

University of Iowa

External/Single IRB (sIRB) Reliance Process

Standard Operating Procedure (SOP)

TABLE OF CONTENTS

I. OVERVIEW	1
II. ABBREVIATIONS AND DEFINITIONS	1
III. SCOPE	3
IV. APPLICABLE REGULATIONS AND GUIDELINES	3
V. IRB FEES	4
VI. PRE-GRANT SUBMISSION SURVEY	4
VII. EXTERNAL IRB RELIANCE PROCEDURES	5
VIII. IRB RELIANCE MODEL (SMART IRB)	6
IX. HIPAA	6
X. OTHER HRPP COMMITTEE REVIEWS	7
XI. MODIFICATIONS AND OTHER POST-APPROVAL SUBMISSIONS	9
XII. ROLES AND RESPONSIBILITIES	10
XIII. FINAL CONSIDERATIONS	14

I. OVERVIEW

The purpose of this Standard Operating Procedures document is to outline the process for all University of Iowa researchers engaging in an External or Single IRB collaborative relationship. The external IRB reliance review process includes; descriptions of the information flow between the IRB of Record and Relying IRB throughout the lifecycle of the initial protocol review, study amendments, reporting, continuing reviews, and study closures. This guidance also outlines the respective responsibilities for the IRB of Record, Relying IRB(s), lead study team, and relying study team(s).

II. ABBREVIATIONS AND DEFINITIONS

ABBREVIATIONS	
sIRB	Single Institutional Review Board
CIRB	Central Institutional Review Board
CITI	Collaborative Institutional Training Initiative
COI	Conflict of Interest
FWA	Federal Wide Assurance
GPC	Greater Plains Collaborative

HIPAA	Health Insurance Portability and Accountability Act
HRPP	Human Research Protections Program
HSO	Human Subjects Office
NCI	National Cancer Institute
NIH	National Institutes of Health
PCORI	Patient Centered Outcomes Research Institute
PHI	Protected Health Information
PI	Principal Investigator
POC	Point of Contact
WIRB	Western Institutional Review Board

DEFINITIONS
<i>Single IRB</i> is a single board that reviews research studies for multiple sites. A Single IRB can be any registered IRB that functions to review multi-site studies where each site follows the same protocol and study procedures.
<i>Central IRB</i> , like a Single IRB, is a single board that reviews large multi-site studies. Central IRBs often review a vast number of studies pertaining to a similar area of study (such as the NCI CIRB). Commonly, the sponsor determines which sites are to participate and suggests or requires those sites to use the Central IRB selected to perform the centralized review.
<i>External IRB</i> is outside the institutional framework. It could refer to being external to the immediate institution or to a larger system or framework of coordinating agreements.
<i>Internal IRB</i> exists within the institution engaged in the study.
<i>IRB of Record</i> is the lead IRB who will oversee the conduct of research related activities at all research locations. The IRB of Record could also be known as the Lead IRB or a single IRB of Record. A <i>Single IRB of Record</i> is a term adopted by the Clinical Trials Transformation Initiative (CTTI). Their website states, a Central IRB is, "...a single IRB of record for a given protocol. The Central IRB assumes all of the usual IRB responsibilities including all reviews of all relevant documents," (CTTI 2014). A Single IRB of record oversees the same research protocol across a number of locations. It might be a consortium or cooperative IRB, an IRB from another institution, a commercial or federal IRB.
<i>Lead Study Team</i> has the obligation to submit the IRB application to the IRB of Record and comply with any requests and clarifications from the IRB or Record.
<i>Relying IRB</i> is an internal IRB that is relying on the review by another IRB. This is rather a misnomer as it is the institution rather than the IRB that is relying on the external IRB or IRB of Record.
<i>Relying Study Team</i> is the study team that is relying on review by an IRB outside of their institution. It is the responsibility of the <i>Relying Study Team</i> to designate a single Point of Contact who will serve as the communication portal with other Relying Site IRBs and the Lead Site IRB.
<i>Point of Contact</i> is generally responsible for being the conduit of information, representing his or her local site, whether it is a lead or a relying institution. The Point of Contact could represent the lead study team coordinator or the IRB staff member identified as the point of contact. The Point of Contact is responsible for facilitation of communication between either the research study team(s) involved in the study or the communication between the IRB of Record and the Relying IRB.

<p><i>Principal Investigator (PI)</i>, whether at a lead or a relying institution, has the primary responsibility for the conduct of the study. The PI at the lead site is accountable for the overall conduct, while the PI at a relying institution is only accountable for the research conducted at his/her institution.</p>
--

III. SCOPE

The policies and procedures described in this SOP apply to all parties involved in research with the University of Iowa. Any institutions or organizations engaged in research with the University of Iowa researchers must have an IRB Reliance Agreement and standard operating procedures for multisite research in place. The delegation of duties between lead and relying institution and the responsibilities of each party conducting research are outlined in the Reliance Agreement and the research application submitted to the IRB of Record.

The External IRB procedures outlined in this SOP are specific to non-Commercial IRB processes. Some procedures may vary between different IRBs, such as the NCI CIRB. It is important that researchers communicate with the University of Iowa External IRB Coordinator during the External IRB process.

All procedures relating to the submission process for WIRB as a Central IRB may be found on the WIRB section of the University of Iowa External-Central IRB website:
<https://hso.research.uiowa.edu/western-irb-wirb-central-irb>

All procedures relating to other Commercial IRBs (Advarra, Prime, Sterling, etc.) may be found by following the links in the second half of the University of Iowa External-Central IRB website:
<https://hso.research.uiowa.edu/external-and-central-irb-reliance-models-using-single-irb-record>

IV. APPLICABLE REGULATIONS AND GUIDELINES

- A. The same regulatory framework applied to research reviewed by the University of Iowa IRB applies for all external IRB reliance review requests. All research involving human subjects must follow one or more of the below regulations, policies, and/or procedures:

Federal Regulations (45 CFR 46, 160, 164 & 21 CFR 50, 56 at minimum. Additional FDA regulations may apply based on the study design)
State and local regulations
Institutional Policies
ICH-GCP (E6) (as applicable)
IRB of Record Policies

Whenever possible, the IRB of Record procedures should also be consistent with the Association for the Accreditation of Human Research Protections Program's (AAHRPP) guidelines for "Reviewing IRBs."

It is the responsibility of the Principal Investigator to be aware of all University of Iowa policies and procedures that may affect the conduct of their research. Regardless of the IRB of record, it is the Principal Investigator's responsibility to adhere to these policies. This also includes any Human Research Protection Program Committee policies, reviews and approvals.

V. IRB FEES

A. IRB Fee Process

- IRB fees will be charged directly to the research project account as soon as the MFK is available. Invoices are not sent directly to the sponsor. It will be the responsibility of the research team to include IRB fees in the budget and request reimbursement from the sponsor.
- 26 percent F&A will be charged consistent with the University's Corporate & Industry Sponsored Clinical Trial Policy (<http://gao.fo.uiowa.edu/corporate-and-industrysponsored-projects-policy-statement-0>).

B. Single IRB of Record (sIRB) fees when the University of Iowa IRB is the lead IRB

- Assessed for NIH grant applications as allowed under NIH Policy (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-109.html>).
- Single IRB of record fees can be provided, upon request, for a pre-grant submission. (See section V; Pre-Grant Submission)

C. IRB Administrative Fee for Industry-Sponsored Projects sent to External IRB (WIRB or other)

- The Initial/Full Board review fee is \$1,500. An additional, annual fee of \$750 will be assessed for continuing review of the protocol.

D. IRB Review Fee for All Industry-Sponsored Studies reviewed by the University of Iowa Biomedical IRB-01

- The Initial/Full Board review fee is \$2,500. An additional \$1,000 fee will be assessed annually for continuing review of the protocol.
- A fee of \$1,000 will be assessed for expedited review. An additional \$500 fee will be assessed annually for continuing review.
- \$0 will be assessed for exempt studies.
- These fees will be charged directly to the research project account as soon as the MFK is available. It will be the responsibility of the research team to include IRB fees in the budget and request reimbursement from the sponsor.

VI. PRE-GRANT SUBMISSION SURVEY

- A. When a University of Iowa researcher plans for the University of Iowa to serve as IRB of Record in a multisite research project utilizing the Single IRB model, a Pre-Grant Submission Survey must be completed. This survey will provide the University of Iowa IRB with the information necessary to determine any fees associated when serving as IRB of Record in a multi-site study.
- B. The Pre-Grant Submission Survey is hosted on Qualtrics, and may be accessed on the main page of the University of Iowa External-Central IRB website, or by following this link: https://uiowa.qualtrics.com/jfe/form/SV_cBGFbx4JMIywUYt

The information provided in this survey is an important and necessary step in the sIRB model process. Please remember to complete this survey as soon as possible in the planning of your study to avoid any delays.

If you have any questions or concerns with the survey, please contact the University of Iowa Human Subjects Office.

VII. EXTERNAL IRB RELIANCE PROCEDURES

- A. All non-exempt external IRB reliance requests are considered on a case by case basis by the University of Iowa *HRPP Review Committee*. The HRPP review process could involve one or more members of the UI HRPP. For studies considered greater than minimal risk, review by an IRB Chair, HSO Director, Institutional Official, Research Counsel, &/or other HRPP components may be required. Criteria reviewed by this committee include, but is not limited to, the size of the study, level of risk involved, the lead and relying study team members, institutional human research protection program committees involved, contract language (when applicable), local or state regulations, accreditation status of the institution(s) and/or expertise of the IRB.
- B. All non-exempt requests to rely on an external IRB for research occurring at the University of Iowa must be submitted via the HawkIRB system for consideration of institutional requirements and HRPP Review Committee approval. All submissions must include: a copy of the protocol, a copy of the external IRB application and/or approvals, and any consent documents (including identification of the lead PI and study coordinator)
 - a. **Please Note:** Studies conducted at the VAHCS cannot utilize a single or external IRB model. This includes projects which propose the use of Veteran's Administration facilities, equipment, research staff, or patients. Full-time VA employees may not be involved as PI, Co-I, or Sub-I on any projects requesting an external IRB model.
- C. The UI HRPP Review Committee concurrence of the external IRB reliance request means that the non-exempt research project remains under the purview of the designated External IRB for the entire lifecycle of the study. The external IRB's policies and procedures will prevail for the conduct of the research. This includes review of the:
 - a. New Project submission.
 - b. Modification(s). Any change in the conduct of a study. Changes must be reviewed and approved by the IRB of Record prior to implementation. The exception to this is when the change is necessary to eliminate apparent immediate hazards to subjects.
 - c. Continuing Review. The IRB of Record is required to review and approve all research projects at intervals appropriate to the degree of risk, but not less than once a year.
 - d. Reportable Event(s). A Reportable Event can be any unanticipated problem, serious adverse event, receipt of new information, or a form of noncompliance. Investigators are required to report these to his or her respective IRB, the IRB of Record, regulatory agencies and sponsors as applicable.
 - e. Project Closure. When a study ends, the PI must complete a Project Closure Form.
- D. All requests for the University of Iowa Institutional Review Board(s) to serve as the lead IRB of record for a multi-site study is considered by selecting the appropriate IRB of record as

designated by the affiliation of the University of Iowa Principal Investigator in the HawkIRB application. Information on this affiliation can be found in the University of Iowa Investigator's Guide in Part 1, Section 4.b.i-ii. The UI HRPP Review Committee will review the request for the University of Iowa IRB to serve as the IRB of Record for all designated research study locations outside of the University of Iowa associated campuses.

- E. The use of an sIRB for research meeting an exempt category of review is acceptable under the following conditions:
- a. Reliance can only be agreed upon for exempt categories 1-6 under [45 CFR 46.104](#).
 - b. Approval from the HRPP Director is required to rely on an external IRB for an exempt approval.
 - c. A formal reliance agreement is required if the UI IRB relies on an external IRB for a project approved under an acceptable exempt category.
 - d. A copy of all external IRB submission materials and approval documentation is required in the eResearch (HawkIRB) application.
 - e. Any subsequent modifications consistent with those outlined in section X of this SOP must be submitted either to the external IRB (if their policies require it) and to the existing eResearch submission.
 - f. All modifications not granted a formal approval by the external IRB must be reviewed and approved by an UI IRB Chair Designee prior to implementation.

VIII. IRB RELIANCE MODEL (SMART IRB)

The University of Iowa is a Participating Institution to the SMART IRB platform. SMART IRB is NOT a review board; conversely, it is a Reliance platform and accompanying Reliance Agreement including reliance terms which have been universally agreed upon by all Participating Institutions. When possible, the University of Iowa prefers to utilize the SMART IRB Reliance Agreement terms to hasten the Reliance Process. Please note; this is a preference and is not a requirement. More information about SMART IRB and the aforementioned template documents may be found by visiting the SMART IRB website at: www.smartirb.org. In the event the SMARTIRB Reliance Agreement can not be utilized, the University of Iowa retains a reliance agreement template for use.

IX. HIPAA

In accordance with §164.512(i)(1)(i)(A), the University of Iowa IRB can retain the HIPAA Privacy Board responsibilities for research activities conducted on, and on subjects originating from, sites that fall under the purview of the University of Iowa Hospitals and Clinics during the course of the review process to provide the following services:

- Approval of written authorizations from the subject (or, where appropriate, from the subject's legally authorized representative) that meet the requirements of 45 CFR §164.508(c) for the use/disclosure of PHI for research; and
- Approval of alterations to, or waivers of (in whole or in part), the authorization requirement, and maintenance of documentation of the same.

The University of Iowa IRB can also serve as the Privacy Board for a relying IRB. This will be negotiated during the collection of local context information.

X. OTHER HRPP COMMITTEE REVIEWS

All research, regardless of the IRB of record, will be required to complete section V of the HawkIRB application form to ensure appropriate HRPP review and other Institutional reviews occur as per University of Iowa policies. The responses provided in the HawkIRB application determine(s) which committee reviews will apply to the study, verification of research team member's human subjects protections training, and Institutional Conflict of Interest disclosure requirements. All committee approvals must be in place prior to final signoff to any External IRB reliance process. These committees consist of:

- ***Division of Sponsored Programs (DSP)***

The Division of Sponsored Programs processes all human research with external support that is funding from governmental or private sources. Staff in the Division of Sponsored Programs review and provide institutional sign-off for all research projects, including negotiation of contracts if applicable.

Proposals for sponsored research must be submitted under signature of the Principal Investigator and approved in turn by the appropriate departmental executives for the Principal Investigator, the Principal Investigator's collegiate dean, and the Office of the Vice President for Research and Economic Development prior to submission to the sponsoring.

The Office of the Vice President for Research and Economic Development has responsibility for approval of all sponsored research applications including budgets, budget revisions, and final agreements. DSP may act as a liaison in negotiating and managing agreement terms and conditions for sponsored research.

Departments and/or individual investigators cannot enter into Corporate or industry contracts; the University of Iowa must enter into contracts. Sponsorship of research within the University of Iowa setting may be awarded as a grant, cooperative agreement, or contract.

- ***Pharmacy and Therapeutics (P&T) Committee***

The P&T Subcommittee has been established to provide the UI Health Care administration and its clinical leadership with information and advice concerning the proper use of drugs and related products. P&T Subcommittee must review a research protocol if it involves:

- the administration of investigational new drugs or drugs that are given "off-label";
- FDA approved drugs that are given as a component of a research protocol;
- any other substance that is ingested (with the exception of enteral feedings such as baby formulas, unless they contain a non-Generally Regarded as Safe [GRAS] ingredient); or
- any other substance that is injected, inhaled, or applied to the body.

- ***Pharmacy and Therapeutics Investigational Drug Service (P&T IDS)***

The Investigational Drug Service stores, dispenses, labels, and distributes study medications. All research involving inpatient medication studies and for outpatient medication studies that involve non-FDA approved medications must use the Investigational Drug Service.

The P&T IDS Subcommittee must review research studies using drugs as described above before final release occurs by the UI HRPP.

- ***Medical Radiation Protection Committee (MRPC)***

The charge of the Medical Radiation Protection Committee is to ascertain that all experimental or research uses of radioactive materials and/or ionizing radiation in or on human beings conform to the currently accepted radiation protection regulations and practices, and the University of Iowa Radioactive Material License on file with the Iowa Department of Public Health. The committee reviews studies involving x-ray, use of radioisotopes, and lasers. This committee also serves as the University of Iowa's Radioactive Drug Research Committee. The Medical Radiation Protection Committee has developed a checklist for investigators to use to determine whether a project needs MRPC review.

- ***Institutional Biosafety Committee (IBC)***

The Institutional Biosafety Committee is responsible for ensuring that recombinant DNA activities comply with the National Institutes of Health (NIH) guidelines. The Principal Investigator is required to submit a registration document to the Environmental Health and Safety Office for all recombinant DNA experiments that are not exempt from the NIH guidelines. Institutional Biosafety Committee must review and approve the registration document prior to the initiation of the research. The Institutional Biosafety Committee will not review projects involving gene therapy until after the NIH Recombinant DNA Advisory Committee (RAC) has completed or waived its review of the protocol. The Institutional Biosafety Committee notifies the University of Iowa HRPP of its approval of projects using recombinant DNA, but the Institutional Biosafety Committee does not share its deliberations

- ***Holden Comprehensive Cancer Center Protocol Reviewing and Monitoring Committee (PRMC)***

The Protocol Review and Monitoring Committee must review all cancer clinical trials at the University of Iowa Holden Comprehensive Cancer Center (HCCC). No investigator may have access to HCCC patients or resources without approval of the Protocol Review and Monitoring Committee. All HCCC intramural studies, industry trials, or cooperative group studies require sanctioning by the Protocol Review and Monitoring Committee.

The purpose of the Protocol Review and Monitoring Committee review is to:

- Conduct a scientific review (oncologic science, pharmacy & therapeutic science, and biostatistical science) of all proposed and ongoing institutional cancer clinical research.
- Monitor all clinical cancer research protocols for sufficient progress.

- Terminate those cancer protocols that are not achieving goals in a reasonable time frame; determine prioritization of patient referrals to competing protocols.

- ***Research Billing and Compliance (RBC)***

University of Iowa Health Care, through the Joint Office for Compliance, has procedures for investigators related to billing for items and services within research studies. The procedures will streamline and centralize the research billing process, and address the risks associated with inappropriate billing to Medicare and other third-party payers.

- ***Clinical Research Unit (CRU)***

The Institute for Clinical and Translational Science Research Protocol Review Committee reviews all protocols that propose to use the Clinical Research Unit. Each protocol is evaluated for scientific merit and utilization of CRU resources. Two reviewers also critique the protocols. This committee does not share its deliberations with the University of Iowa IRB unless there are specific subject protection issues raised. Should such issues arise, the CRU notifies the IRB-01 Chair in writing following its deliberations. If the Chair agrees that the issue(s) are related to subject protection, the Chair will require the Principal Investigator to submit a modification to address the identified issue(s).

It is not a requirement to obtain CRU Advisory Committee approval prior to final approval by the University of Iowa IRB. The CRU Program Executive Director or the Associate/Assistant Program Executive Director may not Chair the CRU. Individuals receiving salary support from the CRU grant shall not be voting members of the CRU. Members of the CRU are excused from the meeting if protocols they participate in are being discussed.

- ***Nursing Research Committee (NRC)***

The Nursing Research Committee must give its approval for research within the Department of Nursing or that utilizes nurses or nursing resources at University of Iowa Health Care. This committee assures the protection of the rights and welfare of patients and nursing personnel. The Nursing Research Committee reviews studies that involve (a) the participation of patients or nursing staff, (b) procedures not normally part of the regular patient care or nursing activities of the unit or clinic, and (c) the development of instruments or procedures.

The Nursing Research Committee does not share its deliberations with the University of Iowa IRB unless there are specific subject protection issues raised by the Nursing Research Committee. Should such issues arise, the Nursing Research Committee notifies the IRB Chair in writing following its deliberations. If the Chair agrees that the issue(s) are related to subject protection, the Chair will require the Principal Investigator to submit a modification to address the identified issue(s).

XI. MODIFICATIONS AND OTHER POST-APPROVAL SUBMISSIONS

The University of Iowa Human Research Protection Program (HRPP) requires that modifications to an ongoing study be reviewed prior to integrating the changes into the study procedures.

All items listed in the following sections below must be submitted to the HSO via the HawkIRB Modification Form:

- A. Changes or Additions to;
- Consent, Assent, or other consent documents
 - Protocol documents including clarifications, letters, and summary documents
 - Investigational Brochures
 - Device-related Investigational New Drugs (IND) and Investigation Device Exemption (IDE) documents
 - Research Team Member changes
- B. Correction notices issued by the IRB of Record. For example, if the external IRB issues a revised/corrected approval notice, it will include the type of correction. Corrections can include administrative changes and additional documents reviewed.
- C. Changes to the current external IRB application content or a “yes” response to a question in a HRPP Committee checklist in Section XIV
- Section XIV contains checklists for the Human Research Protection Program (HRPP) committee(s). Depending on the study, applicable checklists will be required for HRPP committees.

XII. ROLES AND RESPONSIBILITIES

Relying on an external IRB, whether it is for a single protocol or a portion of the organization’s research portfolio creates a different set of responsibilities for both the UI HRPP and the University of Iowa research team. It is important to develop a formal written agreement which clearly delineates the roles and responsibilities of each party. In addition, there should be a working and communicative relationship between the two parties. Below are the respective responsibilities expected of the IRB of Record, relying IRB(s), the Lead Study Team, and Relying Study Team(s). These responsibilities of each role should be included in all written agreements between institutions.

A. IRB Responsibilities

i. IRB of Record Responsibilities

It is the responsibility of the IRB of Record to review and issue approval of new studies. The University of Iowa considers the following to always be responsibilities of the IRB of Record:

1. Conduct review of research according to all applicable regulations and laws, including initial review, continuing review, and review of modification to previously approved research.
2. Suspend or terminate IRB approval.
3. Reviews unanticipated problems involving risks to participants or others.
4. Review incidents of serious or continuing non-compliance.

5. Notify the researchers and organizations in writing of its decisions.
6. Make available relevant IRB minutes to the relying organization upon request.
7. When appropriate, conduct on-site or remote post-approval monitoring or audits, unless delegated to the relying organization.
8. Specify the contact person and provide contact information for the reviewing IRB.
9. Reportable events reviewed according to policies and procedures outlined by the IRB of Record. Additional reporting may occur by relying IRBs if federal funding or other local institutional policies apply
10. If items 2, 3, or 4 should occur, the IRB of Record is responsible for reporting these occurrences to the Relying IRB(s).

ii. Relying IRB Responsibilities

Each Relying IRB is responsible for ensuring compliance with respective local context issues and requirements. Relying IRBs are responsible for adhering to all content outlined in the IRB Reliance agreement (i.e. financial interest disclosure, record documentation, etc.). The University of Iowa considers the following to always be Relying Site responsibilities:

1. Researchers must comply with the determinations and requirements of the IRB of Record. The lead study team is responsible for ensuring compliance with the IRB of Record requirements at the research site.
2. Prior to the IRB of Record review, provide the IRB of Record with any local context issues relevant to the research protocol.
3. Research may be disapproved by officials of the relying organization, but they may not approve the research if it has not been approved by the designated IRB of Record.
4. The Relying IRB and the researchers acknowledge and agree to cooperate in the IRB of Record's responsibility for initial and continuing review, record keeping and reporting requirements. All information requested by the Relying IRB will be provided in a timely manner.
5. Researchers and research staff agree to disclose financial conflicts of interest according to the agreed upon process and comply with any conflict management plans that may result. If their institution has a PHS-compliant conflict of interest policy, they must comply with all aspects of that policy. All managed financial conflicts of interest will be reported to the IRB of Record. If a Relying IRB does not have a PHS-compliant conflict of interest policy, it will follow the conflict of interest policy of the IRB of Record.
6. The Relying IRB or researchers will report promptly to the IRB of Record any proposed changes in the research. The investigator will not initiate changes in the research (including changes in the consent document) without prior IRB of Record review and approval, except where necessary to eliminate apparent immediate hazards to the participants.

7. Researchers will not enroll individuals in research prior to review and approval by the IRB of Record.
8. The researchers, when responsible for enrolling participants, will obtain, document, and maintain records of consent for each participant or each participants legally authorized representative as stipulated by the IRB of Record.
9. Researchers will report to the IRB of Record any unanticipated problems involving risks to participants or others according to the IRB of Record's reporting policy.
10. Researchers will provide any data safety monitoring reports they receive, either at continuing review, upon request by the IRB of Record, or on an emergent basis if appropriate.
11. Researchers will report, to the IRB of Record, any non-compliance, research misconduct, or protocol deviations according to the IRB of Record's reporting policy. If a University of Iowa researcher reports such an instance to the IRB of Record, the IRB of Record will report it to the UI IRB.
12. Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.
13. The organization and researchers acknowledge that they are primarily responsible for safeguarding the rights and welfare of each research participant, and that the participant's rights and welfare must take precedence over the goals and requirements of the research.
14. The relying IRB may conduct post-approval monitoring in addition to, or in cooperation with, the IRB of Record.
15. The written agreement does not preclude the organization or researchers from taking part in research not covered by the agreement.
16. Specify points of contact for both the research team and the relying IRB to the IRB of Record for ongoing communication.

B. Study Team Responsibilities

i. Lead Site Study Team Responsibilities

The lead study team will typically be the study team affiliated with the institution serving as the IRB of Record. The Lead Site Study Team's responsibilities include, but are not limited to:

1. Serve as the coordinating center for the study. This includes coordinating communication across sites throughout the course of the study and ensuring that all participating sites are provided with the IRB-approved versions of all study documents (e.g. consent and authorization forms, protocol, recruitment materials).
2. Designate a single point of contact whose responsibilities will include responding to questions or requests for information from the study teams at relying sites.
3. Assist study teams from relying sites in ensuring consent documents use the IRB of Record's template form and include the applicable institutional required language (e.g. compensation for injury, who to contact with questions) from each relying site.

4. Notify other study teams' points of contact of all IRB of Record determinations and communications, including those for initial review, continuing review, amendments, and reportable events.
5. Upon request, provide access to study records for audit by the relying sites' institutions, the IRB of Record's institution, and other regulatory or monitoring entities.
6. Obtain information from relying sites regarding local variations in study conduct, such as in regard to recruitment materials and process, consent process, and subject identification process.

ii. Relying Site Study Team Responsibilities

Study teams from sites which are approved to rely on UI IRB as a single IRB of Record for a study have responsibilities that include, but are not limited to the following:

1. Designate a single point of contact. The primary role of the point of contact is to serve as the single point of contact for the study team throughout the review process and after the study has been approved by the UI IRB of Record.
2. Promptly respond to questions or requests for information from the lead study team.
3. Each relying site study team will be responsible for drafting consent documents using the UI IRB of Record template, including applicable institutionally required language (e.g. compensation for injury, who to contact with questions) from the relying site.
4. Upon request, provide access to study records for audit by the relying site's institution, the IRB of Record's institution, and other regulatory or monitoring entities.
5. Report to the lead study team any changes (including funding changes and personnel changes), reportable events, and information applicable for continuing review progress reports in accordance with the UI IRB of Record's policies and procedures.

C. Reportable Events – When Should You Report and to Whom?

UI as the Lead Site:

The lead site is responsible for ensuring all REFS from both Iowa's site and all relying sites are reported. All REFS, regardless of site, need to be entered in HawkIRB within 10 days of either:

- A) the event occurring; or
- B) the research team became aware of the incident

Note that the 10-day timeframe includes any time the relying site takes to report to the University of Iowa PI. These timeframes should be defined in your communication plan and in HawkIRB section VII.A.

The University of Iowa currently has five categories for reporting REFS as defined by the [UI Investigator's Guide](#):

- Noncompliance with federal regulations or the requirements or determinations of the IRB

- An unanticipated problem involving risks to subjects or others which occurs in a subject enrolled by a UI investigator/research team member or that would impact subjects or conduct of the study at UI
- A serious adverse drug event (either expected or unexpected) occurring in a subject enrolled by a UI investigator/research team member
- A serious adverse device effect (either anticipated or unanticipated) occurring in any subject enrolled either by the UI investigator/research team member or enrolled by a non-UI investigator at another site
- Receipt of new information that may impact the willingness of subjects to participate or continue participation in the research study

The PI may need to communicate certain REFs to all relying sites depending on the severity and impact to either subject safety or the conduct of the study itself.

The IRB will review each REF. Determinations of Unanticipated Problems and Serious and/or Continuing Noncompliance are made by a convened board, and the University may have regulatory reporting requirements (depending on funding source).

UI as a Relying Site:

The UI PI is responsible for reporting all REFS occurring at the University of Iowa to the Lead IRB consistent with the Lead IRB’s reportable events guidance and the timeframes established by the Lead IRB. In addition, REFS will need to be submitted through HawkIRB if they fall into one of the following categories:

- Any REF occurring at the University of Iowa
 - Non-Compliance (Serious and/or Continuing)
 - Unanticipated Problems
 - HIPAA/Confidentiality breaches
- Events that required a change in the consent or protocol due to either a new risk, procedural change or a change in an existing risk profile. These are events that did not occur at the University of Iowa but still impact Iowa subjects. These will be New Information REFS.

Other sites’ REFS do not need to be reflected in HawkIRB unless instructed to do so by the Lead IRB.

XIII. FINAL CONSIDERATIONS

This SOP is a generalized account of the External IRB and sIRB processes and does not account for the use of WIRB or other Commercial IRBs. As previously mentioned, External and sIRB studies are reviewed on a case-by-case basis, and individual studies may be subject to minor variations. As such, it is important that researchers maintain communication with the University of Iowa External IRB Coordinator throughout the application and review process to ensure all procedures are conducted in agreement with all policies and regulations.

