should submit written summaries of the trial status to the IRB annually, or more frequently, if requested by the IRB.
    2. The investigator should promptly provide written reports to the sponsor, the IRB and, where applicable, the institution on any changes significantly affecting the conduct of the trial, and/or increasing the risk to subjects.
20. Safety Reporting
    1. 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 subjects by unique code numbers assigned to the trial subjects rather than by the subjects' 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 IRB.
    2. 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.
    3. For reported deaths, the investigator should supply the sponsor and the IRB with any additional requested information (e.g., autopsy reports and terminal medical reports).
    4. 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 subjects, should assure appropriate therapy and follow-up for the subjects, and, where required by the applicable regulatory requirements, should inform the regulatory authorities. In addition:
       1. 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 IRB, and should provide the sponsor and the IRB a detailed written explanation of the termination or suspension.
       2. 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 IRB and provide the IRB a detailed written explanation of the termination or suspension.
       3. If the IRB 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.
21. Final Reports by Investigator: Upon completion of the trial, the investigator, where applicable, should inform the institution; the investigator/institution should provide the IRB with a summary of the trial’s outcome, and the regulatory authorities with any reports required.
22. Additional Requirements for Department of Defense (DOD) research
23. When appropriate, research protocols must be reviewed and approved by the IRB prior to the Department of Defense approval. Consult with the Department of Defense funding component to see whether this is a requirement.
24. Civilian researchers attempting to access military volunteers should seek collaboration with a military researcher familiar with service-specific requirements.
25. 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.
26. Service members must follow their command policies regarding the requirement to obtain command permission to participate in research involving human subjects while on-duty or off-duty.
27. Components of the Department of Defense might have stricter requirements for research-related injury than the DHHS regulations.
28. There may be specific educational requirements or certification required.
29. When assessing whether to support or collaborate with this institution for research involving human subjects, the Department of Defense may evaluate this institution’s education and training policies to ensure the personnel are qualified to perform the research.
30. When research involves U.S. military personnel, policies and procedures require limitations on dual compensation:
    1. Prohibit an individual from receiving pay of compensation for research during duty hours.
    2. An individual may be compensated for research if the participant is involved in the research when not on duty.
    3. Federal employees while on duty and non-Federal persons may be compensated for blood draws for research up to $50 for each blood draw.
    4. Non-Federal persons may be compensated for research participating other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.
31. When conducting multi-site research, a formal agreement between institutions is required to specify the roles and responsibilities of each party.
32. Other specific requirements of the Department of Defense research be found in the “Additional Requirements for Department of Defense (DOD) Research” section in the IRB’s “WORKSHEET: Additional Federal Criteria (HRP-318).”
33. Additional Requirements for Department of Energy (DOE) Research
34. Research that involves one or more of the following is considered by DOE to be human subjects research and requires IRB review:
    1. Intentional modification of the human environment
    2. Study of human environments that use tracer chemicals, particles or other materials to characterize airflow.
    3. Study in occupied homes or offices that:
       1. Manipulate the environment to achieve research aims.
       2. Test new materials.
       3. 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.
35. You must complete and submit to the IRB 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.
36. You must report the following to the Department of Energy human subjects research program manager:
    1. Any significant adverse events, unanticipated risks; and complaints about the research, with a description of any corrective actions taken or to be taken
    2. Any suspension or termination of IRB approval of research
    3. Any significant non-compliance with HRPP procedures or other requirements.
37. 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 IRB’s “WORKSHEET: Additional Federal Criteria (HRP-318).”
38. 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 subjects.
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 subjects 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 subjects who are both: No longer in Bureau of Prisons custody. 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 a statistical research or reporting record is provided to the agency.
9. Except as noted in the consent statement to the subject, you must not provide research information that identifies a subject to any person without that subject’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 provide Office of Research and Evaluation with the computerized research data, not identifiable to individual subjects, 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:
    1. Identification of the investigators.
    2. Anticipated uses of the results of the research.
    3. A statement that participation is completely voluntary and that the subject 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).
    4. 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 subject indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the subject is an inmate, indicates intent to leave the facility without authorization.
    5. A statement that participation in the research project will have no effect on the inmate subject'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 IRB application must include a summary statement, which includes:
    1. Names and current affiliations of the investigators.
    2. Title of the study.
    3. Purpose of the study.
    4. Location of the study.
    5. Methods to be employed.
    6. Anticipated results.
    7. Duration of the study.
    8. Number of subjects (staff or inmates) required and amount of time required from each.
    9. Indication of risk or discomfort involved as a result of participation.
15. The IRB application must include a comprehensive statement, which includes:
    1. Review of related literature.
    2. Detailed description of the research method.
    3. Significance of anticipated results and their contribution to the advancement of knowledge.
    4. Specific resources required from the Bureau of Prisons.
    5. Description of all possible risks, discomforts, and benefits to individual subjects or a class of subjects, and a discussion of the likelihood that the risks and discomforts will actually occur.
    6. Description of steps taken to minimize any risks.
    7. 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.
    8. Destroy research records or remove individual identifiers from those records when the research has been completed.
    9. Description of any anticipated effects of the research study on institutional programs and operations.
    10. Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.
16. The IRB 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 IRB’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.
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 subject reports immediate harm to subjects or others.
4. Under a privacy certificate, investigators and research staff do not have to report child abuse unless the subject 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 IRB’s “WORKSHEET: Additional Federal Criteria (HRP-318).”
7. Additional Requirements for Department of Education (ED) Research
8. 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).
9. Provide a copy of all surveys and instructional material used in the research. Upon request parents of children[[16]](#footnote-16) involved in the research[[17]](#footnote-17) must be able to inspect these materials.
10. 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.
11. 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 IRB’s “WORKSHEET: Additional Federal Criteria (HRP-318).”
12. Additional Requirements for Environmental Protection Agency (EPA) Research
13. Research conducted, supported, or intended to be submitted to EPA is subject to Environmental Protection Agency Regulations.
14. Intentional exposure of pregnant women or children to any substance is prohibited.
15. 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.)
16. Research involving children must meet category #1 or #2.
17. 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 IRB’s “WORKSHEET: Additional Federal Criteria (HRP-318).”
18. Single IRB Studies
19. That National Institutes of Health 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.
    1. 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.
    2. 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.
    3. Exceptions to the NIH policywill 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.
20. [Reserved.]

1. <http://www.hhs.gov/ohrp/policy/subjectwithdrawal.html> [↑](#footnote-ref-1)
2. <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126489.pdf> [↑](#footnote-ref-2)
3. <http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.7> [↑](#footnote-ref-3)
4. <http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.60> [↑](#footnote-ref-4)
5. <http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.61> [↑](#footnote-ref-5)
6. <http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.62> [↑](#footnote-ref-6)
7. <http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.64> [↑](#footnote-ref-7)
8. <http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.66> [↑](#footnote-ref-8)
9. <http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.68> [↑](#footnote-ref-9)
10. <http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.69> [↑](#footnote-ref-10)
11. <http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.100> [↑](#footnote-ref-11)
12. <http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.110> [↑](#footnote-ref-12)
13. <http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.140> [↑](#footnote-ref-13)
14. <http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.145> [↑](#footnote-ref-14)
15. <http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.150> [↑](#footnote-ref-15)
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. [↑](#footnote-ref-16)
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. [↑](#footnote-ref-17)