University of Oklahoma
Investigator Manual

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Scope
Throughout this document “University” refers to all University of Oklahoma campuses. Otherwise, each IRB and campus will be identified directly as “HSC” for OU Health Sciences Center and “NC” for Norman Campus.

What is the purpose of this manual?
This document is designed to guide you through policies and procedures related to the conduct of human research that are specific to the University of Oklahoma campuses.

Definitions
Although some terms are defined in this document, a comprehensive set of definitions relevant for human research can be found in “SOP: Glossary”. Please refer to that SOP for clarification of certain terms employed throughout this document.

What is Human Research?
Research as defined by DHHS regulations is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. For definitions per FDA and VA regulations, see the SOP Glossary.

To determine whether an activity is human research, submit the Determination of Human Research Worksheet in the iRIS submission system. The IRB Office makes the ultimate determination as to whether research activity constitutes human research subject to IRB oversight. SOP 406 provides additional information regarding the determination of human research.

- Investigators must obtain IRB approval of human participant research prior to research initiation. Failure to do so may result in non-compliance. The IRB will not review or approve research activity that has already occurred.
- If you have questions about whether an activity is human research, submit the Determination of Human Research Worksheet in iRIS.

What is the Human Research Protection Program (HRPP)?
The HRPP is the University’s established program designed to support the University’s commitment to the protection of human participants in research. The goals of this program are to provide for the safety of human participants in research, to educate the University’s investigators, and to provide continuous quality improvement of the University’s research activities.

The HRPP has jurisdiction to review and approve human participant research conducted at:

- University of Oklahoma
Who can serve as principal investigator?

Every research study requires a principal investigator (PI). This person takes full responsibility for the conduct of the study. See SOP 801: Investigator Qualifications and Responsibilities for additional information.

Below is a list of individuals who may and may not serve as PI according to their University role. Refer to the appropriate row for your campus IRB.

<table>
<thead>
<tr>
<th>Eligible PIs/Co-PIs</th>
<th>Cannot Serve as PI/Co-PI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HSC</strong></td>
<td></td>
</tr>
<tr>
<td>• Paid full-time Faculty/Staff</td>
<td>• Residents</td>
</tr>
<tr>
<td>• Paid part-time Faculty/Staff</td>
<td>• Fellows</td>
</tr>
<tr>
<td>• Paid Adjunct Faculty</td>
<td>• Graduate Students</td>
</tr>
<tr>
<td>• Employees of affiliate institutions for which OU IRB serves as the IRB of record</td>
<td>• Unpaid Adjunct Faculty</td>
</tr>
<tr>
<td><strong>NC</strong></td>
<td></td>
</tr>
<tr>
<td>• Paid full-time Faculty/Staff</td>
<td>• Unpaid Adjunct Faculty</td>
</tr>
<tr>
<td>• Paid part-time Faculty/Staff</td>
<td>• Volunteers</td>
</tr>
<tr>
<td>• Paid Adjunct Faculty</td>
<td>• Interns</td>
</tr>
<tr>
<td>• Graduate Students (with Faculty Advisor)</td>
<td>• Undergrad students</td>
</tr>
<tr>
<td>• Employees of affiliate institutions for which OU IRB serves as the IRB of record</td>
<td></td>
</tr>
</tbody>
</table>
What is the definition of key study personnel (KSP)?

Key study personnel are individuals who provide research project-related services or assistance and who have knowledge of the research protocol and the identity of research participants or their protected health information.

Anyone engaged in research involving human participants must be listed as key study personnel in the study application.

Collection of research data and/or having access identifiable information constitutes research engagement. For more information about engagement, see the Office of Human Research Protection’s guidance here.

What training is required in order to conduct Human Research?

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

1. Collaborative Institutional Training Initiative (CITI) Training:

<table>
<thead>
<tr>
<th>HSC IRB</th>
<th>NC IRB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Participant Research Basic Course</td>
<td>Human Participant Research Basic Course</td>
</tr>
<tr>
<td>Individuals must complete one training group that is relevant to expertise and nature of research:</td>
<td>Individuals must complete the following course:</td>
</tr>
<tr>
<td>• Group 1 – Biomedical; or</td>
<td>• Social Behavioral Modules</td>
</tr>
<tr>
<td>• Group 2 – Social/Behavioral; or</td>
<td></td>
</tr>
<tr>
<td>• Group 3 – Biomedical &amp; Social/Behavioral</td>
<td></td>
</tr>
</tbody>
</table>

CITI training is valid for a three-year period, after which time, individuals must complete the CITI Refresher Course.

For each new submission received in iRIS, the IRB Office will verify that training requirements of all study team members are satisfied. If requirements are unsatisfied, the IRB Office will return that submission to the research team. The research team may re-submit for review only after all training requirements are satisfied or after removing individuals who have not met requirements from your research team, as appropriate.

The IRB Office will monitor currency of training for all study team members at the time of Continuing Review.

2. Required training for researchers with NIH-funding

In addition to the University’s HRPP training, Good Clinical Practice (GCP) training is
required for all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials.

Note: The OUHSC HRPP does not monitor GCP training compliance.

3. Additional Training per Funding Source

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

When should I register my research with ClinicalTrials.gov?

<table>
<thead>
<tr>
<th>Organization</th>
<th>Clinical Trials Definition</th>
<th>ClinicalTrials.gov Obligation</th>
<th>Penalties</th>
</tr>
</thead>
</table>
| FDA (FDAAA 801) | **Applicable Clinical Trial**  
**Drugs & biologics:** controlled clinical investigations, **other than phase 1** of products subject to FDA regulation  
**Devices:** 1) controlled trials with health outcomes of devices subject to FDA regulation, 2) non-compliant studies; 2) pediatric post-market surveillance as required by FDA | **Registration**  
within 21 days of first enrollment, but ICMJE & OU require prospective registration  
"When OU PI or the University is the Responsible Party"  
(trials initiated on/after 1-18-2017) | **Results Reporting**  
no later than 12 months after primary completion date  
(trials initiated on/after 1-18-2017) | **Fines**  
Civil monetary penalties up to $10,000 per day until noncompliance is resolved |
| NIH | a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes | **Registration**  
within 21 days of first enrollment, but ICMJE & OU require prospective registration  
(trials initiated on/after 1-18-2017) | **Results Reporting**  
no later than 12 months after primary completion date  
(trials initiated on/after 1-18-2017) | **Funding**  
Loss of grant funding;  
Future grant funding may be affected |
| ICMJE | any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes | **Registration**  
before enrollment of first participant | **Publication**  
Manuscripts that are not prospectively registered will not be published by ICMJE journals |

What are my responsibilities as PI in order to conduct human research?

The PI must obtain IRB approval before engaging in research involving human participants, except in the case of an emergency exemption from IRB review. More information about emergency exemption is located in SOP 502G: Emergency Use of FDA Regulated Products.

PIs engaged in research involving human participants are responsible for:

- Designing protocols that minimize risks to participants and maximize benefit.
• Providing for the safety and welfare of the participants enrolled.
• Conducting the research in compliance with the IRB-approved research protocol, the applicable regulations, and in accordance with the principles of the Belmont Report.
• Control of FDA test articles under investigation.
• Personally conducting the research and supervising all sub-investigators and key research personnel involved in the research.
• Reviewing and attesting to the accuracy of all electronic submissions submitted to the IRB for review prior to applying their electronic signature to the submission.
• Complying with the Belmont Report, IRB policies, institutional policies, and applicable federal and state law and regulations.
• Not enrolling participants prior to IRB approval or on or after expiration of IRB approval.
• When the investigator is the lead investigator of a research project that involves multiple research institutions, the principal investigator must submit a multi-site management plan which documents plans for:
  o communication process between sites; and
  o the management of information obtained during the course of the research project, such as:
    ➢ Unanticipated problems involving risks to participants or others
    ➢ Protocol deviations
    ➢ Interim results reporting
    ➢ Protocol modifications

The IRB will evaluate the management plan as it relates to the protection of participants to assess that it is adequate.

**Do I need to disclose conflict(s) of interest?**

Researchers and key study personnel working with human participants must follow University of Oklahoma policies governing conflicts of interest and for reporting and managing conflicts of interest.

Researchers are required to disclose potential conflicts of interests in the IRB application by completing the Conflict of Interest sub-form. The IRB Office will work with the Office of the Vice President for Research to ensure management plans and other required materials are in place, as appropriate.

Provided below are links to the policies as well as a summary of the IRB’s approval process and your responsibility for identifying and managing potential conflicts of interest.
Does the IRB charge a fee to review research?
The NC IRB does not charge a fee for IRB review.
The HSC IRB shall charge the following one-time, non-refundable IRB research review fees to all industry-sponsored research projects:
- $2,500 initial research review fee
- $750 continuing review fee

Additionally, the HSC IRB shall charge a non-refundable HRPP administrative fee of $2,000 to all industry-sponsored human research projects that rely on a non-OU IRB.

These fees do not apply to federally-funded research, investigator-initiated research, or research supported by grants from non-profit foundations or organizations.

What approvals are required before initiating human research?

<table>
<thead>
<tr>
<th>Campus</th>
<th>Committee</th>
<th>Timeline for review compared with IRB</th>
</tr>
</thead>
<tbody>
<tr>
<td>HSC &amp; NC</td>
<td>Office of the Vice President for Research (VPR) – Conflict of Interest (COI) Disclosure and Review</td>
<td>Completed and approved prior to IRB review</td>
</tr>
<tr>
<td>HSC</td>
<td>Stephenson Cancer Center – Protocol Review &amp; Monitoring Committee (PRMC)</td>
<td>Completed and approved prior to IRB review</td>
</tr>
<tr>
<td>HSC</td>
<td>VA Health Care System – Research and Development Committee (R&amp;DC)</td>
<td>Initial review completed prior to IRB review</td>
</tr>
<tr>
<td>HSC</td>
<td>Institutional Biosafety Committee (IBC)</td>
<td>Recommended that review is completed prior to IRB review</td>
</tr>
<tr>
<td>HSC</td>
<td>Radiation Safety Committee (RSC)</td>
<td>Concurrent review; RSC application is part of the HSC IRB application</td>
</tr>
<tr>
<td>HSC</td>
<td>Office of Research Administration (ORA) – Contracts &amp; Agreements</td>
<td>Concurrent review allowed</td>
</tr>
<tr>
<td>NC</td>
<td>Office of Research Services (ORS) – Contracts &amp; Agreements</td>
<td>Concurrent review allowed</td>
</tr>
</tbody>
</table>
Do I need IRB review to conduct classroom-based research projects conducted by students?

A classroom project that is conducted for the purpose of learning research skills and with no intent to publish the findings usually does not require IRB review.

Classroom-based research projects that meet the following criteria do not typically require IRB approval:

1) Projects limited in scope and sample size that are conducted for the purpose of learning and applying the process by conducting a minimal risk research study as a requirement of a specific course.
2) Projects that will not yield generalizable knowledge acceptable for scholarly presentation or publication. **Note:** Presenting results to a class or for a departmental/college/University research presentation event does not constitute public dissemination or contribution to generalizable knowledge.
3) Projects that collect non-sensitive information.
4) Projects that collect data in a manner that assures the anonymity or confidentiality of the participants.

Classroom-based research projects that include an elevated level of risk and do require IRB review to determine if they are human participant research. These include:

1) Projects that involve deception or that may elicit a strong emotional response from the participant and require referrals to mental health professional.
2) Projects that include a physical testing procedure, such as blood draws or exposure to radiation.
3) Projects that gather data from protected or vulnerable populations such as children, cognitively impaired persons, prisoners, or the elderly.

Guidelines for course instructors regarding the supervision of projects that do not require IRB review:

- Require students to complete the IRB documentation (without submitting to the IRB) as part of their training within a classroom-based research project for instructional purposes only.
- Do not use the electronic iRIS system for classroom projects.
- The course instructor reviews all IRB documents for completeness and accuracy.
- Require students to conduct their classroom research in the same ethical manner that applies to human participant research requiring IRB review. That is, requiring informed consent, respecting the elements of risk and appropriate safeguards, obtaining approval from the supporting site or organization, etc.
- For all classroom-based research activities, clearly identify these activities to
potential participants as "classroom-based research projects."

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

The IRB may make the following decisions regarding your proposed research:

- **Approval:** When all criteria for approval are met.
- **Contingent Approval (Modifications Required to Secure Approval):** When the IRB stipulates specific revisions to the research project or accompanying documents.
- **Deferred (convened Board action only):** When there are significant questions regarding the submission or when the information provided is inadequate to assess the risk/benefit ratio.
- **Disapproval (convened Board action only):** When the submission fails to meet one or more of the criteria for approval of human participant research.

For additional details, see SOP 409: Categories of Action.

What are the levels of IRB review?

- **Exempt:** All research involving the collection of data about living individuals through intervention or interaction with those living individuals’ private identifiable information during or after their lifetimes shall be reviewed by the IRB. An investigator may not make the determination of whether a research project is exempt from federal regulations (and therefore from IRB review). Refer to SOP 401: Research Exempt from Federal Regulations for additional information.

- **Review Using the Expedited Procedure:** Certain categories of non-exempt human research may qualify for review using the expedited procedure, meaning that an IRB Chair or designee, rather than the convened Board, may approve the project.

- **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.

Which application do I submit to the IRB for initial review?

If you are submitting to the NC IRB, you will submit the Norman campus application in iRIS. Research reviewed by the NC IRB includes:

- NC or Tulsa campus investigators who plan to initiate social/behavioral research

If you are submitting to the OUHSC IRB, you will submit the HSC IRB application. Research reviewed by the OUHSC IRB includes:

- HSC investigators who plan to initiate any type of human participant
research

- VA research
- NC or Tulsa campus investigators who plan to initiate research with a biomedical component (ex. Research involving ionizing radiation that is beyond standard of care treatment for non-participants).

**How do I write a research protocol?**

The HSC IRB maintains a protocol template for investigators found in the Help section of iRIS and on the HRPP’s website.

**Protocol guidelines:**

- Use of the protocol template for new human research is required for non-industry sponsored research
- Protocol templates are designed to be conducive to *multiple types* of research. It is not necessary to complete sections of the template that do not apply to your proposed study.
- If you plan to target or recruit individuals who are members of the following populations, you must indicate this in your inclusion criteria, and consider appropriate safeguards to minimize risks, as these populations have additional regulatory considerations:
  - Adults unable to provide legally effective consent
  - Individuals who are not yet adults (infants, children, teenagers)
  - Pregnant women
  - Prisoners
- See SOP 501: Special Populations for additional information.
- Submit the first version of the protocol without tracked changes enabled.
  - Subsequent modifications to the protocol must be made with tracked changes enabled so all changes applied are apparent to the IRB Office.
  - The IRB Office will accept all changes and provide a clean protocol upon approval.

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

Investigators must submit study documents that support the proposed research study.

The iRIS system will prompt you to upload documents at the end of the submission form. Consent documents are uploaded in the consent section. Any other study-specific documents are uploaded in the “Supporting Documents” section of the submission packet.
Examples of supporting documents include (but are not limited to):

- Protocol (HSC Campus, required for all studies)
- Informed Consent / Assent Form
- HIPAA Form
- Recruitment materials
- Student as Principal Investigator Forms (Norman campus studies only)
- CITI training documents for non-OU collaborators
- Attestation of cultural appropriateness for international research
- Approvals from other committee reviews
- Data collection instruments, including diaries, surveys, questionnaires, or interview scripts
- Formal Certificates of Confidentiality (when not automatically awarded)
- Investigator Brochure (drug studies)
- Package insert or Instructions for use (device studies)
- Reliance agreements

**How do I submit... in iRIS?**

See the instructional documents in the Help section of iRIS for more information, including how to:

- Submit a modification?
- Submit a continuing review?
- Inactivate a study?
- Report protocol deviations and unanticipated problems?

**Can I recruit my own students or my employees to participate in my research?**

Generally, the IRB discourages investigators from recruiting their students, employees or other subordinates in their own studies, but the IRB will review such situations on a case-by-case basis. The IRB shall consider the degree of risk and likelihood of benefit to the participants, as well as the protections for participants from coercion or undue influence.

**Are there restrictions to calling potential participants during recruitment?**

Cold-calling is not permitted.

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

Use the appropriate campus consent template, found in the Help section of iRIS and on
the HRPP website. Each template contains information that is generally relevant for research reviewed at each campus. Note that failure to complete required sections may delay IRB approval, as each campus template contains information required by federal regulations, federal law, and institutional policy.

How do I document consent and/or assent?

Completing the signature sections of the approved consent form in their entirety, as appropriate, documents consent and assent.

The following are the requirements for consent documents:

- The participant or legally authorized representative (LAR) signs and dates the participant lines.
- The individual obtaining consent signs and dates the appropriate lines.
- Whenever the IRB or the sponsor require a witness to the oral presentation, the witness signs and dates the consent document. The person obtaining also may serve as the witness, if appropriate.
- A copy of the signed and dated consent document must be provided to the participant or LAR. It is best practice to photocopy the originally-signed document and give this photocopy to the participant the same day. To document that a copy of the consent document was provided to the participant, investigators may include this process as a box to “check-off” or date in an enrollment log maintained in the study binder.

Do research participants have to sign a consent document?

Yes, the participant or their LAR must sign an IRB-approved consent document if the IRB has not waived the requirement to obtain written documentation of informed consent.

The IRB may waive the requirement to obtain written documentation of informed consent if certain conditions are met. See “How do I obtain a waiver or alteration of informed consent” on page 15 for more information.

How do I obtain informed consent?

Informed consent is the process of telling potential research participants about the key elements of a research study and what their participation will involve. The consent process typically includes providing a written consent document containing the required information (i.e., elements of informed consent) and the presentation of that information to prospective participants.

The entire informed consent process includes the following:
- Recruiting potential participants
- Providing a potential participant adequate information concerning the study,
- Providing adequate opportunity for the potential participant to consider all options,
- Responding to the potential participant’s questions,
- Ensuring that the potential participant comprehends the information,
- Obtaining the potential participant's voluntary agreement to participate and,
- Continuing to provide information as the participant or situation requires.

To be effective, the process should provide ample opportunity for the Investigator and the participant to exchange information and ask questions.

**How do I submit my consent plan to the IRB?**

You must describe the process for obtaining informed consent in the study application (and in the protocol for investigator-initiated studies). The process employed for obtaining informed consent depends on the research setting, participant population, and other factors.

When written documentation of consent is a requirement by the IRB, a participant or LAR must sign the consent document, but only after the investigator completes the consent process.

**Can I enroll individuals who are not proficient in English?**

Participants with limited English proficiency may be enrolled in research, provided that the study team has the resources to communicate effectively with participants during recruitment, while obtaining consent, and for the duration of the research. However, the plan to enroll participants who are not fluent in English, the process to be employed to ensure such participants understand all information relayed to them, and all translated documents must be approved by the IRB prior to enrollment.

The study team must submit a translation attestation for each set of documents translated. All documents a participant will see during the course of the research must be translated (consent document, HIPAA Form(s), questionnaires, information sheets, etc.) A translator attestation template, as well as Spanish HIPAA Form templates, are available in the Help section of iRIS and on the HRRP website.

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

The study team indicates and substantiates their wish for a waiver or alteration of
informed consent in the study application. The IRB may waive the requirement to obtain written documentation of informed consent if all regulatory conditions are satisfied. This means that the study team must provide the potential participant with the required consent information, but the study team is not required to obtain the participant's signature on the informed consent document.

A waiver of documentation is permissible when any of the following conditions are met:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>The signature on the informed consent document would be the only record linking the participant to the research and the principal risk of harm to the participant would be a breach of confidentiality. For example, for research on sensitive topics, such as domestic violence or illegal activities;</td>
<td>For example, for research on sensitive topics, such as domestic violence or illegal activities;</td>
</tr>
<tr>
<td>The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context. For example, minimal risk research that involves surveys/interviews conducted via telephone or online.</td>
<td>The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context. For example, minimal risk research that involves surveys/interviews conducted via telephone or online.</td>
</tr>
<tr>
<td>NEW! Under the 2018 Common Rule: Where the participants are members of a cultural group in which signing forms is not a normal/acceptable practice.</td>
<td>NEW! Under the 2018 Common Rule: Where the participants are members of a cultural group in which signing forms is not a normal/acceptable practice.</td>
</tr>
</tbody>
</table>

See the Help section of iRIS or the HRPP website for consent templates, such as information scripts.

What is the difference between a HIPAA Form and a consent form?

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, a consent document is an individual's agreement to participate in the research study and includes, among other things, a description of the study, anticipated risks and benefits, and how the confidentiality of records will be protected.

The Authorization must be written in plain language. A copy of the signed Authorization must be provided to the individual signing it if the covered entity itself is seeking the Authorization.

When am I required to obtain a HIPAA Authorization?

If you plan to use or share protected health information (PHI) when conducting your research, they must obtain signed authorization from the participant to use or share their PHI. This HIPAA Authorization is specific to PHI used or shared for the purposes of research and is separate from HIPAA Authorization obtained in the clinic setting. Alternatively, the investigators may apply for a HIPAA Waiver of Authorization.
HIPAA templates are available on the HRPP websites. For additional information about HIPAA, see the OUHSC HIPAA website.

When is a Waiver of HIPAA Authorization appropriate?

The IRB may waive the requirement for a HIPAA Authorization or alter the authorization process, provided conditions documented in the federal regulations are met.

The study team applies for a Request for Waiver of HIPAA Authorization by submitting the form with the same name to the IRB. This template is located in the Help section of iRIS.

If the IRB has not waived the requirement to obtain HIPAA Authorization, you must obtain HIPAA Authorization from each participant prior to accessing or using PHI.

What is required for Preparatory to Research activities?

The Preparatory to Research Form is a sub-form in the iRIS application that is completed when a chart review is performed to assess the feasibility of a study. The investigator must certify the following:

- Use or disclosure is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research;
- No PHI is to be removed from the covered entity by the researcher in the course of the review; and
- The PHI for which use or access is sought is necessary for the research purposes.

How do I store human research data to protect confidentiality?

The study team must have plans and procedures in place to maintain the confidentiality of the research records per University security standards. Investigators must include a description of your data storage methods in the application and protocol.

- Your electronic data storage plan must be consistent with any of University IT Policies, Guidelines, and Practices, which can be found at the following websites:
  - http://www.ou.edu/ouit/security
  - https://it.ouhsc.edu/services/infosecurity/

  For additional information, see SOP 1002: Privacy & Confidentiality.

Should I obtain a Certificate of Confidentiality (CoC) for my research?

Some research projects may require that the investigator obtain a CoC to protect the privacy of research participants. Investigators generally may not be compelled to release data covered by a CoC in any Federal, State, or local civil, criminal, administrative,
legislative, or other proceedings. Note that a CoC does not protect information as it relates to the Oklahoma State mandate or the University policy to report child abuse and neglect.

Effective Oct 1, 2017, NIH automatically issues CoCs to all research funded by NIH that is collecting or using identifiable, sensitive information. In such cases, investigators do not have to formally apply for the CoC and the NIH will not provide the investigators formal documentation of the CoC.

However, investigators who are not recipients of NIH funding may still apply for a traditional CoC via the NIH’s CoC kiosk and portal. If applying for a CoC that is not automatically awarded, IRB approval is contingent upon the study team providing CoC documentation.

Note that CoC template language must be included in the consent form document if the study has a CoC.

If you have questions about the CoC process or how to apply for a CoC, call the HRPP Office.

For additional information about CoCs, see SOP 1002: Privacy and Confidentiality.

**Am I a mandated reported of child abuse?**

All University employees (including all faculty, staff, and student employees), regardless of their position or assignment, are required by law and by University policy to report suspected cases of child abuse and/or neglect. All students, volunteers, and third-party contractors who are engaged in research activities are required by University policy to report suspected cases of child abuse and/or neglect.

**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 that information from inappropriate disclosures and to inform potential research participants about their rights under the law.

Required GINA language is provided in the OUHSC consent template for applicable studies.

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

Research records must be maintained for inspection of federal agencies, the sponsor, the University, and the IRB. The following table specifies the length of time documents must be maintained, per federal regulations:
<table>
<thead>
<tr>
<th>PHI?</th>
<th>Length of time to keep</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>At least 3 years</td>
<td>Responsibility log, consent forms (no PHI), records submitted to the IRB with evidence of approval, data collection forms, participant enrollment log</td>
</tr>
<tr>
<td>Yes</td>
<td>At least 6 years</td>
<td>HIPAA forms, Business Associate Agreements, Data Use Agreements, and any communication, action, activity, or designation required by the Privacy Regulations to be documented</td>
</tr>
</tbody>
</table>

After the appropriate timeframe specified above lapses, contact the sponsor before disposing of human research records, if applicable.

Note that if the study team leaves the University prior to the lapse of the appropriate timeframe specified above, the study team must designate an individual in their department to maintain the records for the remaining time.

What should I do if I plan to leave the University of Oklahoma?

If you are planning to leave the University of Oklahoma, you must notify the IRB Office. You may decide to transfer responsibility of your research to another University of Oklahoma researcher, inactivate your research at the University of Oklahoma prior to your move, or transfer IRB oversight of your research to another IRB.

Regardless of which option you choose, you will need to develop a plan for transfer. Additionally, you must develop a plan for informing research participants of your move, if appropriate, and explain how it will affect them. The IRB Office will advise you accordingly.

What are my responsibilities if I hold the IND for an investigational drug or an IDE for an investigational device?

Research involving investigational drugs, biologics, or devices for which the investigator holds the IND or IDE is subject to additional regulatory oversight that is generally outside of the IRB’s purview. For investigator-initiated research involving investigational drugs, 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.

See SOP 802: Sponsor Responsibilities for additional information.
What if I need to use an unapproved drug, biologic, or device and there is no time for IRB review?

Emergency use of a test article is defined as the use of a test article with a human participant in a life-threatening situation for which no standard acceptable treatment is available and there is not sufficient time to obtain IRB approval.

See the Emergency Use Consent Form Template in the Help section of iRIS and see SOP 502G: Emergency Use of FDA Regulated Products for additional information.

Can I utilize an external IRB?

The NIH has required that a single IRB review NIH-funded multi-site studies that were approved on or after January 25, 2018.

Additionally, under the Revised Common Rule, most U.S. government-funded cooperative studies that meet the criteria for non-exempt human participant research and involve more than one site will also require single IRB review as of January 2020.

There may be other circumstances when the University decides to defer IRB review to an outside IRB. Examples include when the University has an institutional conflict of interest, when an outside IRB may have a particular expertise of the proposed research, or when OU IRB oversight of a particular study or group of studies is not feasible. The University will make an IRB of record determination on a case-by-case basis.

How can I request a reliance agreement?

Because the process to request a reliance agreement differs based on the campus and reviewing IRB arrangement, investigators are encouraged to visit the HRPP website or call the appropriate IRB Office to learn more about the process and request a reliance agreement.
Can OU serve as the IRB of record for multiple sites?

The OU IRB may serve as the reviewing IRB for multicenter studies in which the lead investigator of the research is University faculty, staff or an affiliate and has direct responsibility for the conduct of the research or of the human participants.

The OU investigator must include in their protocol and application a communication and oversight plan for the collaborating sites. The plan shall outline what research activities will occur at each site, the communication plan with the sites, and the plan for ensuring study and regulatory compliance of each site. The OU Investigator must also provide information about each site, including each site’s local context and PI information.

An approved reliance agreement must be fully executed between the University and the relying site(s) prior to each sites’ participation in the IRB-approved research.

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 OU HRPP website at https://compliance.ouhsc.edu/hrpp.

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

<table>
<thead>
<tr>
<th>OUIHC IRB</th>
<th>NC IRB</th>
</tr>
</thead>
<tbody>
<tr>
<td>1105 North Stonewall Avenue Bird Library, Room 176  📞 (405) 271-2045  📧 (405) 271-1677  📧 <a href="mailto:IRB@ouhsc.edu">IRB@ouhsc.edu</a></td>
<td>201 Stephenson Parkway Five Partner’s Place, Suite 4300A  📞 (405) 328-8110  📧 <a href="mailto:IRB@ou.edu">IRB@ou.edu</a></td>
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