



# **Investigator Manual**

**October 25, 2021**



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## Scope

Throughout this document, “institution” refers to Northwestern University.

## What is the purpose of this manual?

This document, “INVESTIGATOR MANUAL (HRP-103),” is designed to guide you through policies and procedures related to the conduct of Human Research that are specific to this institution.

General information regarding Human Research protections and relevant federal regulations and guidance is incorporated into the required human protections training. For additional information, see below: “What training do my staff and I need to conduct Human Research?”

This document references guidance, policies, standard operating procedures (SOP), forms, worksheets, checklists, templates, and other documents. The IRB Office continuously updates these tools and posts them to the IRB Office [website](#) for use by the research community. Please contact the [IRB Office](#) with questions or if you identify any broken links.

## Definitions

Although some terms are defined in this document, a comprehensive set of definitions relevant for Human Research can be found in “SOP: Definitions (HRP-001).” Please refer to the SOP definitions of terms employed throughout this document, represented by Double Underlines.

## What is Human Research?

Guidance for determining whether an activity is Human Research can be found in the “WORKSHEET: Human Research Determination (HRP-310),” located in the Templates, Forms, and SOP page of the IRB website. Use this document for guidance as to whether an activity meets either the U.S. Department of Health and Human Services (DHHS) or U.S. Food and Drug Administration (USFDA) definition of Human Research, keeping in mind that the IRB Office makes the ultimate determination as to whether research activity constitutes Human Research subject to IRB oversight.

- You are responsible for obtaining appropriate IRB review and approval before conducting Human Research. The IRB will only review research before the initiation of research activities.
- If you have questions about whether an activity is Human Research, contact the IRB Office. If you wish to have a written determination, submit a new study in eIRB+ using the “Human Research Determination Form (HRP-503)” in place of a protocol.
- See “WORKSHEET: Exempt Determination (HRP-312)” for activities that are exempt from IRB regulatory requirements. Note that “exempt” does not mean you do not need IRB review. It means it is no greater than minimal risk human research exempt from further regulatory review but still subject to IRB Office ethics review and approval.



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- In certain scenarios, Human Research may be reviewed and approved by an External IRB. See “Can I utilize an external IRB?” below for those scenarios. Even if your research does fit into one of the described scenarios, your Human Research must still be submitted to and approved by the IRB Office.

## ***What is the Human Research Protection Program?***

The document “HUMAN RESEARCH PROTECTION PROGRAM PLAN (HRP-101)” describes this institution’s overall plan to protect participants in Human Research, and includes the following:

- 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 someone acts as an agent of the institution conducting Human Research;
- The roles and responsibilities of individuals within the institution.
- 
- ***Who is an agent of the institution?***
- An organization’s employees or agents refers to individuals who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. “Employees and agents” can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

## ***Who may be a principal investigator?***

Every research study requires a Principal Investigator (PI). This person takes full responsibility for the conduct of the study. Below is a list of who may and may not serve as PI, though unique circumstances (e.g., requests from staff) may be given special consideration.

PI Eligible	Case-by-case	Not PI Eligible
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<ul style="list-style-type: none"><li>• Curators;</li><li>• Instructors;</li><li>• Librarians;</li><li>• Non-tenure-track research and/or clinical faculty (full, associate, and assistant professors);</li><li>• Tenure-track faculty (full, associate, and assistant professors); and</li><li>• Senior research investigators (Faculty with emeritus status or who are tenured and retired but wish to continue as PI).</li></ul>	<ul style="list-style-type: none"><li>• Adjunct Faculty;</li><li>• Lecturers;</li><li>• Contributed Services Faculty;</li><li>• Health System Clinicians;</li><li>• Visiting faculty;</li><li>• Visiting scholars; and</li><li>• Postdoctoral Fellows.</li></ul> <p><b><u><a href="#">Contact the Associate Vice President for Research</a></u> via email to request permission for such faculty. Please include your CV, a copy of your protocol, and a letter of support from your Department Chair/Division Chief.</b></p> <p><b>If approval is granted, upload the confirmation email into the “Supporting Documents” section in your eIRB+ submission.</b></p>	<ul style="list-style-type: none"><li>• Research assistants and graduate students;</li><li>• Residents;</li><li>• Research associates; and</li><li>• Undergraduate students.</li></ul>
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### ***Who may be a Co-Investigator, Sub-Investigator, or study personnel?***

A Co-Investigator (Co-I) / Sub-Investigator (Sub-I) is an appropriately qualified study team member that makes significant contributions to the scientific development or execution of a study. The Co-I or Sub-I should be qualified by training and experience and may perform some of the PI functions, but they do not have the ultimate responsibility for conducting the research study.

### ***Study Personnel / Key Personnel***

Study personnel are appropriately qualified research staff engaged in human participant research who may perform research related tasks as delegated by the PI.

Please see the [Initial Studies Page](#) for details on Co-Investigator, Sub-Investigator, and study personnel responsibilities and eligibility.

If you are seeking to add external or non-affiliated study personnel, please review our [Reliance](#) webpage. Requests for Northwestern to serve as the IRB of Record for external personnel or sites are reviewed on a per-study basis to ensure compliance with federal regulations.



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Individuals who fail to meet Northwestern University Human Research Protections training requirements as outlined below are not qualified to serve as study personnel.

Minors (persons under age 18) may not be listed as study personnel nor be “engaged” in the research (interactions with participants or their identifiable data).

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

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

Northwestern University requires all individuals involved in human research activities to complete human participant protection training and re-certify their training every three years. The IRB will withhold approval if these training requirements are not met.

These requirements apply to all persons engaged in human research and who are included in the eIRB+ study application. Those individuals include, but are not limited to:

- Principal Investigator and Co-investigators,
- Individuals named on a study grant or contract proposal,
- Individuals listed on an FDA form 1572 for the conduct of the research at the institution or an affiliate institution,
- Individuals who are responsible for the informed consent process or recruitment of research participants, and
- Individuals who obtain individually identifiable health information under a Northwestern Business Associate Agreement.

The Collaborative Institutional Training Initiative (CITI) Program provides research ethics education to the research community. The CITI program offers both initial and refresher courses covering human research and HIPAA requirements. The CITI program is the primary option for completing the Northwestern University IRB human participant protection training requirement.

Live Training conducted by the IRB Office is available for groups of four or more people. More information can be found at <http://irb.northwestern.edu/training/in-person>.

- The [CITI site](http://www.citiprogram.org/) can be accessed at <http://www.citiprogram.org/>.

The following training options are also available and acceptable to satisfy the requirement:

- Protecting Human Research Participants (PHRP) Online Training\*
- CIRTification: Community Involvement in Research Training\*
- Office for Human Research Protections (OHRP): Human Research Protection Training\*



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\* These additional training are recommended for those unaffiliated with Northwestern and who do not have access to complete CITI training.

Additional training may be required for individuals when conducting research funded by certain federal agencies (e.g., Department of Defense, Department of Navy, etc).

Training is valid for three years, after which time the individual must recertify.

All members of the study team involved in the conduct of Human Research must complete training. Members of the study team who have not completed human research protections training may not participate in aspects of the research involving human participants or their identifying information. Study team members should also receive protocol-specific training before the study starts, when there are changes to study personnel or responsibilities, and whenever study expectations change.

For each new initial submission received in eIRB+, the IRB Office will verify that all study team members (including volunteers and interns) have met the training requirement. If they have not met the requirement, the IRB Office will return that submission to the study team. You may re-submit for review only after all training requirements have been met or after removing individuals who have not met requirements from your study team as appropriate.

After the initial submission, it is the responsibility of the PI to verify and maintain a record that the training of all study team members is current in eIRB+. The IRB will continue to monitor human participant protection training dates for all PIs, Co-Is, and study team members for all submissions

For individuals from outside of the institution with whom there is an IRB Authorization Agreement (IAA), it is the responsibility of the home institution to monitor and maintain current human participant protection training. For all external collaborators for whom Northwestern covers research oversight through an Individual Investigator Agreement (IIA), the Northwestern IRB and Principal Investigator are responsible for ensuring the collaborators maintain active and valid human participant protection training.

Maintaining a Delegation of Authority (DOA) log allows you to track study team training, in addition to keeping copies of certificates of completion of human participant protection training. Please find DOA templates on IRB's [Study Support Resources and Templates](#) page.

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

You are responsible for following all Northwestern University Conflict of Interest (COI) policies and procedures, and can find those at <http://www.northwestern.edu/coi/policy/>.

### ***What other approvals or notifications are required before initiating Human Research?***

In addition to securing IRB approval for Human Research (or IRB Office approval for exempt Human Research), you may need to secure other approvals or notifications before initiating your





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research. Below are examples where other approvals or notifications are relevant. However, this list is not all-inclusive. The IRB Office may ask you to obtain other approvals not listed below on a case-by-case basis depending on the particulars of your research:

- Clinical Affiliates. If you are conducting research at one of the institution's clinical affiliates, additional approvals or notification may be required. Please find details on securing approval or notification from Clinical Affiliates at <https://www.irb.northwestern.edu/additional-committee-review-and-approval/>. These include but are not limited to:
  - Radiation Safety
  - NMH Clinical Specimens Release Committee (CSRC)
  - NMH Nursing Committee
  - NMH Office for Research
  - NMH Quality Management Committee
  - NU Clinical Research Unit (CRU)
  - NU Institutional Biosafety Committee (IBC)
  - NU RHLCCC Scientific Review Committee (SRC))
  - NU Student Surveys Planning Group (SSPG)
  - Investigational Drug Service (IDS) Pharmacy
- Other Laws and Regulations:
  - Childhood Educational Settings. Some school districts have their own IRB or Research Review Board process. You are required to follow the policies and procedures of those bodies. In addition, if you are conducting research within childhood educational settings, e.g., pre-school, primary school, or secondary school, you are required to obtain permission from an educational official such as the Principal and the teacher(s) at your research site before initiating research. See, Additional Requirements for Department of Education (USED) Research (Appendix A-7) for more information about research using educational records (see also WORKSHEET: FERPA Compliance (HRP-331)).
  - International Research. If you are conducting research outside of the United States, you are required to follow local regulations governing Human Research for the host country in addition to the requirements described in this document. The IRB Office may request evidence of local Human Research review by an official review body. For additional guidance, please consult the latest [The International Compilation of Human Research Standards](#) and the [Review of International Research](#) page of the Northwestern IRB website.
  - Nursing Home Research in the State of Illinois. Research in nursing homes in the State of Illinois requires additional state approvals. Please note if you are



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conducting nursing home research outside the State of Illinois, you may need additional approvals. Please contact the IRB Office for assistance.

- Medical Students and Postdoctoral Trainees as Research Participants: If you plan to enroll the group as mentioned above as research participants, you must obtain additional approval from the Feinberg School of Medicine (FSM) Vice Dean for Education. The Enrollment of Students and Trainees in Research Studies Administrative Policy includes additional guidance.
- See the “When am I required to obtain HIPAA Authorization?” section below for more information about research using Protected Health Information.

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

Log in to eIRB+ using your NU NetID and password. Click “Create New Study” under “My Current Activities.” Complete each section of the online IRB Application with the relevant documents using the currently approved protocol and consent templates: <https://www.irb.northwestern.edu/templates-forms-sops/>. Reference this webpage for new study requirements: <https://www.irb.northwestern.edu/new-study-requirements/>. The eIRB+ system maintains electronic copies of all information submitted to the IRB in case revisions are required.

Once you complete the eIRB+ submission, if you are FSM affiliated or using medical records for your research, you will also be required to complete the associated Research Supplemental Submission (RSS) form. Although RSS information is collected in tandem with IRB information, RSS information is not a component of your IRB submission. It is, therefore, not reviewed or accessible by the IRB. Instead, the institution uses RSS information for operating and reporting purposes. Any questions regarding RSS information should be directed to the appropriate institutional office managing that information, as indicated in the RSS submission form.

### ***How do I submit a grant project to the IRB?***

If your federal funder sent you Just-in-Time (JIT) notification for your proposal, you need to submit a completed IRB protocol and related documents for review to the IRB (<https://www.irb.northwestern.edu/just-in-time-process/>). The IRB review process will take time to complete; therefore, if your IRB submission is still under review at the time of the grant submission for funding, inform your SR Grant Officer, who will inform the funding agency. For additional guidance from the Sponsored Research Office on JIT submissions, see: <https://osr.northwestern.edu/NIH-JIT>.

### ***How do I submit a request to use a Humanitarian Use Device (HUD) for clinical use?***

This Institution utilizes the IRB to review and approve HUDs before they are used at a facility for clinical care. Refer to WORKSHEET: Criteria for Approval HUD (HRP-323) for additional information regarding the IRB's criteria to review and approve HUD uses. The clinical use of a



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HUD is not considered Human Research. However, it must still be submitted for review and approval by the IRB before clinical use (except for emergency use, which must be reported to the IRB within five days). The IRB does not require a research informed consent form for HUD use.

Complete the new submission in the eIRB+ system and attach all requested supplements. The PI should click the “Submit” activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

### ***Does the IRB charge to review research?***

Yes, the IRB does charge a fee for the review of industry-sponsored research, including the use of an external IRB. Please see the following webpage on [Fees](http://irb.northwestern.edu/about/fees) for more information: <http://irb.northwestern.edu/about/fees>. Additionally, the IRB Office charges fees for federally funded research, where Northwestern is the IRB of Record for external site(s). For additional information, please refer to the [IRB Reliance webpage](#).

### ***How can I request an IRB Reliance (Authorization) Agreement?***

Per the Human Research Protection Program Plan (HRP-101), the IRB Office reviews and determines if it is appropriate to execute an Authorization Agreement for either:

1. The Northwestern University IRB to serve as the Single IRB or IRB of Record for a Multi-Site Study, Collaborative Study, or an individual investigator, in alignment with the requirements outlined in “SOP: Northwestern University serving as IRB of Record (HRP-093),” or
2. The Northwestern University IRB to cede IRB review to (i.e., rely on) an external IRB from another institution/organization, in alignment with the requirements outlined in “SOP: External IRBs (HRP-092).”


Please refer to the IRB Office Reliance Agreement webpage at: <https://irb.northwestern.edu/reliance-agreements> for instructions on the types of Reliance Agreements, how to submit a request for a Reliance Agreement, how to determine if a site is engaged, and additional information about the Reliance Agreement process.

### ***Can I utilize an external IRB?***

The IRB Office reviews and determines when it is appropriate for Northwestern University to cede IRB review to (i.e., rely on) an external IRB from another institution/organization in alignment with the requirements outlined in “SOP: External IRBs (HRP-092).”

### ***Will Northwestern University’s IRB serve as the IRB of Record for another institution or site?***

On a case-by-case basis, Northwestern University’s IRB may serve as the Single IRB (sIRB) or IRB of Record for a Multi-Site Study, Collaborative Study, or an individual investigator. The IRB Office reviews and determines if it is appropriate in alignment with the requirements outlined in “SOP: Northwestern University serving as IRB of Record (HRP-093).”

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The IRB Office has a Single IRB Consultation process to aid research teams in identifying the best route to sIRB compliance. There are several ways for Northwestern University and its researchers to comply with the revised Common Rule Single IRB mandate for cooperative research and the NIH sIRB mandate, such as: 1) Use of a Central (Commercial) IRB; or 2) Northwestern University serving as the IRB of Record; or 3) Another academic IRB (from one of the participating sites) serving as IRB of Record. As a part of the Single IRB Consultation process, which includes determining the appropriate route, the IRB Office will provide a Letter of Support for one of the three options above. The IRB of Record is not determined based on which institution is the primary grant recipient.

Please also refer to the IRB Office's Single IRB webpage at: <https://irb.northwestern.edu/single-irb> for detailed information about the consultation process, how to submit a request for a Letter of Support for federal funding proposals, and an overview of the criteria that the IRB Office takes into consideration when determining whether it is appropriate for Northwestern to serve as the IRB of Record.

## ***How do I write an Investigator Protocol?***

Write your protocol using the appropriate protocol templates from the IRB website at: <https://www.irb.northwestern.edu/templates-forms-sops/>. Use the “Biomedical Protocol Template (HRP-593)” for Biomedical research or “Social Behavioral Protocol Template (HRP-583)” for Social Behavioral research as a starting point for drafting a new Investigator Protocol. Use the “Data and Specimen Analysis Protocol (HRP-1704)” for a study focused on analyzing data or specimens. Please see the “Registry (Subject Pool) Best Practices (HRP-1103)” for creating a list or database of participants that multiple investigators will use for recruitment in the future. Please note that a registry requires IRB approval as an independent project. Reference the instructions and guidance in the template for the information the IRB looks for when reviewing research.

If you received an Investigator Protocol from your study sponsor or lead study investigator for multi-site research, use the “Local Protocol Addendum Template (HRP-508)” to document relevant local information not included in the sponsor or multi-site protocol. Upload both the received multi-site protocol and the local protocol addendum in eIRB+. The use of the Local Protocol Addendum applies to both Biomedical and Social Behavioral research.

Here are some key points to remember when developing an Investigator Protocol:

- You are required to use one of the template protocols listed above for new Human Research, where the local protocol addendum alone will not suffice to describe all of your research activities.
- There are questions and statements about what to consider in the protocol templates that guide investigators when developing an Investigator Protocol for submission to the IRB. You should delete all of the guidance comments before submitting the protocol to the IRB.



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- When writing an Investigator Protocol, always keep an electronic copy. You will need to modify this copy using the tracked changes function in Word when making changes to the Investigator Protocol. The eIRB+ system stores electronic copies.
- Note that not everything that is in the protocol template will be relevant to every research study. Therefore, do not delete any primary sections if they do not apply, simply indicate NA (not applicable).
- You may not involve any individuals of the following populations as participants in your research without specifically including them in your inclusion criteria and providing study-specific justification for their inclusion. This is because the inclusion of participants in these populations has regulatory implications.
  - Adults unable to provide legally effective consent
  - Individuals who are not yet adults (persons who have not attained the legal age for consent to treatments or procedures involved in research, under the applicable law of the jurisdiction where the research will be conducted)
  - Prisoners

### ***What if my research involves community engagement?***

Community-engaged research is a process for working collaboratively with stakeholders such as patients, healthcare providers, public health leaders, policymakers, local human service agencies, and community partners to strengthen and contribute to the well-being of the stakeholders and the development and dissemination of knowledge. Community-engaged research embraces the use of many forms of engagement such as informing, consulting, involving, collaborating, and empowering. When engaging the community in research, there are specific considerations a researcher should keep in mind:

- Level of engagement with the community the research will require,
- Ability to develop and maintain relationships with community partners,
- Level of input or collaboration community partners will have during the research, and
- Process for disseminating results to community partners.

Community-engaged research often involves partnerships and coalitions, which help mobilize resources, influence systems, and catalyze changing policies, programs, and practices. The IRB will review community-engaged research projects to ensure appropriate methods are consistent with the local needs of the participant demographic involved in the research concerning collaboration, respect, and impact on the community.

The Center for Community Health within the Feinberg School of Medicine supports researchers to ensure meaningful community and academic engagement across the research spectrum to improve health and health equity. Additional resources in support of community-engaged research can be found at <https://www.feinberg.northwestern.edu/sites/cch/>.



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### ***How do I store Human Research data to protect confidentiality?***

You must have plans and procedures in place to maintain the confidentiality of research records. You must include a description of your data storage methods in the protocol or the local protocol addendum you upload in eIRB+.

- Your electronic data storage plan must be consistent with NUIT Policies, Guidelines, and Practices, which can be found at <http://www.it.northwestern.edu/policies/index.html>.
- If you are conducting Human Research under the auspices of Feinberg School of Medicine, you must follow Feinberg's data security policies, which can be found at <http://www.feinberg.northwestern.edu/it/standards-policies/index.html>.

### ***Should I obtain a Certificate of Confidentiality for my research?***

A Certificate of Confidentiality (CoC) is a tool for protecting certain information from forced or compelled disclosure, e.g., to oppose a subpoena. Effective Oct 1, 2017, NIH automatically issues CoCs to all research funded by NIH that is collecting or using identifiable, sensitive information. The new disclosure rules apply to everyone. For additional information, see the NIH website regarding Certificates of Confidentiality. Note that a Certificate of Confidentiality does not protect information related to the Illinois State mandate or the University policy to report child abuse and neglect.

The National Institute of Justice (NIJ) requires a Privacy Certificate if you are working with prisoners. You can find the NIJ Privacy Certificate guidelines at: <http://www.nij.gov/funding/humansubjects/pages/privacy-certificate-guidance.aspx>.

The Privacy Certificate is not the same as a Certificate of Confidentiality and it is important to complete the application to comply with the confidentiality regulations found in 28 CFR Part 22.

If you have a Certificate of Confidentiality or a Privacy Certificate, the IRB will consider that information as part of its review.

### ***Am I a mandated reporter of child abuse?***

All University employees (including all faculty, staff, and student employees) regardless of their position or assignment, are required by law (under the Abused and Neglected Child Reporting Act (ANCRA), 325 ILCS 5/1 et seq.) and by University policy ([http://policies.northwestern.edu/docs/Reporting\\_Child\\_Abuse\\_and\\_Neglect.pdf](http://policies.northwestern.edu/docs/Reporting_Child_Abuse_and_Neglect.pdf)) to report suspected cases of child abuse or neglect. University policy requires all students, volunteers, and third-party contractors engaged in research activities to report suspected cases of child abuse or neglect.

University employees are not mandated reporters in Illinois of elderly abuse, neglect, or exploitation. However, it is possible that during the conduct of research, you will encounter a circumstance in which an elderly participant in your research reports abuse, neglect, or exploitation. One of the founding ethical principles of human participant research is beneficence,





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protecting them from harm, and making efforts to secure their well-being. While no University policy requires reporting, you may decide it is your ethical duty to make a report in good faith to the Illinois Department of Aging. By law, anyone making an elder abuse report in good faith has civil and criminal immunity from liability and professional disciplinary action.

### ***How do I conduct research using genetic information?***

The Genetic Information Nondiscrimination Act of 2008 (GINA) prohibits discrimination in health coverage and employment based on genetic information. If you conduct research using genetic information, you are responsible for becoming familiar with the provisions of the law, both to implement measures to protect genetic information from inappropriate disclosures and to inform potential research participants about their rights under the law.

Required GINA language is provided in “Biomedical Template Consent Document (HRP- 592)” for you to include for participants.

### ***How do I obtain Institutional Certification for submission of genomic data to an NIH-designated data repository?***

You may be required to submit genomic data to an NIH-designated data repository as a condition of your federal award. In this case, the Institutional Official or designee must certify that your genomic data sharing plan is acceptable. The IRB Office verifies for the Institutional Official or designee that your genomic data sharing plan meets the criteria for submission to an NIH-designated data repository. Contact the IRB Office for instructions on how to submit that verification plan. The Institutional Official or designee will communicate certification of approval to you after the verification process is complete.

### ***What if I hold the IND for an investigational drug or biologic, or an IDE for an investigational device?***

Research involving investigational drugs, biologics, or devices where the investigator holds the IND or IDE is subject to additional regulatory oversight in addition to that within the IRB’s purview. For investigator-initiated research involving investigational drugs or biologics, follow FDA requirements in 21 CFR Part 312, Subpart B for obtaining Investigational New Drug (IND) clearance/approval. For investigator-initiated research involving investigational devices, follow FDA requirements in 21 CFR Part 812, Subpart B for obtaining Investigational Device Exemption (IDE) approval. Please refer to Appendix A-2, *Additional Requirements for USFDA Regulated Research*.

The institution has resources available to investigators who wish to conduct such research. Please see the following [webpage](https://www.nucats.northwestern.edu/resources/clinical-research-support/index.html) for more information:

<https://www.nucats.northwestern.edu/resources/clinical-research-support/index.html>.



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### ***When should I register my research with ClinicalTrials.gov?***

You must register your research with ClinicalTrials.gov if it meets the requirements. Please see the [ClinicalTrials.gov](https://clinicaltrials.gov) website for more information:

<https://clinicaltrials.gov/ct2/manage-recs/background>. If you are required to register your research with ClinicalTrials.gov, you must also include a statement indicating so in your consent document. Please refer to the “Biomedical Consent Document (HRP-592)” and the “[Supplemental Consent Language \(HRP-1722\)](#)” for the statement that you must include verbatim.

Please also see the following webpage for more information:

<https://www.nucats.northwestern.edu/resources/clinical-research-support/multi-center-clinical-trials.html>.

### ***What is an appropriate recruitment method?***

Recruitment of research participants is the beginning of the informed consent process; it is usually the first information that participants see about your study. Therefore, it is vital for recruitment information to represent the research accurately and not cause undue influence. You must include a description of your recruitment methods in the protocol or the local protocol addendum to the received protocol you upload in eIRB+. You can find additional considerations or requirements for recruitment at <https://www.irb.northwestern.edu/recruitment-materials-and-guidelines/>.

### ***Do I need IRB review for classroom-based research projects conducted by students?***

The University recognizes that some student projects conducted to fulfill course requirements involve activities that might meet the definition of human subjects research in a different context. It is the policy of the University not to require IRB review of classroom research projects designed to teach students research methods. In the circumstance of a classroom assignment that might otherwise constitute human subjects research but which does not require IRB review because it is a classroom assignment, the individual faculty members and departments are responsible for overseeing the activities as defined in the Classroom-Based Research Projects guidance. See <https://www.irb.northwestern.edu/classroom-based-research-projects/> for additional guidance.

However, there are some student human research projects that will always require IRB review, including but not limited to: Doctoral dissertations; funded research; research conducted through collaborations external to NU, Master’s theses, Honors theses, and other undergraduate research projects funded through URG, Weinberg, Buffet, and others. All of these must be reviewed and approved by the IRB before students may begin their research. If you have any questions about whether student projects need IRB review, contact the IRB Office.





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### ***Can I recruit my students or people in my employ to participate in my research?***

An Investigator's use of students, employees, or other subordinates as research participants presents the possibility for undue influence or even coercion. The regulatory requirements for IRB review and approval provide that when some or all of the participants are likely to be vulnerable because of a power differential, additional safeguards are needed to protect the rights and welfare of these participants. (See [45 CFR 46.111\(b\)](#)). This also applies in cases of incidental enrollment of students and subordinates when they meet study criteria but are not a target population, including healthy volunteers. Although it is possible to recruit students, employees, and others that may be susceptible to coercion or undue influence to your projects, in such situations, the IRB will review the protocol, recruitment plan, and research procedures to ensure that participation is voluntary, private and confidential, and that the decision to participate or not participate will not affect grades, class standing or employment in any way. Contact the IRB Office if you have any questions about building the necessary protections into your research process.

### ***Can I participate in my research?***

A Principal Investigator (PI) or research staff member who participates in their research study ("self-experimentation") is a Human Subject themselves. Therefore, any protocol that involves self-experimentation requires prior IRB review to evaluate risks, adequacy of the informed consent process, and appropriate safeguards for all participants. The protocol should explain how consent will be obtained from all participants, including specific details about the consent process for the researcher, and must describe any additional safeguards that will be employed to protect the researcher. Researchers cannot be compensated for serving as a participant in their own research.

### ***How do I obtain a waiver or alteration of informed consent?***

The IRB may waive the requirement for you to obtain informed consent from participants or alter the consent process if you meet certain conditions. See "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" for the criteria the IRB uses to determine whether a waiver or alteration is acceptable. Include information in your protocol that will help the IRB decide. If the IRB has not waived or altered the consent process, you must obtain informed consent and document the process prior to interacting or intervening with participants or using participants' private identifiable information for research purposes.

### ***How do I obtain informed consent from participants?***

You must describe your process for obtaining informed consent from participants for taking part in Human Research. Informed consent is an ongoing process and not just a single event or document. Informed consent allows participants to understand the nature of the research and assures that they can voluntarily and knowledgeably decide whether or not to participate. The process you employ for obtaining informed consent will depend on the research setting and your participant population. The consent process is distinct from the consent document. When written



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documentation of consent is a requirement for IRB approval, a participant or Legally Authorized Representative (LAR) must sign the consent document, but only after you have led them through your approved consent process. See the “Consent Process” section of “WORKSHEET: Criteria for Approval (HRP-314)” for required elements to include in your consent process. See also [Process for Obtaining Consent](#) on the IRB website.

It is considered a best practice to document in the participant file that the informed consent process has occurred. The study team should document the consent process in the study record, such as through the documentation of the consent process form or notes-to-file.

**NOTE:** For FDA-regulated clinical trials, it is considered a required process to document in the participant file that the informed consent process has occurred. Lack of such documentation will result in a non-compliance finding by a FDA auditor inspecting the study.

If your research study meets the requirements for an exempt determination and there are interactions with participants, you may use an abbreviated process for obtaining consent. The abbreviated consent process must provide all of the following information to participants through an information sheet or written verbal script:

- The participant is being asked to participate in a research study.
- A description of the procedure(s) the participant will be asked to complete.
- Participation is voluntary.
- The investigator’s name and contact information.

### ***Do research participants have to sign a consent document?***

The IRB may waive the requirement to obtain written documentation of informed consent if the research meets certain conditions. See “CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)” for the criteria the IRB uses to determine whether a waiver of written documentation of consent is acceptable. If the IRB grants a waiver of documentation of consent, you are still responsible for incorporating all of the principles of informed consent and conducting a comprehensive verbal consent process to obtain the voluntary consent of participants. Once consent is obtained, the consent process should be documented within the research record.

Include study-specific information in your protocol to support your request for a waiver of documentation of consent. A participant or Legally Authorized Representative must sign a consent document if the IRB has not waived the requirement to obtain written documentation of informed consent.

### ***How do I create consent or assent documents?***

Use the template “Biomedical Consent Document (HRP-592)” for Biomedical Research, “Social Behavioral Consent Document (HRP-582)” for Social Behavioral Research, or “[Social](#)

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[Behavioral Consent Document with HIPAA Authorization \(HRP-1721\)](#)” for Social Behavioral Research requiring a HIPAA Authorization, to create a consent document. Each template consent document contains information that is generally relevant for each type of research.

Ensure that you write the consent document using terms that all potential participants can understand to make an informed decision. You should write the consent forms in lay language at or below an eighth-grade reading level and define complex terms at their first use.

Note that all consent documents and summaries for short form consent documents must contain all of the required and 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 you address these elements. In addition, when using the short form to document consent, you must include the appropriate signature block from one of the template consent documents above on the short form.

The IRB Office recommends that you date the revisions of your consent documents to ensure that you use the most recent version approved by the IRB. The IRB Office also will watermark consent documents with IRB approval and expiration date if applicable.

Include the appropriate signature block from the consent document template in the consent document you submit for review. Refer to the [Guidance on Children as Research Participants, Parental Permission, and Child Assent](#) for details. Study teams are encouraged to develop a separate assent document when appropriate, considering the research context, to support the informed consent and assent process. When developing an assent form, please keep in mind the audience you are writing for, and ensure the language would be understandable to them.

### ***How do I document consent or assent (permission)?***

Use the signature sections on the stamped consent form approved by the IRB. Ensure all items are completed, including dates and optional elements.

The following are the requirements for long form consent documents:

- The participant or representative signs and dates the consent document.
- The individual obtaining consent signs and dates the consent document.
- Whenever the IRB or the sponsor requires a witness to the oral presentation, the witness signs and dates the consent document. The person obtaining consent also may serve as the witness if appropriate.
- If the study includes records related to mental health or developmental disabilities, a witness who can attest to the participant’s identity must sign and date the consent document. If appropriate, the witness may be the person obtaining informed consent.
- For participants who cannot read, write, talk, or are blind, and whenever required by the IRB or the sponsor, a witness to the oral presentation signs and dates the consent document. The witness must be an impartial individual (not a member of the study



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team) and not the individual obtaining consent.

- A copy of the signed and dated consent document is made available to the participant.

The following are the requirements for short form consent documents:

- The participant or their legally authorized representative signs and dates the short form consent document and the summary.
- The individual obtaining consent signs and dates the summary.
- The witness is an impartial individual and is not the individual obtaining consent. The witness should be fluent in both English and the language of the participant. When a translator assists the person in obtaining consent, the translator may serve as the witness.
- The witness to the oral presentation signs and dates the short form consent document and the summary.
- Copies of the signed and dated short form consent document and summary are made available to the participant or their legally authorized representative.

The IRB may require separate signatures for the assent of adults incapable of providing consent or for children. The template consent documents provided by the IRB Office include compliant signature sections for use by the Investigator. If research includes adults incapable of providing consent or children who do not sign the consent document, then incorporate the appropriate assent documentation signature sections from the templates in the consent documents you submit for review.

### ***How do I document the Consent Process?***

Documenting the informed consent process usually occurs after the person obtaining consent and the potential participant have discussed the research study. The person obtaining consent must document the consent process within the participant's research record or within the participant's medical record. The IRB Office provides templates to document consent on the Office's [website](#).

### ***When am I required to obtain a HIPAA Authorization?***

If you plan to use or share Protected Health Information (PHI) when conducting your research, you must conduct your study in accordance with the Privacy Rule of the [Health Insurance Portability and Accountability Act \(HIPAA\)](#). Review [Northwestern University's HIPAA webpage](#) and the guidelines below to determine your need for a valid HIPAA Authorization.

A HIPAA Authorization is an individual's signed permission to allow a covered entity to use or disclose the individual's Protected Health Information (PHI) as described in the Authorization. In contrast, an Informed Consent Document is an individual's agreement to participate in the research study. It includes, among other things, a description of the study, anticipated risks and



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benefits, and how the investigator will protect the confidentiality of records. A HIPAA Authorization is part of the Informed Consent Document or other permission to participate in research.

If you need to include a HIPAA Authorization, the Biomedical and Social Behavioral Consent Document Templates (HRP-592 and HRP-1721) already include all the required HIPAA Authorization elements. Therefore, you do not need to submit a separate HIPAA Authorization form for IRB review. One signature block will suffice for both informed consent and HIPAA Authorization.

You must write the Authorization in plain language and provide a copy of the signed Authorization to the individual signing it.

A research participant may revoke his/her Authorization at any time. However, a covered entity may continue to use and disclose PHI obtained before the participant revoked Authorization to the extent that the entity has taken action in reliance on the Authorization. This would permit the covered entity to continue using or disclosing the PHI as necessary to maintain the integrity of the research, as, for example, to account for a participant's withdrawal from the research study, to conduct investigations of scientific misconduct, or to report adverse events.

The Privacy Rule does not specify who must draft the Authorization, so a researcher may draft it. However, the Privacy Rule does specify core elements and required statements that an Authorization must include. An Authorization may also, but is not required to, include additional, optional elements provided the elements are not inconsistent with the required elements and statements and are not otherwise contrary to the Authorization requirements of the Privacy Rule.

An Authorization, whether prepared by a covered entity or by a person requesting PHI from a covered entity, must include the following core elements and required statements:

Authorization Core Elements (see Privacy Rule, 45 CFR §164.508(c)(1))

- Description of the PHI to be used or disclosed (identifying the information in a specific and meaningful manner).
- The name(s) or other specific identification of person(s) or class of persons authorized to make the requested use or disclosure.
- The name(s) or other specific identification of the person(s) or class of persons who may use the PHI or to whom the covered entity may make the requested disclosure.
- Description of each purpose of the requested use or disclosure. Researchers should note that this element must be research study-specific, not for future unspecified research.



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- Authorization expiration date or event that relates to the individual or to the purpose of the use or disclosure (the terms "end of the research study" or "none" may be used for research, including for the creation and maintenance of a research database or repository).
  - Illinois law requires an expiration date if mental health or developmental disabilities information may be accessed ("this permission will expire on xx/xx/xxx").
- Signature of the individual and date. If an individual's personal representative signs the Authorization, a description of the representative's authority to act for the individual.

### Authorization Required Statements (see Privacy Rule, 45 C.F.R. § 164.508(c)(2))

- The individual's right to revoke his/her Authorization in writing and either (1) the exceptions to the right to revoke and a description of how the individual may revoke Authorization or (2) reference to the corresponding section(s) of the covered entity's Notice of Privacy Practices.
- Notice of the covered entity's ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the Authorization, including research-related treatment, and, if applicable, consequences of refusing to sign the Authorization.
- The potential for the PHI to be re-disclosed by the recipient and no longer protected by the Privacy Rule. This statement does not require an analysis of risk for re-disclosure but may be a general statement that the Privacy Rule may no longer protect health information.

Under certain conditions, the IRB may waive the HIPAA authorization requirement or alter the authorization process. See "CHECKLIST: HIPAA Waiver of Authorization (HRP-441)" for the criteria the IRB uses to determine whether a waiver of HIPAA Authorization is acceptable. Including information on how your research meets the criteria for a HIPAA Authorization/alteration in your protocol will help the IRB decide.

You must request a waiver or alteration of HIPAA Authorization when applying for a waiver of documentation of consent. The IRB can grant the waiver if it determines your research meets the following criteria:

1. An adequate plan to destroy identifiers at the earliest opportunity absent a health or research justification or legal requirement to retain them, and
  - a. An adequate plan to protect health information identifiers from improper use or disclosure,
  - b. An adequate plan to destroy identifiers at the earliest opportunity absent a health or research justification or legal requirement to retain them, and
  - c. Adequate written assurances that the PHI will not be used or disclosed to a third party except as required by law, for authorized oversight of the research study, or for other research uses and disclosures permitted by the Privacy Rule;
2. Research could not practicably be conducted without the waiver or alteration; and





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3. Research could not practicably be conducted without access to and use of PHI.

If the IRB has not waived the requirement to obtain HIPAA authorization, you must obtain HIPAA authorization before accessing or using Protected Health Information.

*Note: IRB approval of a HIPAA Authorization or a waiver of HIPAA Authorization does not mean that you have approval to access or use PHI held by a Covered Entity. The Covered Entity holding the PHI may have additional requirements that you must meet before accessing or using that information.*

### ***What if I want to enroll participants with limited English proficiency?***

You may enroll participants who have limited English proficiency in your research provided that you have the resources to communicate effectively with participants during recruitment, while obtaining consent, and for the duration of the research. You may use a short form as described above in the “How do I document consent or assent?” section to document consent. Please note, you are required to submit to the IRB every time you use a short form. Consult “WORKSHEET: Short Form of Consent Documentation (HRP-317)” and the IRB website (<https://www.irb.northwestern.edu/short-form-written-consent/>) for more information and details on how to submit a short form to the IRB. The IRB Office has also provided Short Form consent templates in several languages along with their certificates of translation for your convenience, which you can find at the following webpage: <https://www.irb.northwestern.edu/templates-forms-sops/#short-form>.

If you expect to enroll participants with limited English proficiency or if you or your designee will conduct the study internationally, the IRB expects you to translate your approved consent document into the appropriate language for your research. If you are using a commercial translation service, the IRB Office recommends that you first obtain IRB approval for your English-language consent document to reduce translation costs. After you receive approval, translate your document, and submit that document in eIRB+ as a modification, including a Certificate of Translation.


[Certificate of Translation template](#)

[Non-exclusive list of translation service providers](#)

Please note that when appropriate, the IRB Office does accept translations by a native speaker provided that person has the appropriate language fluency in English and the other language to provide an accurate translation. You must provide documentation equivalent to the Certificate of Translation.

### ***What supporting documents must I include with my IRB submission?***

The eIRB+ system will prompt you to upload documents throughout the submission form, including protocol(s), consent document(s), recruitment material(s), etc. You are required to submit all participant-facing materials to the IRB for review and approval before using them in your research. In addition, upload any other study-specific documents in the “Supporting

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Documents” section of the submission form. Examples of supporting documents include (but are not limited to):

- Data collection instruments including diaries, surveys, questionnaires, or interview scripts
- Childhood educational permission letters
- CITI Training Documents for external research team members
- Evidence of international Human Research review and approval
- Radiation Safety Office approval documentation
- Certificates of Confidentiality from a federal agency
- Authorization agreements or agreements to collaborate

### ***What are the different regulatory classifications under which research activities may fall?***

The IRB is the only authority that can determine under which regulatory category your research project falls. 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 are not subject to IRB oversight or review. Review the IRB Office’s “WORKSHEET: Human Research Determination (HRP-310)” for reference. Contact the IRB Office in cases where it is unclear whether an activity is Human Research.
- Exempt: Certain categories of Human Research may be exempt from some of the regulations but are still human subject research and, therefore, subject to IRB review under the ethical principles of Belmont. Projects which are determined to be exempt will not require annual review by the IRB. It is the responsibility of the IRB Office, not the investigator, to determine whether Human Research meets the criteria for an exempt determination. See the IRB Office’s “WORKSHEET: Exemption Determination (HRP-312)” and the [IRB website](#) to reference the categories of research that may be exempt. Once your project receives an exempt determination from the IRB Office, you do not need to submit anything additional to the IRB unless there are changes to research procedures, changes that may alter risk to participants, or changes to the scope of the project from that which was originally approved. If risk or scope/procedures change, a new project should be submitted to the IRB for review before implementation, as a new initial submission in eIRB+.
- Expedited: Certain categories of non-exempt Human Research may qualify for review using the expedited procedure, meaning that a single designated IRB reviewer, rather than the convened board, may approve the project. Review the IRB Office’s “WORKSHEET: Expedited Review (HRP-313)” and the [IRB website](#) to reference the categories of research that the IRB may review 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.





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### ***What happens after I submit in eIRB+?***

The IRB Office will conduct an administrative review (pre-review) to clarify outstanding issues, ensure your submission includes all required documents, and generally prepare the submission for review by the convened IRB or designated IRB reviewer.

If your submission does not move forward in the review process due to inactivity on your part or your designee's part for 30 business days, the IRB Office may administratively discard the submission from the eIRB+ system. Please communicate the status of any ongoing efforts to the IRB Office by writing a comment in the eIRB+ submission.

### ***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, defer research, or disapprove research:

- Approval: Made when your research meets all criteria for approval. 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 they issue final approval.
- Deferred: Made when the IRB determines that the board cannot approve research and the IRB suggests modifications that 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 provides you the opportunity to respond to the IRB in writing.
- Disapproval: Made when the IRB determines that it cannot approve the research and the IRB cannot describe modifications that might make the research approvable. When making this motion, the IRB describes its reasons for this decision and provides you the opportunity to respond to the IRB in writing.

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

You can find the criteria for IRB approval in the “WORKSHEET: Exemption Determination (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.

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 as guidance to write your Investigator Protocol in a way that addresses the criteria for approval.

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## ***What other state or federal requirements must I meet?***

In addition to the criteria for IRB approval mentioned above, other state or federal laws or regulations may apply to your research, such as, but not limited to:

- [The Illinois Medical Studies Act](#)
- [The Illinois Mental Health and Developmental Disabilities Confidentiality Act](#)
- [The Illinois Nursing Home Act](#)
- See Appendix A for additional federal regulatory criteria for approval of Human Research.

## ***What will happen after IRB review?***

The IRB will provide you with a written decision within eIRB+ indicating that the IRB has approved the Human Research, requires modifications to secure approval, has deferred review of the submission, or has disapproved the Human Research.

- If the IRB has approved the Human Research: You may begin Human Research after you meet all other institutional approvals. IRB approval will usually be for a limited period, not more than one year from the approval date, for greater than minimal risk studies or, as noted in some minimal risk studies. The IRB provides the expiration date in the approval letter.
- If the IRB requires modifications to secure approval: Only address the required modifications from the determination letter submit them in eIRB+ within 21 business days after receiving your determination letter. Do not add any new changes to the study submission at this stage. The IRB will issue a final approval when you have made all required modifications. You cannot commence research until this final approval is received. If you do not accept the modifications, provide justification in your response and submit it to the IRB. If you submit the required modifications to the IRB after 21 business days, it will be evaluated on a case-by-case basis if it needs to go to a convened meeting.
- 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 allow you to respond in writing. In most cases, if you address the IRB's reasons for the deferral, the IRB can approve the Human Research.
- If the IRB disapproves the Human Research: The IRB will provide a statement of the reasons for disapproval and allow you to respond in writing.

If the IRB determined your study does not meet the criteria for approval, the IRB Chair or IRB Vice-Chair may reach out to you to convey the IRB's concerns. If you are unable to resolve the issues, you may request to attend the next panel meeting to discuss the IRB's concerns and provide additional information that may assist in the review. The IRB Chair or IRB Vice-Chair may grant your request at their discretion.



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If your submission does not move forward in the review process due to inactivity on your or your designee's part for 30 business days, the IRB Office may administratively discard the submission from the eIRB+ system. Please communicate the status of any ongoing efforts to the IRB Office by writing a comment in the eIRB+ submission.

### ***What are my obligations as Investigator to conduct Human research?***

1. Do not start Human Research activities until you have the final IRB approval letter.
2. Do not start Human Research activities until you have obtained all other required institutional approvals, including approvals of departments or divisions that require approval before commencing research that involves their resources.
3. Ensure that there are adequate resources to carry out the research safely. Including, but not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.
4. Ensure that Research Staff continue to remain 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 for the duration of the study.
  - a. Delegate responsibilities to Research Staff by staff experience, training, and qualifications.
  - b. Assure that all research procedures are performed with appropriate supervision and only by individuals who are licensed, trained, or otherwise qualified to perform them in the state of Illinois and according to institutional policies.
  - c. Monitor the research study and perform quality assurance activities to ensure that participants are protected, and that data are reliable.
5. Update the IRB office with any changes to the list of study personnel.
6. Update the IRB office with any changes to investigative sites.
7. Personally conduct or supervise the Human Research.
  - a. Conduct the Human Research following the current protocol as approved by the IRB.
  - b. When required by the IRB, ensure that you or your designee obtains consent or permission following the current protocol as approved by the IRB.
  - c. Do not modify the Human Research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to participants.
  - d. Protect the rights, safety, and welfare of participants involved in the research.
  - e. Make arrangements to oversee the research and protect participants if you become temporarily unavailable to conduct or oversee the research personally.



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8. Obtain the legally and ethically effective informed consent of research participants according to the plan approved by the IRB.
  - a. Ensure that only qualified Research Staff obtain informed consent.
9. Maintain accurate and complete research records.
10. Submit to the IRB:
  - a. Proposed modifications as described in this manual. (See “How do I submit a modification?”)
  - b. A continuing review application as requested in the approval letter, if applicable. (See “How do I submit continuing review?”)
  - c. A continuing review application when the Human Research is closed. (See “How Do I Close Out a Study?”)
  - d. Reportable New Information. You or your designee must submit Reports of New Information within five (5) business days of knowledge or notification. (See “What new information needs to be reported to the IRB?”)
11. Submit an updated disclosure of financial interests within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.
12. Do not accept or provide payments to professionals in exchange for referrals of potential participants (“finder’s fees”).
13. Do not accept payments designed to accelerate recruitment tied to the rate or timing of enrollment (“bonus payments”).
14. See additional requirements of various federal agencies in Appendix A. These represent additional requirements and do not override the baseline requirements of this section.
15. Engage in routine post-approval monitoring activities and directed reviews (for-cause audits).
16. If the study is a clinical trial supported by a Common Rule agency, you must post one IRB-approved version of a consent form used to enroll participants on a public federal website designated for posting such consent forms. You must post the form after you close recruitment and no later than sixty (60) days after the last study visit. Please contact the study sponsor with any questions.
  - a. The supporting Federal department or agency may permit or require redactions to the information posted if certain information should not be made publicly available on a Federal website (e.g., confidential commercial information). Contact the Federal department or agency supporting the clinical trial for a formal determination.
  - b. Contact the supporting Federal department or agency sponsor with any other questions regarding consent form posting obligations.



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### ***What are my obligations as the overall study PI where Northwestern is the IRB of Record for a multi-site or collaborative study?***

1. Coordinate with HRPP staff to determine whether this institution's IRB can act as the IRB of Record for all or some institutions participating in the study or if an external IRB will assume oversight.
2. Identify all sites that will be engaged in the human research and requiring oversight by the IRB.
3. Submit a Single IRB Consultation Request Form if the proposed research involves federal funding, human participants, and multiple research sites.
4. Follows procedures to submit a new study application to this institution, including the relevant study information for this institution's IRB to make an initial assessment.
5. Prepare and submit the initial IRB application, modifications, personnel updates, reportable new information, and continuing review information for all sites.
6. Establish a process for obtaining and collating information from all sites and submitting this information to the reviewing IRB, including site-specific variations in study conduct, such as the local consent process and language, research participant identification and recruitment processes, and local variations in study conduct.
7. Ensure 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.
8. Ensure that this institution's study staff are appropriately qualified, have completed Human Subjects Protections training, and have been adequately trained to conduct the study in alignment with the reviewing IRB approved protocol.
9. 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.
10. Respond to questions or information requests from study teams or the IRB or HRPP staff at relying sites.
11. Provide site investigators with all determinations and communications from the reviewing IRB and maintain documentation following the reviewing IRB and relying sites' policies.
12. Provide relying site investigators with the IRB-approved versions of all study documents.
13. Obtain all appropriate institution/organization permissions (i.e., IRB, OSR, COI, etc.) before implementing procedures at this institution and relying sites.
14. Submit reportable new information from relying sites to the reviewing IRB following the terms outlined in the authorization agreement or communication plan.




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15. Report the absence of continuing review information from relying sites if they do not provide the required information before submitting the continuing review materials to the reviewing IRB.
16. Notify relying sites of their lapses in approval and applicable corrective actions.
17. Provide 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. Follow procedures to submit new study applications to this institution's IRB for this institution's IRB staff to make an initial assessment before seeking review by another IRB.
2. Provide the reviewing IRB with the requested information about local requirements or local research context issues relevant to the IRB's determination before IRB review.
3. Disclose conflicts of interest determined by this institution, and as required by the reviewing IRB, and comply with any management plans that may result.
4. Cooperate in the reviewing IRB's responsibility for initial and continuing review, record keeping, and reporting, and provide all information requested by the reviewing IRB promptly.
5. Ensure that this institution's study staff are appropriately qualified, have completed Human Subjects Protections training, and have been adequately trained to conduct the study in alignment with the reviewing IRB approved protocol.
6. Comply with determinations and requirements of the reviewing IRB and maintain documentation following the reviewing IRB and this institution's policies.
7. Obtain all appropriate institution/organization permissions (i.e., IRB, OSR, COI, etc.) before implementing procedures at this institution.
8. Notify the reviewing IRB when local policies that impact IRB review are updated.
9. Promptly report to the reviewing IRB any proposed changes to the research and do not implement those changes without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the participants.
10. Promptly report to the reviewing IRB and this institution any unanticipated problems involving risks to participants or others, terminations, or suspensions of the study.
11. Report non-compliance, participant complaints, protocol deviations, or other events to the reviewing IRB and this institution.
12. When enrolling participants, obtain, document, and maintain records of consent for each participant or each participant's legally authorized representative.

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13. Provide the reviewing IRB with data safety monitoring reports following the reviewing IRB's reporting policy.
14. Specify the contact person and provide their contact information for researchers and research staff to obtain answers to questions, express concerns, and convey suggestions regarding the use of the reviewing IRB.

### ***How do I submit a modification?***

Log in to eIRB+ using your Northwestern NetID and password. Next, navigate to the study you wish to modify. Next, click "Create Modification/CR " on the left-hand side of the study workspace and select "Modification." (Note that you may also submit a combined Modification and Continuing Review. See "How do I submit continuing review?" for additional information.) Next, select the Modification Scope and click "Continue." (Note that you may only have one Modification per Modification Scope type open at any given time.) Complete all Modification information and then make corresponding changes to the IRB Application. For changes to documents previously uploaded in eIRB+, use the electronic copies maintained by the system as "draft" to ensure that you are revising the most recent versions. You will accept all tracked changes from previous modifications and upload your revised documents with tracked changes related to the current modification. If you do not upload tracked changes, the IRB Office may return the Modification to you before starting pre-review. Please note that changes submitted within a modification may not be implemented until IRB approval is received.

If a modification remains in the "Clarifications requested" state for more than 30 business days, the IRB Office may administratively discard the submission. This means that your modification draft is no longer active in eIRB+, and you will need to submit a new modification.

### ***How do I submit continuing review?***

Log in to eIRB+ using your NU NetID and password. Navigate to the study for which you wish to submit a continuing review request. In the left-hand side of the study workspace, click: Create Modification / CR" and select "Continuing Review." (Note that you may also submit a combined Modification and Continuing Review. See the section "How do I submit a modification?" for additional information.) Complete all Continuing Review / Study Closure Information. You will not be able to make any changes to your study at continuing review unless you submit a combined Modification and Continuing Review. Before submitting the research for continuing review, you should verify the current list of research team personnel and whether their human protection training is current, and if there has been any change in financial interest related to the research.

As of August 31, 2018, the IRB may approve non-exempt minimal risk, non-FDA regulated studies without setting an expiration date for IRB approval. As a result, these studies no longer require an annual continuing review. For more information, see "SOP: Determining and Processing 'No Continuing Review' (HRP-033)."

If the approval of Human Research includes an expiration date for IRB approval and thus the requirement of Continuing Review, and if the study approval expires, you must cease all Human





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Research procedures. These procedures include recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collecting or analyzing private identifiable information. Continuing Human Research procedures after approval expiration is a violation of institutional policy. If current participants will be harmed by stopping Human Research procedures available outside the Human Research context, provide these on a clinical basis as needed to protect current participants. If current participants will be harmed by stopping Human Research procedures that are not available outside the Human Research context, immediately contact the IRB Office and provide a written list of the currently enrolled participants and why they will be harmed by stopping Human Research procedures.

### ***How do I close out a study?***

You must close your study in eIRB+ when you have finished all of the following activities: research participant recruitment, study participation and follow-up, and collecting and analyzing identifiable data. Refer to the [Guidance on Study Closure](#) for more details.

To close a study, log in to eIRB+ using your Northwestern NetID and password. Next, navigate to the study you wish to close. Then, on the left-hand side of the study workspace, click “Create Modification / CR” and select “Continuing Review.” Finally, complete all Continuing Review / Study Closure Information, ensuring that the research milestones align with when a study may be closed.

If your study expires and your IRB approval lapsed for more than thirty (30) business days, the IRB Office may administratively close your study. However, allowing a study to expire is not an appropriate mechanism to close a study and is considered non-compliance. Lapsed studies should either be renewed or closed.

### ***How do I promptly report new information to the IRB?***

In the conduct of research, Unanticipated Problems Involving Risk to Subjects or Others (UPIRSOs) and Non-compliance may occur, which you must report to the IRB. You can find the process for managing the reportable information in “Reportable New Information SOP (HRP-024).” You must report the death of a Northwestern or Northwestern affiliate participant or a participant at a site relying on the Northwestern IRB for review that is both Unanticipated and Related or Possibly Related within **24 hours** of knowledge or notification. You must report any other information about an event at Northwestern or Northwestern affiliate or information about an event at a site relying on the Northwestern IRB for review that fits into any of the categories listed below within **five business days** of knowledge or notification. You must report the use of the short form consent process within **ten business days**.

The following information must be reported:

- **Risk:** Information that indicates a new or increased risk, or a safety issue. This includes a chance that something bad could happen.





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- **Harm\*:** Any harm experienced by an NU participant or other individual that, in the opinion of the investigator, is unexpected and related or possibly related to the research procedures. Harms can include psychological, economic, legal, and other non-physical harms.
    - a. 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.
    - b. A harm is “possibly related”† to the research procedures if, in the opinion of the investigator, the research procedures more likely than not caused the harm.
  - **Death of a Research Participant:** Northwestern University investigators are required to report deaths of NU\* participants to the IRB office if the death was:
    - a. not anticipated, and
    - b. related or possibly related† to participation in the study.
- \* The Harm and Death were previously combined into the same category, but are now separate categories as of June 7, 2021.
- † The criteria for a harm or a death of a research participant were both previously defined as probably related but were changed to possibly related as of June 7, 2021.
- **(Reportable) Non-compliance:** Serious or continuing non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB that causes harm, increases the risk of harm, adversely affects the rights or welfare of participants or undermines the scientific integrity of the data, or an allegation of such non-compliance. Incidents of non-compliance on the part of research participants which do not involve risk need not be reported to the IRB (i.e., failure to turn in medication diary).
  - **Audit:** Audit, inspection, or inquiry by a federal agency and any resulting reports (e.g., FDA Form 483).
  - **Reports:** Only certain written reports of study monitors must be reported. Prompt reporting (within 5 business days) is required for monitoring reports for which the industry sponsor determined the findings could affect the safety of participants or influence the conduct of the study.
  - **Researcher Error:** Failure to follow the protocol due to the action or inaction of the investigator or research staff.
  - **Confidentiality:** Breach of confidentiality, data breach, or data incident. (For additional guidance on the notification process, please see the IRB’s Guide on [Evaluating Reports of Data Incidents](#)).
  - **Unreviewed change:** Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a participant.



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- **Incarceration:** Incarceration of a participant in a study not approved by the IRB to involve prisoners.
- **Complaint:** Complaint of a participant that cannot be resolved by the research team.
- **Suspension:** Premature suspension or termination of the research by the sponsor, investigator, or institution.
  - a. NOTE: A voluntary hold of research activities instituted by an investigator or a sponsor that does not apply to interruptions of research related to concerns regarding the safety, rights or welfare of human research participants or others and may not warrant a determination of suspension or termination of IRB approval. A voluntary suspension should be promptly reported to the IRB via a Reportable New Information application. In order for research activities to resume, the investigator must obtain IRB approval via submission of a modification request in the eIRB+ system that addresses the actions that have been taken or new information that resolves the concerns that initially warranted the suspension or voluntary hold of research activities.
- **Unanticipated adverse device effect:** Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of participants.
- **Investigational Pharmacy Error:** An error involving the investigational pharmacy that puts participants' rights and/or welfare at risk or undermines the scientific integrity of the data. Please also notify the Investigational Pharmacy at [INVdrugser@nm.org](mailto:INVdrugser@nm.org) to get additional information for your RNI (e.g., Corrective Action Plan).
- **Short Form:** If using a translated short form from the IRB website and the English language consent document as the written summary, the short form consent process may take place prior to IRB review. An RNI should be submitted to the IRB within 10 business days, to report the use of the short form consent process.

### Information that does not fit into one of the categories above does not need to be submitted.

To help determine if information fits into one of the categories above, you may reference examples on the [Reportable New Information \(RNI\)](#) webpage.

To report new information, log in to eIRB+ using your NU NetID and password. You may report new information in the following ways:

- If the Reportable New Information is related to a particular study, navigate to the study. In the left-hand side of the study workspace, click "Report New Information". Review the list of categories of information that should be reported to the IRB. If your new information fits into one or more of the categories on the list, then select those categories and provide other relevant information.



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- If the Reportable New Information is not related to a particular study, click “Report New Information” in the upper left-hand corner of your Inbox. Review the list of categories of information that should be reported to the IRB. If your new information fits into one or more of the categories on the lists, then select those categories and provide other relevant information.
- If the Reportable New Information is related to multiple studies under the same PI, click “Report New Information” in the upper left-hand corner of your Inbox, or navigate to any of the related studies and in the left-hand side of the study workspace, click “Report New Information”. Multiple studies may be added in the “Related studies” section of the submission. Review the list of categories of information that should be reported to the IRB. If your new information fits into one or more of the categories on the lists, then select those categories and provide other relevant information.
- If the Reportable New Information is related to multiple studies with different PIs, open a separate Reportable New Information for each PI.

The IRB Office will follow the “SOP: External Reporting Process (HRP-094)” to notify applicable federal agencies within 30 business days of any IRB determinations that constitute Serious Non-Compliance, Continuing Non-Compliance, Unanticipated Problems Involving Risks to Subjects or Others, Suspension of IRB Approval or Termination of IRB Approval of that research. For US Department of Defense (USDOD) research, the report is sent to the USDOD human research protection officer.

### ***How long do I keep records?***

Maintain your Human Research records, including signed and dated consent documents, in accordance with the policies on Retention of University Records

([http://policies.northwestern.edu/docs/Retention\\_of\\_University\\_Records\\_030410.pdf](http://policies.northwestern.edu/docs/Retention_of_University_Records_030410.pdf)) and Research Data: Ownership, Retention and Access (<https://cpb-us-e1.wpmucdn.com/sites.northwestern.edu/dist/4/1207/files/2020/02/research-data-policy.pdf>).

You must retain regulatory and IRB records for IRB reviewed studies in accordance with applicable policies even if you have not enrolled any participants or abstracted any data. If your Human Research is sponsored, contact the sponsor before disposing of Human Research records.

### ***What should I do if I leave Northwestern University?***

If you are planning to leave Northwestern University, you must notify the IRB Office. You may decide to transfer responsibility of your research to another Northwestern University researcher, close your research at Northwestern University prior to your move, or transfer IRB oversight of your research to another IRB. Please see “CHECKLIST: Principal Investigator (PI) Transfer of Responsibilities (HRP-1408)” for a comprehensive list of study record considerations to be completed when transitioning a human research study to a new PI. Reference the IRB’s webpage Principal Investigator Transfer of Responsibility Guidelines for additional information: <https://www.irb.northwestern.edu/principal-investigator-transfer-of-responsibility-guidelines/>.



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Regardless of which option you choose, you will need to develop a plan for transfer and a plan for informing research participants of your move if appropriate and how it affects them. IRB Office staff will be able to advise you on what actions you will need to take. Please refer to the NU Policy on Research Data: Ownership, Retention, and Access: <https://cpb-us-e1.wpmucdn.com/sites.northwestern.edu/dist/4/1207/files/2020/02/research-data-policy.pdf>.

Please also refer to the Office for Research PI Check-Out Procedure at: [https://cpb-us-e1.wpmucdn.com/sites.northwestern.edu/dist/d/2780/files/2019/11/PI\\_Checkout\\_Checklist\\_112219\\_fillable.pdf](https://cpb-us-e1.wpmucdn.com/sites.northwestern.edu/dist/d/2780/files/2019/11/PI_Checkout_Checklist_112219_fillable.pdf)

### ***What if I need to use an unapproved drug, biologic, or device and there is no time for IRB review?***

Contact the IRB Office or IRB Chair immediately to discuss the situation. If there is no time to make this contact, see the “WORKSHEET: Emergency Use (HRP-322)” for the regulatory criteria allowing such a use and make sure these are followed. Use the “TEMPLATE: Emergency Use Consent Document (HRP-506)” to prepare your consent document. You will need to submit a report of the use to the IRB within five (5) business days of the use and for drugs and biologics, submit an IRB application for initial review within thirty (30) days.

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

Emergency use of an unapproved device without prior IRB review is not “research” as defined by USFDA and the individual getting the test article is not a “participant” as defined by USFDA. However, USFDA guidance recommends following similar rules as for emergency use of an unapproved drug or biologic.

Individuals getting an unapproved drug, biologic, or device without prior IRB review cannot be considered a “participant” as defined by DHHS and their results cannot be included in prospective “research” as that term is defined by DHHS.

### ***How do I get additional information and answers to questions?***

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

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

Biomedical IRB  
Arthur Rubloff Building, 7th Floor  
750 N. Lake Shore Dr.  
Chicago, IL 60611  
Phone: (312) 503-9338

Social Behavioral IRB  
Chambers Hall, 2nd Floor  
600 Foster Street  
Evanston, IL 60201  
Phone: (847) 467-1723



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[irb@northwestern.edu](mailto:irb@northwestern.edu)

[sbsirb@northwestern.edu](mailto:sbsirb@northwestern.edu)

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



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### Appendix A-1 ***Additional Requirements for DHHS-Regulated Research***<sup>1</sup>

1. 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.
2. 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.
3. For research not subject to regulation and review by the USFDA, 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.
4. 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.

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<sup>1</sup> <http://www.hhs.gov/ohrp/policy/subjectwithdrawal.html>



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### Appendix A-2 ***Additional Requirements for USFDA-Regulated Research***

1. The FDA defines a human subject as: An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen an investigational medical device is used. When medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects.
2. When a subject withdraws from a study:<sup>2</sup>
  - a. The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.
  - b. An investigator may ask a participant who is withdrawing whether the participant wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the participant would distinguish between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review, and address the maintenance of privacy and confidentiality of the participant's information.
  - c. If a participant withdraws from the interventional portion of the study, but agrees to continued follow-up of associated clinical outcome information as described in the previous bullet, the investigator must obtain the 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.
  - d. 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 participant's medical record or other confidential records requiring the participant's consent.
  - e. 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.
3. For USFDA-regulated research involving investigational drugs:
  - a. Investigators must abide by USFDA restrictions on promotion of investigational drugs:<sup>3</sup>
    - i. For clinical investigations requiring an Investigational New Drug (IND), the IRB will not approve the investigation until one of the following are satisfied:

<sup>2</sup> <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126489.pdf>

<sup>3</sup> <http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.7>



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1. The IRB receives evidence that an IND has been approved (e.g. including an IND number on the protocol or other sponsor document); or
2. The IRB receives evidence that an IND application was received by the USFDA and 30 calendars days have elapsed with no communication(s) from the USFDA. (Note: The IND goes into effect 30 days after the USFDA receives the IND application, unless the sponsor receives earlier notice from the USFDA).
- ii. 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.
- iii. 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.
- iv. An investigator must not commercially distribute or test market an investigational new drug.
- b. Follow USFDA requirements for general responsibilities of investigators<sup>4</sup>
  - i. An investigator is responsible for ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of subjects under the investigator's care; and for the control of drugs under investigation.
  - ii. An investigator must, in accordance with the provisions of 21 CFR §50, obtain the informed consent of each human subject to whom the drug is administered, except as provided in 21 CFR §50.23 or §50.24.
  - iii. Additional specific responsibilities of clinical investigators are set forth in this part and in 21 CFR §50 and 21 CFR §56.
- c. Follow USFDA requirements for control of the investigational drug<sup>5</sup>
  - i. 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.
  - ii. The investigator must not supply the investigational drug to any person not authorized under this part to receive it.
- d. Follow USFDA requirements for investigator recordkeeping and record retention<sup>6</sup>
  - i. Disposition of drug:

<sup>4</sup> <http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.60>

<sup>5</sup> <http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.61>

<sup>6</sup> <http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.62>



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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.
- ii. 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 progress notes of the physician, the individual's hospital charts, and the nurses' notes. The case history for each individual must document that informed consent was obtained prior to participation in the study.
- iii. Record retention: An investigator must retain required records for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.
- e. Follow USFDA requirements for Expanded Access to Investigational Drugs for Treatment Use per 21 CFR 312.300 (Subpart I). This is often referred to as “compassionate use”. The aim of this subpart is to facilitate the availability of investigational new drugs and approved drugs to patients with serious diseases or conditions when there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the patient’s disease or condition. Expanded access to investigational drugs requires prior IRB review and approval (with the exception of [Emergency Use](#)).
- f. Follow USFDA requirements for investigator reports<sup>7</sup>
  - i. Progress reports: The investigator must furnish all reports to the sponsor of the drug who is responsible for collecting and evaluating the results obtained.
  - ii. Safety reports: An investigator must promptly report to the sponsor any adverse effect that may reasonably be regarded as caused by, or possibly caused by, the drug. If the adverse effect is alarming, the investigator must report the adverse effect immediately.

<sup>7</sup> <http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.64>



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- iii. Final report: An investigator must provide the sponsor with an adequate report shortly after completion of the investigator's participation in the investigation.
  - iv. Financial disclosure reports:
    1. The clinical investigator must provide the sponsor with sufficient accurate financial information to allow an applicant to submit complete and accurate certification or disclosure statements as required under 21 CFR §54.
    2. The clinical investigator must promptly update this information if any relevant changes occur during the course of the investigation and for 1 year following the completion of the study.
  - g. Follow USFDA requirements for assurance of IRB review<sup>8</sup>
    - i. 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.
    - ii. 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.
  - h. Follow USFDA requirements for inspection of investigator's records and reports<sup>9</sup>
    - i. An investigator must, upon request from any properly authorized officer or employee of FDA, at reasonable times, permit such officer or employee to have access to, copy, and verify any records or reports made by the investigator pursuant to 312.62.
    - ii. 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.
  - i. Follow USFDA requirements for handling of controlled substances<sup>10</sup>
    - i. If the investigational drug is subject to the Controlled Substances Act, the investigator must take adequate precautions, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.
4. For USFDA-regulated research involving investigational devices:
- a. General responsibilities of investigators.<sup>11</sup>

<sup>8</sup> <http://www.accessdata.fda.gov/SCRIPTS/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.66>

<sup>9</sup> <http://www.accessdata.fda.gov/SCRIPTS/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.68>

<sup>10</sup> <http://www.accessdata.fda.gov/SCRIPTS/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.69>

<sup>11</sup> <http://www.accessdata.fda.gov/SCRIPTS/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.100>

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- i. An investigator is responsible for ensuring that an investigation is conducted according to the signed agreement, the investigational plan and applicable USFDA 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.
- b. Specific responsibilities of investigators<sup>12</sup>
  - i. 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 USFDA approval.
    1. When the IRB determines an Investigational Device Exemption (IDE) is required for a clinical investigation, the IRB will not approve the investigation until one of the following are satisfied:
      - a. The IRB receives a copy of a letter from the USFDA indicating that an IDE has been approved; or
      - b. The IRB receives evidence that an IDE application was received by the USFDA and 30 days have elapsed with no communication(s) from the USFDA. (Note: The IDE goes into effect 30 days after the USFDA receives the IDE application, unless the sponsor receives earlier notice from the USFDA).
  - ii. Compliance: An investigator must conduct an investigation in accordance with the signed agreement with the sponsor, the investigational plan, and other applicable USFDA regulations, and any conditions of approval imposed by an IRB or USFDA.
  - iii. 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.
  - iv. Financial disclosure:
    1. A clinical investigator must disclose to the sponsor sufficient accurate financial information to allow the applicant to submit complete and accurate certification or disclosure statements required under 21 CFR §54.
    2. The investigator must promptly update this information if any relevant changes occur during the course of the investigation and for 1 year following completion of the study.

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

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- v. Disposing of device: Upon completion or termination of a clinical investigation or the investigator's part of an investigation, or at the sponsor's request, an investigator must return to the sponsor any remaining supply of the device or otherwise dispose of the device as the sponsor directs.
- c. Maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation:<sup>13</sup>
  - i. All correspondence with another investigator, an IRB, the sponsor, a monitor, or USFDA, including required reports.
  - ii. Records of receipt, use or disposition of a device that relate to:
    - 1. The type and quantity of the device, the dates of its receipt, and the batch number or code mark.
    - 2. The names of all persons who received, used, or disposed of each device.
    - 3. Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of.
  - iii. Records of each subjects' 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 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.
  - iv. The protocol, with documents showing the dates of and reasons for each deviation from the protocol.
  - v. Any other records that USFDA requires to be maintained by regulation or by specific requirement for a category of investigations or a particular investigation.

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

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## d. Inspections<sup>14</sup>

- i. Entry and inspection: A sponsor or an investigator who has authority to grant access must permit authorized USFDA employees, at reasonable times and in a reasonable manner, to enter and inspect any establishment where devices are held (including any establishment where devices are manufactured, processed, packed, installed, used, or implanted, or where records of results from use of devices are kept).
- ii. Records inspection: A sponsor, IRB, or investigator, or any other person acting on behalf of such a person with respect to an investigation, must permit authorized USFDA employees, at reasonable times and in a reasonable manner, to inspect and copy all records relating to an investigation.
- iii. Records identifying subjects: An investigator must permit authorized USFDA employees to inspect and copy records that identify subjects, upon notice that USFDA 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.

## e. Prepare and submit the following complete, accurate, and timely reports:<sup>15</sup>

- i. Unanticipated adverse device effects. An investigator must submit to the sponsor and to the reviewing IRB a report of any unanticipated adverse device effect occurring during an investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect.
- ii. Withdrawal of 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.
- iii. Progress. An investigator must submit progress reports on the investigation to the sponsor, the monitor, and the reviewing IRB at regular intervals, but in no event less often than yearly.
- iv. Deviations from the investigational plan:
  1. An investigator must notify the sponsor and the reviewing IRB of any deviation from the investigational plan to protect the life or physical 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, USFDA and IRB in accordance with § 812.35(a) is also is required.

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

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



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- v. Informed consent. If an investigator uses a device without obtaining informed consent, the investigator must report such use to the sponsor and the reviewing IRB within 5 working days after the use occurs.
- vi. Final report. An investigator must, within 3 months after termination or completion of the investigation or the investigator's part of the investigation, submit a final report to the sponsor and the reviewing IRB.
- vii. Other. An investigator must, upon request by a reviewing IRB or USFDA, provide accurate, complete, and current information about any aspect of the investigation.

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## Appendix A-3 ***Additional Requirements for Clinical Trials (ICH-GCP)***

### 1. Investigator's Qualifications and Agreements

- 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.
- 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.
- 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.
- The investigator should be aware of, and should comply with, Good Clinical Practice (GCP) and the applicable regulatory requirements.
- The investigator/institution should permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authorities.
- The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.

### 2. Adequate Resources

- 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.
- The investigator should have sufficient time to properly conduct and complete the trial within the agreed trial period.
- 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.
- 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.

### 3. Medical Care of Trial Subjects

- 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.
- 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 co-existing illnesses of which the investigator becomes aware.





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- c. 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.
  - d. 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.
4. Communication with IRB
  - a. 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.
  - b. 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.
  - c. During the trial the investigator/institution should provide to the IRB all documents subject to review.
5. Compliance with Protocol
  - a. The investigator/institution should conduct the trial in compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authorities and which was given approval opinion by the IRB. The investigator/institution and the sponsor should sign the protocol, or an alternative contract, to confirm agreement.
  - b. The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval opinion from the 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).
  - c. The investigator, or person designated by the investigator, should document and explain any deviation from the approved protocol.
  - d. The investigator may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard to trial 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.
6. Investigational Product
  - a. Responsibility for investigational product accountability at the trial site rests with the investigator/institution.
  - b. Where allowed/required, the investigator/institution may/should assign some or all of the investigator's/institution's duties for investigational product



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accountability at the trial site to an appropriate pharmacist or another appropriate individual who is under the supervision of the investigator/institution.

- c. The investigator/institution and/or a pharmacist or other appropriate individual, who is designated by the investigator/institution, should maintain records of the product's delivery to the trial site, the inventory at the site, the use by each 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.
  - d. The investigational product should be stored as specified by the sponsor and in accordance with applicable regulatory requirements.
  - e. The investigator should ensure that the investigational product(s) are used only in accordance with the approved protocol.
  - f. The investigator, or a person designated by the investigator/institution, should explain the correct use of the investigational product to each subject and should check, at intervals appropriate for the trial, that each subject is following the instructions properly.
  - g. Randomization Procedures and Unblinding: The investigator should follow the trial's randomization procedures, if any, and should ensure that the code is broken only in accordance with the protocol. If the trial is blinded, the investigator should promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the investigational product.
7. Informed Consent of Trial Subjects
- a. In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirements, and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki. Prior to the beginning of the trial, the investigator should have the IRB's written approval opinion of the written informed consent form and any other written information to be provided to subjects.
  - b. 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.
  - c. Neither the investigator, nor the trial staff, should coerce or unduly influence a subject to participate or to continue to participate in a trial.



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- d. 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.
- e. 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.
- f. The language used in the oral and written information about the trial, including the written informed consent form, should be as non-technical as practical and should be understandable to the subject or the subject's legally acceptable representative and the impartial witness, where applicable.
- g. Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the 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.
- h. 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.
- i. If a subject or a legally acceptable representative is unable to read, write, talk, or is blind, or if 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.
- j. 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:
  - i. That the trial involves research.
  - ii. The purpose of the trial.
  - iii. The trial treatments and the probability for random assignment to each treatment.



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- iv. The trial procedures to be followed, including all invasive procedures.
- v. The subject's responsibilities.
- vi. Those aspects of the trial that are experimental.
- vii. The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant.
- viii. The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.
- ix. The alternative procedures or courses of treatment that may be available to the subject, and their important potential benefits and risks.
- x. The compensation and/or treatment available to the subject in the event of trial related injury.
- xi. The anticipated prorated payment, if any, to the subject for participating in the trial.
- xii. The anticipated expenses, if any, to the subject for participating in the trial.
- xiii. 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.
- xiv. 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.
- xv. 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.
- xvi. 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.
- xvii. 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.
- xviii. The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.
- xix. The expected duration of the subject's participation in the trial.
- xx. The approximate number of subjects involved in the trial.
- k. 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



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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.

- l. 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.
  - m. 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.
  - n. 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.
  - o. 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.
8. Records and Reports
- a. The investigator should ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRFs and in all required reports.
  - b. Data reported on the CRF, that are derived from source documents, should be consistent with the source documents or the discrepancies should be explained.
  - c. Any change or correction to a CRF should be dated, initialed, and explained (if necessary) and should not obscure the original entry (i.e. an audit trail should be maintained); this applies to both written and electronic changes or corrections. Sponsors should provide guidance to investigators and/or the investigators'



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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.

- d. The investigator/institution should maintain the trial documents as specified in Essential Documents for the Conduct of a Clinical Trial and as required by the applicable regulatory requirements. The investigator/institution should take measures to prevent accidental or premature destruction of these documents.
  - e. Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period however if required by the applicable regulatory requirements or by an agreement with the sponsor. It is the responsibility of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained.
  - f. The financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/institution.
  - g. Upon request of the monitor, auditor, IRB, or regulatory authority, the investigator/institution should make available for direct access all requested trial-related records.
9. Progress Reports
- a. The investigator should submit written summaries of the trial status to the IRB annually, or more frequently, if requested by the IRB.
  - b. 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.
10. Safety Reporting
- a. All serious adverse events (SAEs) should be reported immediately to the sponsor except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports. The immediate and follow-up reports should identify 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.
  - b. Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol.





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- c. 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).
  - d. Premature Termination or Suspension of a Trial If the trial is prematurely terminated or suspended for any reason, the investigator/institution should promptly inform the trial 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:
    - i. If the investigator terminates or suspends a trial without prior agreement of the sponsor, the investigator should inform the institution where applicable, and the investigator/institution should promptly inform the sponsor and the IRB, and should provide the sponsor and the IRB a detailed written explanation of the termination or suspension.
    - ii. If the sponsor terminates or suspends a trial, the investigator should promptly inform the institution where applicable and the investigator/institution should promptly inform the IRB and provide the IRB a detailed written explanation of the termination or suspension.
    - iii. 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.
11. 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.





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## Appendix A-4 ***Additional Requirements for Department of Defense (USDOD) research***

1. 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.
2. Civilian researchers attempting to access military volunteers should seek collaboration with a military researcher familiar with service-specific requirements.
3. Employees of the Department of Defense (including temporary, part-time, and intermittent appointments) may not be able to legally accept payments to participate in research and should check with their supervisor before accepting such payments. Employees of the Department of Defense cannot be paid for conducting research while on active duty.
4. Service members must follow their command policies regarding the requirement to obtain command permission to participate in research involving human subjects while on-duty or off-duty.
5. Components of the Department of Defense might have stricter requirements for research-related injury than the DHHS regulations.
6. There may be specific educational requirements or certification required.
7. When assessing whether to support or collaborate with this institution for research involving human subjects, the Department of Defense may evaluate this institution's education and training policies to ensure the personnel are qualified to perform the research.
8. When research involves U.S. military personnel, policies and procedures require limitations on dual compensation:
  - a. Prohibit an individual from receiving pay of compensation for research during duty hours.
  - b. An individual may be compensated for research if the participant is involved in the research when not on duty.
  - c. Federal employees while on duty and non-Federal persons may be compensated for blood draws for research up to \$50 for each blood draw.
  - d. Non-Federal persons may be compensated for research participating other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.
9. When research involves large scale genomic data (LSGD) collected on DOD-affiliated personnel, additional protections are required:
  - a. Additional administrative, technical, and physical safeguards to prevent disclosure of DoD-affiliated personnel's genomic data commensurate with risk (including secondary use or sharing of de-identified data or specimens)
  - b. Research will apply an HHS Certificate of Confidentiality
10. DoD Component security review
11. Other specific requirements of the Department of Defense research be found in the "Additional Requirements for Department of Defense (USDOD) Research" section in the IRB's "WORKSHEET: Additional Federal Agency Criteria (HRP-318)".



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## Appendix A-5 ***Additional Requirements for Department of Energy (USDOE) Research***

(See DOE Order 443.1C)

1. Research that involves one or more of the following must be submitted to the appropriate IRB for human subjects research review and determination:
  - a. Study of humans in a systematically modified environment. These studies include but are not limited to intentional modification of the human environment:
    - i. Study of human environments that use tracer chemicals, particles or other materials to characterize airflow.
    - ii. 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.
  - b. Use of social media data.
  - c. Human Terrain Mapping (HTM).
  - d. All exempt HSR determinations must be made by the appropriate IRB and/or IRB office.
2. Personally identifiable information collected and/or used during HSR projects must be protected in accordance with the requirements of DOE Order 206.1, Department of Energy Privacy Program, current version. The Central DOE IRBs require submission of DOE's HRP- 490-CHECKLIST-Reviewing Protocols that use Personally Identifiable Information (PII) if your research includes PII.
3. You must report the following to the DOE human subjects research Program Manager (and, when an NNSA element is involved, the NNSA HSP Program Manager) prior to initiation of any new human subjects research project, even if it meets the regulatory definition of exempt human subjects research as outlined in 10 CFR Part 745.104, involving:
  - a. An institution without an established Institutional Review Board (IRB);
  - b. A foreign country;
  - c. The potential for significant controversy (e.g., negative press or reaction from stakeholder or oversight groups);
  - d. Research subjects in a protected class (prisoners, children, individuals with impaired decision making capability, or DOE/NNSA federal or DOE/NNSA contractor employees as human subjects, who may be more vulnerable to coercion and undue influence to participate) that is outside of the reviewing IRB's typical range/scope; or
  - e. The generation or use of classified information.



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4. The IRB must be notified immediately and the DOE HSP Program Manager (and, when an NNSA element is involved, the NNSA HSP Program Manager) must be notified within 48 hours and consulted regarding planned corrective actions if any of the following occur:
  - a. Adverse events. Notify the IRB for all adverse events and the DOE/NNSA HSP Program Manager if the IRB determines them to be significant, as defined in DOE Order 443.1C.
  - b. Unanticipated problems and complaints about the research.
  - c. Any suspension or termination of IRB approval of research
  - d. Any significant non-compliance with HSP Program procedures or other requirements.
  - e. Any finding of a suspected or confirmed data breach involving PII in printed or electronic form. Report immediately to the IRB, the DOE/NNSA HSP Program Manager(s), and the DOE-Cyber Incident Response Capability, in accordance with the requirements of the CRD associated with DOE O 206.1.
  - f. Serious adverse events and corrective actions taken must be reported immediately to the IRB and the DOE/NNSA HSP Program Manager(s). The time frame for “immediately” is defined as upon discovery.
5. Requirements for human participant protections for classified research apply to all classified research conducted or supported by the DOE and its national laboratories, including contracts, and including Human Terrain Mapping research.
6. Researchers conducting human subjects research in any other country or on citizens or other individuals residing in that country must be cognizant of country-specific human subjects research requirements and consult the IRB regarding applicability of such requirements.
7. No human subjects research conducted with DOE funding, at DOE institutions (regardless of funding source), or by DOE or DOE contractor personnel (regardless of funding source or location conducted), whether done domestically or in an international environment, including classified and proprietary research, may be initiated without both a Federalwide Assurance (FWA) or comparable assurance (e.g., Department of Defense assurance) of compliance and approval by the cognizant Institutional Review Board (IRB) in accordance with 10 CFR §745.103.
8. Human subjects research involving multiple DOE sites (e.g., members of the research team from more than one DOE site and/or data or human subjects from more than one DOE site) must be reviewed and approved by one of the Central DOE IRBs prior to initiation, or if authorized by the DOE and/or NNSA HSP Program Manager, other appropriate IRB of record. In all cases, an IRB Authorization Agreement (IAA) or Memorandum of Understanding (MOU) must be in place between the organization(s) conducting the HSR and the organization responsible for IRB review.
9. Human subjects research that involves DOE Federal and/or contractor employees must first be reviewed and approved by the appropriate DOE IRB (the DOE site IRB or one of the Central DOE IRBs), or if deemed more fitting by the Federally assured DOE site or Headquarters, other appropriate IRB of record, in accordance with an IAA or MOU



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negotiated between the DOE site or Headquarters and the organization responsible for IRB review.

10. Classified and unclassified human subjects research that is funded through the Strategic Intelligence Partnership Program (SIPP) must be reviewed and approved by the Central DOE IRB-Classified.
11. If applicable, federally funded HSR must comply with the requirements of the Paperwork Reduction Act.
12. Other specific requirements of the USDOE research can be found in the “Additional Requirements for Department of Energy (DOE) Research” section in the IRB’s “WORKSHEET: Additional Federal Agency Criteria (HRP-318).”



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### Appendix A-6 ***Additional Requirements for Department of Justice (USDOJ) Research***

#### **Additional Requirements for USDOJ 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, and 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:
  - a. Identification of the investigators.
  - b. Anticipated uses of the results of the research.



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- c. 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).
  - d. A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, an investigator may not guarantee confidentiality when the 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.
  - e. 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:
  - a. Names and current affiliations of the investigators.
  - b. Title of the study.
  - c. Purpose of the study.
  - d. Location of the study.
  - e. Methods to be employed.
  - f. Anticipated results.
  - g. Duration of the study.
  - h. Number of subjects (staff or inmates) required and amount of time required from each.
  - i. Indication of risk or discomfort involved as a result of participation.
15. The IRB application must include a comprehensive statement, which includes:
  - a. Review of related literature.
  - b. Detailed description of the research method.
  - c. Significance of anticipated results and their contribution to the advancement of knowledge.
  - d. Specific resources required from the Bureau of Prisons.
  - e. 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.
  - f. Description of steps taken to minimize any risks.
  - g. Description of physical or administrative procedures to be followed to: Ensure the security of any individually identifiable data that are being collected for the study.
  - h. Destroy research records or remove individual identifiers from those records when the research has been completed.
  - i. Description of any anticipated effects of the research study on institutional programs and operations.
  - j. Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.



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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 (USDOJ) Research Conducted within the Federal Bureau of Prisons (BOP) can be found in the “Additional Requirements for Department of Justice (USDOJ) Research Conducted within the Federal Bureau of Prisons (BOP)” section in the IRB’s “WORKSHEET: Additional Federal Agency 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.
  - a. At least once a year, the researcher shall provide the Chief, Office of Research and Evaluation, with a report of the progress of the research.
  - b. At least 12 working days before any report of findings is to be released, the researcher shall distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board, the regional director, and the





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warden of each institution that provided data or assistance. The researcher shall include an abstract in the report of findings.

- c. In any publication of results, the researcher shall acknowledge the Bureau's participation in the research project.
  - d. The research shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
  - e. Prior to submitting for publication the results of a research project conducted under this subpart, the researcher shall provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.
6. Other specific requirements of the Department of Justice (USDOJ) Research Funded by the National Institute of Justice can be found in the “Additional Requirements for Department of Justice (USDOJ) Research” section in the IRB’s “WORKSHEET: Additional Federal Agency Criteria (HRP-318).”



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### Appendix A-7 ***Additional Requirements for Department of Education (USED) Research***

1. Each school at which the research is conducted must provide an assurance that they comply with the Family Educational Rights and Privacy Act (FERPA) and the Protection of Pupil Rights Amendment (PPRA).
2. Provide a copy of all surveys and instructional material used in the research. Upon request, parents of children<sup>16</sup> involved in the research<sup>17</sup> must be able to inspect these materials.
3. The school in which the research is being conducted must have policies regarding the administration of physical examinations or screenings that the school may administer to students.
4. 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.
5. 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.
6. Other specific requirements of the US Department of Education (USED) Research can be found in the “Additional Requirements for Department of Education (USED) Research” section in the IRB’s “WORKSHEET: Additional Federal Agency Criteria (HRP-318).”
7. “WORKSHEET: FERPA Compliance (HRP-331)” provides guidance for the research community and support for the FERPA officer in determining whether personally identifiable information can be released from student educational records, student records, or personal education information from an education program. Education Program is defined as: any program principally engaged in the provision of education, including, but not limited to, early childhood education, elementary and secondary education, postsecondary education, special education, job training, career and technical education, and adult education.

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<sup>16</sup> 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.

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



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### Appendix A-8 ***Additional Requirements for Environmental Protection Agency (USEPA) Research***

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



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## Appendix A-9     ***Additional Requirements for Research Subject to EU General Data Protection Regulations (GDPR)***

1. Human Research involving personal data about individuals located in (but not necessarily citizens of) European Union member states, Norway, Iceland, and Liechtenstein, are subject to EU General Data Protection Regulations.
2. For all prospective Human Research subject to EU GDPR, contact the [Northwestern GDPR Steering Committee](#) to ensure that the following elements of the research are consistent with institutional policies and interpretations of EU GDPR:
  - a. Any applicable study design elements related to data security measures.
  - b. Any applicable procedures related to the rights to access, rectification, and erasure of data.
  - c. Procedures related to broad/unspecified future use consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.
3. Where USFDA or DHHS regulations apply in addition to EU GDPR regulations, ensure that procedures related to withdrawal from the research, as well as procedures for managing data and biospecimens associated with the research remain consistent with Appendices A-1 and A-2 above.
4. “WORKSHEET: GDPR Data Protection (HRP-335)” and “TEMPLATE: GDPR Compliant Consent (HRP-590)” are tools available to provide guidance regarding the collection, management, protection and ongoing handling of personal and other research data when conducting research in one of the countries of the European Economic Area. Please refer to HRP-335 and HRP-590 when drafting the Letter of Information and Consent Document, and when completing the protocol template for submission in eIRB+.



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### Appendix A-10 *Single IRB Studies*

1. 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.
  - a. This policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. It does not apply to career development, research training or fellowship awards.
  - b. This policy applies to domestic awardees and participating domestic sites. Foreign sites participating in NIH-funded, multi-site studies will not be expected to follow this policy.
  - c. Exceptions to the NIH policy will be made where review by the proposed sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy. Requests for exceptions that are not based on a legal, regulatory, or policy requirement will be considered if there is a compelling justification for the exception. The NIH will determine whether to grant an exception following an assessment of the need.
2. The Office for Human Research Protections expects that all sites located in the United States participating in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

The following research is not subject to this provision:

- a. Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or
- b. Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.
- c. For research not subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort.