University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
Revision #6	**TITLE: IRB Reliance**		**Page 1 of 6**
Approved By: ORI Director	Signature	Date	Date First Effective: 07-24-06
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Executive IRB Chair	Signature	Date	Revision Date: 2/20/2024

OBJECTIVE

To describe the policies and procedures for ensuring the rights and welfare of research participants are protected when the University of Kentucky (UK) Institutional Review Board (IRB) is sharing oversight of research with another organization.

GENERAL DESCRIPTION

UK protects the rights and welfare of participants when collaborating with other organizations for the oversight of research.

UK has established procedures to define the responsibilities of each institution, coordinate communication among responsible IRBs, promote compliance of all involved institutions and investigators, and manage information shared in external or multi-site research to ensure the protection of human subjects. The Office of Research Integrity (ORI) staff, in consultation with the Vice President for Research (VPR) and UK Legal Counsel, also take into consideration the source of funding for the research activity, federal regulations, specific sponsor regulations governing human research protections, and institutional policy.

UK may enter into formal agreements with other institutions that are not legal entities of UK to provide research review (i.e., to act as the Reviewing IRB), to rely on other institutions for research review, or to share IRB review. UK enters into these types of arrangements through an IRB Authorization Agreement (IAA)/Reliance Agreement or other written contract with the institution(s) in question.

Definitions

Authorization Agreement – (also called a Reliance Agreement) identifies and describes the respective authorities, roles, responsibilities, and methods of communication between an institution/organization providing the ethical review of research and a participating site relying on the institution/organization.

Central IRB (CIRB)/Single IRB (sIRB) – the selected IRB of record that conducts the ethical review of research for all participating sites of a multi-site study.

Federal wide Assurance (FWA) - a formal, written, binding attestation in which an institution ensures to the U.S. Department of Health and Human Services (HHS) that it will comply with applicable regulations governing the protection of human subjects.

Institutional Official (IO) - the signatory on the FWA filed with the Office for Human Research Protections (OHRP). OHRP requires the IO to be a high-level official who has the authority to represent the institution named in the FWA. The VPR serves as the IO for UK and is responsible for signing IAAs and Individual Investigator Agreements (IIAs) on behalf of the institution.

Multi-site research study – uses the same protocol to conduct non-exempt human subjects research at more than one site.

Participant site – entity that will rely on the IRB of another institution/organization (a.k.a. an external IRB) to carry out the IRB review of human subjects research for a multi-site study.

Relying IRB or Organization – is relying on the review of or has ceded IRB review to another IRB to provide oversight for a specific research study or set of studies. This process is also referred to as deferring IRB review.

Reviewing IRB – (also referred to as the IRB of record) the IRB that provides the ethical review of the research.

RESPONSIBILITY

Execution of SOP: Principal Investigator (PI)/Study Personnel, UK IRB, ORI Staff, VPR or designee, UK Legal Counsel, recipients of subaward agreements to conduct research involving human subjects.

PROCEDURES

When UK serves as the Reviewing IRB

1. When a UK principal investigator (PI) requests that the UK IRB serve as the reviewing IRB for a non-UK research site, the PI submits a UK specific protocol for review and approval prior to the addition of non-UK sites. The UK IRB determines on a case-by-case basis whether to review the site additions as separate protocols or as modifications to the previously approved research. If a site is added through a modification, the UK IRB decides whether to handle such a modification using expedited review procedures or the convened IRB for review.

Please note: UK limits the number of external sites to 5, whenever possible. Additionally, UK's IRB will not serve as the Reviewing IRB for exempt activities or activities deemed to be not human subject research (exceptions may be made on a case-by-case basis).

2. The relying site provides the UK IRB with general information (e.g., FWA, Point of Contact (POC)/IO, AAHRPP Accreditation status, ancillary reviews, local consent language, local laws, investigator qualifications, local resources, recruitment materials). The UK IRB considers this information when conducting its review. The relying site investigator provides this information to the UK IRB in accordance with the Reliance Communication Plan. (See Relying Site Survey.)

3. The UK IRB determines whether an investigator/research staff conflict of interest management plan, if any, allows the research to be approved at UK. (See Investigator Conflict of Interest/OSPA/IRB Coordination SOP.)

4. The UK IRB reviews the following issues for all relying sites, and ensures reporting of such events in accord with the requirements specified in the reliance agreement:
   - Suspension or termination of IRB approval;
   - All unanticipated problems involving risks to participants or others; and
   - Requests for audits of research protocols.

   (See Protocol Violation Review, Termination or Suspension of Research by the IRB, and Administrative Assessment Review SOPs for additional information.)

5. The UK IRB does not review Health Insurance Portability and Accountability Act of 1996 (HIPAA) for organizations outside of UK's covered entity. Each relying site must comply with its own institution's HIPAA policies and procedures.

6. The UK IRB notifies the investigators (and if applicable, the external organization) of its review decisions consistent with any reliance agreement and the Reliance Communication Plan.

7. The UK IRB makes available relevant IRB records, including (but not limited to) minutes, approved protocols, consent documents, and other records that document the IRB's determinations to the relying organization upon request.

8. The ORI website contains relevant IRB policies readily available to the relying organization, including its Human Research Protection Program (HRPP) staff and investigators/research staff. The ORI communicates updates via the UK ORI Listserv, which is distributed to subscribed UK investigators. The UK investigator forwards applicable updates to collaborators at relying organizations. (See "A Principal Investigator's Guide to Responsibilities, Qualifications, Records, and Documentation of Human Research.")

9. The UK IRB provides contact information to investigators/research staff to obtain answers to questions, express concerns, and convey suggestions regarding IRB review.

When UK relies on an External IRB

1. The UK investigator submits a written request (i.e., a Reliance Request Form) to defer IRB review to another organization. UK will defer IRB review to an external organization when a non-Exempt study is federally funded by an agency or department that has adopted the Revised Common Rule and both institutions are engaged in research activities.

A researcher may request to use a single IRB for a non-federally funded study, but it is reviewed on a case-by-case basis. Determinations may be made by the VPR, the ORI Director, and/or the ORI Reliance Manager in consultation with UK Legal Counsel and/or UK IRB Leadership. Some of the items that are considered for non-federally funded studies include: risk level of the project, accreditation status of the external institution, and anticipated oversight by the Reviewing IRB.

Please Note: UK's IRB does not sign reliance agreements for exempt activities or activities deemed to be not human subject research (exceptions may be made on a case-by-case basis).

2. The UK IRB/ORI Reliance team ensures that UK investigators understand the activities that are eligible for review by another IRB and/or the requirements to obtain approval from other UK committees (e.g., the Institutional Biosafety Committee (IBC)) by maintaining the IRB Reliance tab on the ORI website and meeting with investigators individually as necessary. The Reliance team also provides the Reviewing IRB with local research context issues relevant to the IRB's determinations and notifies the Reviewing IRB when local policies are updated (see the Reliance Communications Plan).

3. The UK IRB reviews authorization forms and/or waiver of authorization forms for UK investigators. UK's IRB may allow the external IRB to review authorization forms if the external IRB agrees to incorporate UK's authorization template language in the combined consent/authorization form. UK does not allow other institutions to act as the Privacy Board on behalf of UK.

4. The UK investigator complies with the reviewing IRB's policies and procedures for initial and continuing review, record keeping, and reporting requirements. All information requested by the reviewing IRB must be provided by the investigator in a timely manner. (See Reliance Communication Plan and the PI Responsibilities and Qualifications Guidance document.)

Organizational Responsibilities

The UK IRB requires a written agreement to be completed between organizations involved in a reliance relationship. The written agreement describes which organization (reviewing or relying) is responsible for the following:

- Human subjects research education qualifications of investigators and research staff;

- Scientific review (if applicable);
- Review of potential non-compliance, including complaints, protocol deviations, and results of audits:
  - Identifying which organization is responsible for deciding whether each allegation of non-compliance has a basis in fact;
  - Identifying which organization's process is used to decide whether each incident of non-compliance is serious or continuing;
- Management plans for investigators and research staff when a conflict of interest exists;
- Management of organizational conflict of interest related to the research; and
- Continued oversight of active studies until closure or a mutually agreed upon transfer of the studies, should a reliance agreement be terminated.

Protocols under U.S. Department of Health and Human Services (HHS) & U.S. Food and Drug Administration (FDA) purview

The UK IRB requires a written agreement (i.e., a Communication Plan and/or Local Context Form) to be completed between the organizations involved in the reliance relationship. The written agreement(s) outline(s) which organization (reviewing or relying) is responsible for determining the following:

- Whether the relying organization applies its FWA to some or all research and ensuring the IRB review is consistent with the relying organization's FWA;
- Which organization is responsible for obtaining additional approvals, if necessary, from HHS when the research involves: pregnant women, fetuses, and/or neonates; children; and/or prisoners; and
- Which organization is responsible for reporting serious or continuing non-compliance, unanticipated problems involving risks to subjects or others, and suspensions or terminations of IRB or EC approval to the Reviewing and Relying sites, funding agencies, and/or sponsors as required.

Protocols under the NIH Single IRB Policy

The NIH requirement for single IRB (sIRB) review applies to awardees and participating research sites within the United States. For nonexempt protocols that fall under the NIH Single IRB policy, the UK IRB requires a written agreement to be completed between the organizations involved in the reliance relationship. The written agreement describes the responsibility for:

- Ensuring reliance agreements are in place and that documentation is maintained;
- Additional certification requirements such as the NIH Genomic Data Sharing Policy; and
- Determining the reliance on a single IRB versus conducting local IRB review in accordance with NIH policy on exceptions from single IRB review.

Non-AAHRPP Accredited IRB's

1. UK may agree to defer responsibility for IRB review to a non-AAHRPP accredited institution's IRB for research that is not greater than minimal risk. To defer responsibility, the non-UK IRB must have an OHRP-approved FWA and OHRP-registered IRB. Under the terms of the FWA, an institution guarantees that it complies with the federal regulations governing human subjects research and follows a statement of ethical principles for protecting the rights and welfare of human subjects in research. Additionally, UK requires the institution to submit documentation to the Reliance Team of the policies and procedures that cover Initial Review, Continuing Review, Adverse Event/Unanticipated Problem/Protocol Violation Review, Reporting of Serious/Continuing Non-Compliance, Unanticipated problems involving risks to subjects or others, and suspension or termination of research.

2. Assurance of compliance with the applicable laws and regulations is further documented through the completion of a written reliance agreement. UK investigators comply with UK's standard operating procedures (SOPs) as previously outlined above when relying on an external IRB.

Other HRPP Requirements

1. Ancillary reviews such as biosafety or radiation safety review are conducted by the Relying Institution, To ensure the Reviewing IRB/HRPP is appropriately informed of these reviews, UK requires the completion of a Reliance Communication Plan. The Reliance Communication Plan also documents circumstances when the external IRB must consider additional regulatory requirements such as those of the Department of Defense (DoD) and Department of Justice (DOJ).

2. UK investigators are informed of ancillary reviews and the requirements for communicating the outcomes to the Reviewing IRB in the UK Investigator's Reliance Toolkit.

REFERENCES

21 CFR 50
21 CFR 56
45 CFR 46.114
AAHRPP Standard I-9
FDA Cooperative Research Guidance
FDA Non-Local IRB Review Guidance
OHRP Engagement Memo
OHRP Terms of the Federal wide Assurance of Protection for Human Subjects

Purpose of the form: *This form can be used by Reviewing IRBs and others to identify and document key communication roles for a study. It is recommended that the form be used to document the various responsibilities. However, the form also could be used less formally to guide conversations among the Reviewing IRB, Relying Institutions, and Lead Study Team.*

Template Communication Plan for SMART IRB

Definitions

- REVIEWING IRB - Point of Contact (POC): Main person responsible for addressing questions related to the Reviewing IRB's policies and procedures and review status for a ceded study
- LEAD STUDY TEAM - POC: Main person responsible for communication with the Reviewing IRB and facilitating communication between relying site study teams and the Reviewing IRB regarding the ceded study
- RELYING SITE - POC: Main person responsible for communication with the Reviewing IRB and local study team regarding the ceded study (e.g., personnel in the local IRB office or local human research protection program personnel)
- RELYING SITE STUDY TEAM POC: Main person responsible for communication with the Lead Study Team regarding the ceded study

Role	Name(s)	Contact Information
REVIEWING IRB – POC		
LEAD STUDY TEAM - POC		

Communication Plan

Communication Responsibility	Responsible Party	Notes
COI: Providing applicable conflict of interest management plans for relying site study teams to the Reviewing IRB	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	
STUDY TEAM TRAINING / QUALIFICATIONS / RESOURCES: Providing confirmation to the Reviewing IRB that relying site study teams have completed relevant training and are qualified to conduct the proposed research and have adequate resources to conduct the study	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	
LOCAL CONTEXT INFORMATION: Providing local context information to the Reviewing IRB regarding state laws and institutional requirements that pertain to the review of the ceded study	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s)	

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, through grant number 3UL1TR002541-01S1.

Purpose of the form: *This form can be used by Reviewing IRBs and others to identify and document key communication roles for a study. It is recommended that the form be used to document the various responsibilities. However, the form also could be used less formally to guide conversations among the Reviewing IRB, Relying Institutions, and Lead Study Team.*

Communication Responsibility	Responsible Party	Notes
	☐ Other, specify:	
IRB APPLICATION – STUDYWIDE: Preparing and submitting the studywide application for initial IRB review and studywide amendments to the Reviewing IRB	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	
IRB APPLICATION – SITE-SPECIFIC: Preparing and submitting the site-specific applications and site-specific amendments to the Reviewing IRB that address site variations in study conduct, informed consent language, HIPAA Privacy Rule requirements, subject identification and recruitment processes (including recruitment materials), and any other applicable components of the research	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	
IRB DETERMINATIONS: Providing documentation of IRB determinations to relying site study teams. Reviewing IRB will obtain additional approvals from DHHS for prisoners, children, pregnant women, and/or neonates as necessary.	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	
IRB-APPROVED DOCUMENTS: Providing copies of IRB-approved materials to the lead study team	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team ☐ Relying Site POC ☐ Other, specify:	

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Purpose of the form: *This form can be used by Reviewing IRBs and others to identify and document key communication roles for a study. It is recommended that the form be used to document the various responsibilities. However, the form also could be used less formally to guide conversations among the Reviewing IRB, Relying Institutions, and Lead Study Team.*

Communication Responsibility	Responsible Party	Notes
IRB-APPROVED DOCUMENTS – RELYING SITES: Providing copies of the most current versions of IRB-approved materials to relying site study teams in a timely manner	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	
CONSENT FORM TEMPLATE: Providing the consent form template to relying site study teams	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	
CONSENT FORM LANGUAGE: Incorporating site-specific language into consent form(s) and providing these consent form(s) to the Reviewing IRB	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	
REVIEWING IRB POLICIES: Providing relevant Reviewing IRB policies to the lead study team	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	
CONTINUING REVIEW INFORMATION: Obtaining and collating studywide information for continuing review to the Reviewing IRB	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s)	

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Purpose of the form: *This form can be used by Reviewing IRBs and others to identify and document key communication roles for a study. It is recommended that the form be used to document the various responsibilities. However, the form also could be used less formally to guide conversations among the Reviewing IRB, Relying Institutions, and Lead Study Team.*

Communication Responsibility	Responsible Party	Notes
	☐ Other, specify:	
CONTINUING REVIEW SUBMISSION: Submitting continuing review progress report to the Reviewing IRB	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	
REPORTABLE EVENTS: Reporting reportable events to the Reviewing IRB (e.g., unanticipated problems, noncompliance, subject complaints)	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	
CLOSURE REPORTS: Providing the Reviewing IRB with required information when a study is closed.	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	

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IRB Reliance Request/Registration Form

The purpose of this form is to facilitate the decision-making process in choosing the relied-upon IRB for cooperative research. The Office of Research Integrity (ORI) supports multi-site collaborations and will try to eliminate, where possible, multiple IRB reviews. The request will be considered by ORI and decisions will be made on a case-by- case basis.

You may be asked to submit a copy of the full protocol or other information to ORI to aid in the decision-making process. The reliance arrangement must be approved by the ORI staff, and may involve consultation with UK Legal Counsel, the UK IRB Chair, and the UK Vice President for Research. IRB Reliance arrangements may also require the completion of a detailed agreement that clearly outlines the responsibilities of each site.

Please follow the appropriate checklist in order to ensure completion of all documentation requirements: Lead PI Checklist or Relying PI Checklist.

General inquiries/questions about IRB reliance and the University of Kentucky's policies and procedures may be submitted to: IRBReliance@uky.edu.

Definitions:

Reviewing IRB - The IRB of record that provides review services for multiple sites. It is relied upon by other sites. Relying IRB

- The IRB of an institution which will not be the IRB of record, but will rely on the Reviewing IRB.

***PLEASE NOTE: If the project meets criteria for an exempt application, there is a possibility that one or both institutions will require local IRB review.**

I. Initial Reliance Determination Questions		
Is the protocol non-exempt (i.e., the protocol does not meet any exemption criteria as defined by 45 CFR 46.104)?	**Yes** ☐	**No** ☐
Will the protocol receive Federal Funding (i.e., NIH, HHS, etc.)?	**Yes** ☐	**No** ☐
Are Study Personnel from the proposed Relying Institution intervening, interacting, consenting, and/or viewing identifiable participant information?	**Yes** ☐	**No** ☐
Does the Reviewing IRB require single IRB (if so, please attach the letter from the institution stating this)?	**Yes** ☐	**No** ☐
Will the protocol receive funding from the:		
FDA?	**Yes** ☐	**No** ☐
DoD?	**Yes** ☐	**No** ☐

II. UK PI/Protocol Information	
University of Kentucky Principal Investigator:	
Title of Protocol:	
Sponsor (funding):	
Is UK the primary awardee? **Yes** ☐ **No** ☐	
What is the Risk Assessment Level?	
Briefly describe the study. Additionally, explain the roles and responsibilities of the UK researchers (ex. informing reviewing IRB of changes in research, consenting subjects, study team training and qualifications, using site-specific language in consents, etc.):	

III. Non-UK Site Information	
Non-UK Site Principal Investigator:	
Institution Name:	

Is the non-UK Institution accredited by AAHRPP?

Yes ☐ **No** ☐

If No, please answer the following questions:
Has the institution's HRPP/IRB been cited in the last three years by FDA or OHRP?

N/A ☐ **Yes** ☐ **No** ☐

Can the institution's HRPP/IRB leadership attest that it has completed its own internal quality review process (i.e., use of AAHRPP's Evaluation Instrument for Accreditation to conduct a self-assessment, completion of the US FDA's self-evaluation checklist for IRBs or ECs, or an equivalent process)?

N/A ☐ **Yes** ☐ **No** ☐

4. Please submit to irbreliance@uky.edu this institution's HRPP/IRB policies and/or procedures regarding the following*:

- **a. Initial Review**
- **b. Continuing Review**
- **c. Adverse Event/Unanticipated Problem/Protocol Violation Review**
- **d. Reporting of serious/continuing noncompliance, unanticipated problems involving risks to subjects or others, suspension or termination of research**

***Please note, upon review, additional policies/procedures may be requested by UK's HRPP staff.**

Federalwide Assurance (FWA) Number: *If the institution does not have an FWA, please type N/A in the space provided.	
List the research sites that will be relying on the Reviewing IRB.	
Briefly describe the study. Additionally, explain the roles and responsibilities of the Site's Reviewing researchers (ex. providing IRB-approved documents, consenting subjects, reportable events determinations, continuing review, closure reports, etc.):	

IV. IRB Information	
Is there a preferred reviewing external IRB? If yes, please list name of the IRB.	
Provide any other information you think is pertinent to the decision-making process:	

Reliance Agreement
Signature Assurances

Study Title: _____

Principal Investigator's Assurance Statement:

I understand the University of Kentucky's policies concerning research involving human subjects and I agree:

To comply with all of the Reviewing/Relying IRB's and the UK IRB/Human Research Protection Program's (HRPP) policies, decisions, conditions, and requirements. Please see the PI Responsibilities, Sections VII & VIII for a detailed list which includes, but is not limited to the following:

- To accept responsibility for the scientific and ethical conduct of the research study.
- To obtain prior approval from the Reviewing IRB before amending or altering the research protocol or implementing changes in the approved consent/assent form.
- To report to the Reviewing/Relying IRB and the UK IRB, in accordance with IRB and Institutional policies, any adverse event(s) and/or unanticipated problem(s) involving risks to subjects. Each institution may have unique policies and procedures for reporting.
- To complete, on request from the Reviewing IRB, the Continuation/Final Review Forms.
- To notify the UK Office of Sponsored Projects Administration (OSPA) and the UK IRB of the development of any financial conflict of interest not already disclosed.
- To verify that each individual listed as study personnel at UK for this application has completed the mandatory human research protections education (e.g. CITI).
- To verify that each individual listed as study personnel at UK for this application possesses the necessary experience and qualifications for conducting the research activities in the role described for this research study.

Furthermore, by signing below, I also attest that I have appropriate facilities and resources for conducting the study.

SIGNATURE _____ DATE _____

Printed Name _____

FOR OFFICIAL ORI USE ONLY

Based on the information provided above, the University of Kentucky Office of Research Integrity Reliance team has determined that a Single IRB is:

Needed ☐ Not Needed ☐

Will UK act as the Reviewing IRB or Rely on another IRB?

N/A ☐ Review ☐ Rely ☐

Reliance Team Member Signature _____ DATE _____

Purpose: When the Overall Principal Investigator and/or Lead Study Team is located at UK, this document can be used to provide them with guidance regarding the additional responsibilities accrued in assuming that role.

Overall Principal Investigator/Lead Study Team Guidance and Checklist

As the Overall Principal Investigator for a study for which research activities involving human subjects will be overseen by the UK IRB for all or most sites, you should be aware of your additional responsibilities in assuming that role. Once you have agreed to collaborate with investigators at another institution and intend to use a single IRB (sIRB) for oversight of this study:

You should contact the IRB Reliance Staff at UK to:

- ☐ Discuss whether UK's IRB can act as the sIRB for all or some institutions participating in this study or whether another external IRB would be appropriate.
- ☐ Identify who will act in the role of the Lead Study Team (e.g., your own study team, a coordinating center, or both). The Lead Study Team assumes additional responsibilities when sIRB review will be used.
- ☐ Provide relying sites with details about the study, including the studywide protocol and template consent document(s), which will help facilitate the discussion with the UK IRB/HRPP.
- ☐ Identify all sites that will be engaged in human subjects research and thus need IRB coverage.

If UK agrees to serve as sIRB for the study, you will need to ensure the Lead Study Team does the following:

- ☐ Completes a reliance request with the UK IRB using the process required by the UK HRPP.
- ☐ Works in collaboration with the UK IRB to determine and document specific roles and responsibilities for communicating and coordinating key information to Relying Institutions; this includes developing a plan for communicating with collaborators across the lifetime of the study (i.e. regular conference calls, site initiation procedures and training materials).
- ☐ Promptly responds to questions or requests for information from study teams and IRB/HRPP personnel at institutions who are relying on the UK IRB.
- ☐ Participates in conference calls regarding a study as requested.
- ☐ Provides the Site Investigators with the IRB policies of the UK IRB. This includes, but is not limited to, policies for reporting unanticipated problems, noncompliance, and subject complaints.
- ☐ Provides participating Relying Site Study Teams with the IRB-approved versions of all study documents (e.g., consent and authorization forms, protocol, recruitment materials).
- ☐ Prepares and submits IRB applications on behalf of all sites (UK and relying), including initial reviews, local amendments, personnel updates, local reportable events, and studywide information for continuing review.

As part of preparing the IRB application, the Lead Study Team (or designee) must:

- ☐ Have a mechanism in place to obtain and collate information from Relying Site Study Teams and/or Relying Site Points of Contacts (POCs), depending on who is designated to provide that information at the Relying Institution, regarding local variations in study conduct, such as recruitment materials and process, consent process and language, and subject identification processes.

- ☐ Assist Relying Site Study Teams and/or POCs at the Relying Institution(s), depending on who is designated to provide that information, in ensuring consent documents follow the UK IRB's template form and include applicable local institutional required language from each Relying Institution.

☐ Notifies Site Investigators of all UK IRB determinations and communications, including those for initial review, continuing review, amendments, reportable events, suspensions, and terminations.

☐ When agreed upon, in coordination with the UK IRB, promptly reports to the Site Investigator (or designee on the Relying Site Study Team) any unanticipated problems involving risks to subjects or others, research-related subject injuries, or subject complaints that are related to or may affect subjects participating in the research (i.e., the specific study or studies ceded to the UK IRB) at the Relying Institution.

☐ If a Relying Site Study Team does not provide the Lead Study Team (or designee) with the site-specific required progress report information before the continuing review application is submitted to the UK IRB, reports the absence of this information as part of the continuing review and notifying affected Relying Site Study Team of lapse in approval for their site and any applicable corrective action plans.

☐ Providing access, upon request, to study records for audit by the Relying Institution, the UK IRB, and other regulatory or monitoring entities.

☐ Follow all requirements of the Relying Institution with regard to ceded review, such as ensuring administrative requirements for documenting ceded review have been met before study activation occurs at a Relying Institution.

Purpose: When a study is under the oversight of an IRB external to UK, this document can be used to provide UK's local study team with guidance regarding the investigator's responsibilities.

Relying Investigator Guidance and Checklist

As Principal Investigator (PI) at UK (**Relying Institution)** for a study that may be overseen by an external IRB, you should be aware of your responsibilities. Once you have agreed to collaborate with an investigator at another institution and plan to use an external IRB for oversight of this study:

You should contact the UK IRB Reliance Staff to:

- ☐ Discuss whether ceding IRB oversight to an external IRB is appropriate.
- ☐ Provide UK IRB Reliance Staff with details about the study (including your study team's role), the proposed reviewing IRB, and the lead PI's name and institution. Complete a Reliance Request Form and a General Information Sheet (GIS). Both documents can be found on UK ORI's Reliance Webpage.
    - ☐ Obtain a copy of the studywide protocol and template consent documents(s), which will help facilitate the discussion with the UK Reliance Staff and the IRB.

If the UK IRB agrees to cede review to an external IRB, you will be asked to:

Provide the UK IRB with:

- ☐ The names and roles of all key study personnel on the UK study team.
- ☐ Any management plans for potential conflicts of interest (COI) relevant to the study that will be ceded to the external IRB, including any new or altered management plans put in place throughout the lifespan of the study.

- ☐ Register the study at UK according to local processes (such as creating an abbreviated application in the E-IRB, or submitting pertinent study documents via e-mail). See "*Steps to Creating an Abbreviated sIRB*..."
- ☐ Promptly respond to questions or requests for information from the Lead Study Team/PI/Reviewing IRB.
- ☐ Participate, as required, in conference calls regarding the study as requested by the Lead Study Team/PI, Reviewing IRB, or UK IRB/HRPP.
- ☐ Become familiar with the reportable event policy of the Reviewing IRB to ensure that you appropriately report protocol deviations/violations, noncompliance, significant subject complaints, subject injuries, unanticipated problems, or other events required by the Reviewing IRB to be reported and within the timeframes required.
- ☐ Ensure completion of all local reviews and sign offs that, in addition to IRB approval, are in place before a study is activated, such as coverage analysis, department approvals, data use agreements, material transfer agreements, ancillary committee reviews (e.g., radiology, nursing, and pharmacy).
- ☐ Work with the Lead Study Team and the Reliance staff from UK's IRB/HRPP to incorporate locally required language into the consent template to be used by the local study team, such as institutionally required compensation for injury language, local study team contact information, and additional costs that subjects may incur that differ from those identified in the template consent form.
- ☐ For externally funded studies, provide OSPA with documentation that IRB oversight for a study has been ceded to and approved by an external IRB.

☐ Notify UK ORI Reliance Staff of any staff changes so they can confirm training is current and help ensure any relevant COI management plans are communicated to the Reviewing IRB.

Notify the lead PI of:

- ☐ Any reportable events that occur locally, according to regulations and the Reviewing IRB's policy.
- ☐ Any changes (including those related to funding and personnel) in accordance with the Reviewing IRB's policies and procedures for timing and content of such submissions.
- ☐ Any management plans, including any updates to these plans, as relevant to the study
- ☐ Any applicable information for continuing review progress reports in accordance with the Reviewing IRB's policies and procedures for timing and content of such submissions.

☐ Follow all determinations of the Reviewing IRB.

☐ Only implement changes of protocol, including local variations, after the Reviewing IRB has approved them, except in cases where a change is required to avoid an apparent immediate hazard to participants.

☐ Provide, upon request, access to study records for audit by the UK HRPP/IRB, the Reviewing IRB's institution, and other regulatory or monitoring entities.

This survey template can be sent by a Reviewing IRB to a relying institution SMART IRB Point of Contact (POC) to obtain key local context information.

Potential Relying Site SMART IRB Point of Contact Survey

General Information

1. Name of Study:

2. Overall Principal Investigator:

3. Proposed Reviewing IRB:

4. Name of Relying Institution:

5. Name and title of person completing this survey:

6. Has the institution's FWA (federal wide assurance) been extended to non-federally funded research?
   ○ Yes ○ No

7. Provide any other names the site is known by:

8. Please identify any affiliations this site has relevant to this study, such as a university, clinic, or hospital. Note: This information is collected to allow us to confirm that all sites engaged in the research are covered by a reliance arrangement and to identify relationships between institutions.

9. If any of the sites identified in question 8 are within a network or system, do they have a separate FWA?
   ○ Yes ○ No

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10. If you answered “yes” to question 9, please identify the sites with the separate FWAs.

11. Are there any investigations, audits, or findings (e.g., OHRP, FDA, or local audits) over the past three years that would be relevant to the conduct of new human subjects research proposed at the site?

    ○ Yes ○ No

12. If the answer to question 11 was “yes”, please explain any investigations, audits or findings that may be relevant.

13. Does the institution have a post approval monitoring program or other regulatory oversight for ongoing research?

    ○ Yes ○ No

14. If the answer to question 13 was “yes”, does the post approval monitoring program or other regulatory oversight monitor studies that have been deferred to an external IRB?

    ○ Yes ○ No

15. If the answer to question 13 was “yes”, please provide a link (URL) to the post approval monitoring program/ regulatory oversight information, or paste information here.

Local Context Information

1. Are there any state laws that the Reviewing IRB will need to consider when reviewing this study?

   ○ Yes ○ No

2. If the answer to question 1 is “yes”, please describe the relevant state laws and provide a link to any key documents (e.g., institutional policy for applying state law or link to the statute).

3. Are there any community or cultural differences for the local population of subjects that require consideration?

   ○ Yes ○ No

4. If the answer to question 3 is “yes”, please describe the relevant information.

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5. Is 18 the age of majority for the state in which your site is located?
   ○ Yes ○ No
6. If the answer to question 5 is "no", please identify the age of majority.

7. Does the institution require approval of a waiver of authorization under HIPAA for review of medical records to identify eligible subjects (e.g., the institution does NOT consider this "Preparatory to Research" activities)?
   ○ Yes ○ No ○ Not applicable – the HIPAA Privacy Rule does not apply to this study or institution.

Site Policies

1. Does the site have a posted policy for the following? NOTE: Please only select those for which there is a posted institution policy; generally accepted practice and guidance are not policy.

   ☐ Age of Assent Policy

   If selected, please provide a link (URL) to the policy, or paste the policy below

   ☐ Consent Process for those with Impaired Decision-Making Capacity

   If selected, please provide a link (URL) to the policy, or paste the policy below

   ☐ Use of short forms for non-English speaking individuals

   If selected, please provide a link (URL) to the policy, or paste the policy below

   ☐ Translation of consent forms for non-English speaking individuals

   If selected, please provide a link (URL) to the policy, or paste the policy below

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2. Please provide any institutionally-required consent form language for compensation in the event of research-related injury:

3. Please provide any institutionally-required consent form language for pregnancy testing in minors:

4. Please provide any institutionally-required consent form language for genetic testing:

5. Please provide any other consent form language required by site policy or state law:

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