

University of Kentucky Office of Research Integrity (ORI) OFF-SITE RESEARCH GUIDANCE

Research activities conducted at performance sites that are not owned or operated by the University of Kentucky, at sites that are geographically separate from UK, or at sites that do not fall under the UK IRB's authority are subject to special procedures for the coordination of research review. The term *off-site research* designates research meeting any one of these criteria.

Off-site research may involve more than one institutional review board (IRB) responsible for research oversight. In these cases, UK has established additional procedures to define the responsibilities of each IRB, coordinate communication among responsible IRBs, and manage information obtained in off-site or multi-site research to ensure protection of human subjects. Research procedures should not be initiated at an off-site location prior to IRB review of the appropriate documentation for that site.

Investigators conducting research at Shriners Hospital for Children are not required to provide this information.

General Requirements in the IRB Application for Off-Site Research:

- Complete Item #16 in the Medical IRB General Information Sheet/#14 in the Nonmedical IRB General Information Sheet.
- Complete "Form N" (Off-Site Research form).
- Submit appropriate supplementary documentation as needed (letters of support, information about participating sites, non-UK IRB approval letters, etc.) These items should be submitted prior to IRB review at UK if at all possible.

Types of Off-Site Research and Associated Requirements

I. Cooperative Research

Cooperative research is defined as research conducted in cooperation with and at a performance site of an institution or facility that is not affiliated with UK or that does not fall under the UK IRB's authority. An off-site institution or facility may be domestic or international and may or may not have its own IRB.

Step 1: Determine if the non-UK institution is "engaged" in the human subject research activity.

An institution becomes "engaged" in human subjects research when its employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes (45 CFR 46.102(d),(f)). Examples of engagement are included in the OHRP Guidance Document, "Engagement of Institutions in Research." (<http://www.hhs.gov/ohrp/policy/Correspondence/ohrp20090113.html>).

Step 2: Determine additional requirements for engaged vs. non-engaged non-UK institutions.

A. If the non-UK institution IS NOT engaged in the research:

Submit a letter from the appropriate administrator of the non-UK institution (on the facility's letterhead stationery), that addresses the following items:

1. Agreement of the institution's administration for the study to be conducted at that site;
2. Review of the project by someone at the facility with respect to the issues of appropriateness for its human subject population, and adequacy of the facility to perform the procedures as approved by the UK IRB;
3. Written confirmation that the facility personnel have the appropriate expertise to carry out the research procedures as reviewed and approved by the IRB.

B. If the non-UK institution IS engaged in the research:

Submit a letter from the appropriate administrator of the non-UK institution (on the facility's letterhead stationery), that addresses the following items:

1. Agreement of the institution's administration for the study to be conducted at that site;
2. Review of the project by someone at the facility with respect to the issues of appropriateness for its human subject population, and adequacy of the facility to perform the procedures as approved by the UK IRB;
3. Written confirmation that the facility personnel have the appropriate expertise to carry out the research procedures as reviewed and approved by the IRB;
4. Assurance that personnel from the facility who are involved in data collection have appropriate training in human subject research protection.

Step 3: Determine whether or not an assurance mechanism is required for engaged sites.

If the research is supported or conducted by a division of the Department of Health and Human Services, such as the National Institutes of Health, a Federalwide Assurance of Compliance (FWA) for **each** separate institution must be approved by the Office for Human Research Protections (OHRP). The FWA is submitted from each separate institution directly to OHRP. Additional information, instructions and sample application forms may be found at <http://www.hhs.gov/ohrp/assurances/assurances/index.html>. If you have questions, contact Hal Blatt, (240) 453-8232 orhal.blatt@hhs.gov. If the research is supported by a federal agency that is not a division of DHHS, there may be additional requirements. Contact ORI for advice when preparing the IRB application.

Step 4: Determine the relied upon IRB for each engaged site and whether an IRB Authorization Agreement is needed.

If the cooperative site(s) has its own IRB, the University of Kentucky IRB preference is that each site be responsible for reviewing the research activities to be conducted at the respective site. The UK investigator should obtain copies of the non-UK institution's IRB approval letter and FWA number and submit them to the IRB in the application (or make arrangements to do so when the documents become available). In cases in which research undergoes joint IRB review at UK and at the non-UK institution, no IRB Authorization Agreement is necessary.

If the cooperative site(s) does not have its own IRB, University of Kentucky policy requires that (except in the limited circumstances described below) the site establish its own IRB (or contract with a "for-hire" IRB) prior to its participation in the research. The cooperative site should register its IRB with the Office for Human Research Protections (OHRP) as instructed by that agency.

Under certain limited circumstances, the UK IRB may serve as the relied upon IRB for the non-UK institution. These limited circumstances may include research that is not greater than minimal risk and the non-UK institution does not have an IRB and is not the type of

institution that would typically establish an IRB (e.g. a school system). UK may also serve as the relied upon IRB if the PI of the study is a UK employee and the study is conducted at an off-site facility. In such cases, the off-site facility signs an IRB Authorization Agreement to abide by the decisions and determinations of the UK IRB in the conduct of the research. The Vice President for Research in consultation with ORI and, if appropriate, UK Legal Counsel, makes the final determination whether the UK IRB will serve as the relied-upon IRB. The ORI staff assist the investigator in the preparation of an IRB Authorization Agreement.

The University of Kentucky may also agree to defer responsibility for IRB review to a non-UK institution's IRB under limited circumstances. To defer, the non-UK IRB must have an approved Federalwide Assurance. Circumstances when UK may defer IRB review may include: funding agency requirements; UK employee role is limited to data analysis only; the research began at another institution prior to employment of the investigator at UK, and remains active only at the other institution (and any funds supporting the research remain under control of the non-UK institution); and/or the research is not greater than minimal risk. An IRB Authorization Agreement is signed between the two institutions. The Vice President for Research in consultation with ORI and, if appropriate, with UK Legal Counsel, makes the final determination whether the UK IRB will defer review and oversight responsibility to another IRB.

II. Research Projects Involving Multiple Sites and UK is the Lead Site/Lead Investigator

1. If the University of Kentucky is the lead site in a multi-site study, or the UK investigator is the lead investigator, additional information must be provided to the UK IRB to ensure on-going communication among the participating IRBs and sites. The UK investigator should submit the following information along with the IRB application:
 - For each non-UK site, provide a contact name and contact information (e.g. phone or e-mail) and indicate who will be responsible for such contact (Provide on **Form N**);
 - For each non-UK site, submit a letter from the appropriate administrator granting permission for the research to be conducted at its site (see instructions under "Cooperative Research," above);
 - If the non-UK site has an approved Federalwide Assurance (FWA), provide the non-UK site's FWA number (Provide on **Form N**);
 - Determine the relied upon IRB for each non-UK site and submit appropriate documentation as needed (if joint review, submit a copy of the non-UK site's IRB approval letter; if relied upon review, an IRB Authorization Agreement must be completed. See the instructions under "Cooperative Research," above).
2. Additionally, the UK investigator must submit a written plan for the management of information that is relevant to the protection of human subjects, such as the reporting of unexpected problems, protocol modifications, and interim results from all participating sites. This information should be provided on **Form N**.

III. Geographically Separate Off-Site Location with No Cooperating Institution/Facility/Organization

1. In the IRB application, the PI provides the necessary information, as appropriate, on the subject populations, the cultural context, and the languages understood by the human

subjects. (Provide in “**Form B**,” the Research Description; “**Form C**,” the Informed Consent Form; and “**Form H**,” Non-English Speaking Subjects or Subjects from a Foreign Culture.)

2. If the IRB membership does not have the appropriate expertise for conducting the review, ORI staff and/or the PI assists the IRB in identifying cultural consultants following procedures outlined in the IRB Standard Operating Procedures (SOPs) (see “Initial Full Review,” “Expedited Initial Review,” and “IRB Member and Consultant Conflict of Interest.”). The PI may supply the name of an appropriate consultant in **Form N**.
3. Cultural consultants may review consent forms, provide verifications of translations, provide guidance on the impact of the research on subjects and the impact of the culture on the research to be conducted.

IV. Research at Geographically Separate UK-Owned Site with Non-UK Employees

1. The ORI staff assists the PI in determining whether the non-UK employees are actively participating in the implementation of research procedures or are obtaining individually identifiable private data about human subjects for research purposes. If the non-UK employees are engaged in the research, then the University of Kentucky human research protection policy applies to those personnel and they must complete the appropriate human subjects protection training and be listed as study personnel on the **General Information Sheet** (GIS) of the IRB application.
2. The PI provides the IRB the necessary information, as appropriate, on the subject populations, the cultural context, and the languages understood by the human subjects. (Provide in “**Form B**,” the Research Description; “**Form C**,” the Informed Consent Form; and “**Form H**,” Non-English Speaking Subjects or Subjects from a Foreign Culture.)
3. If the IRB membership does not have the appropriate expertise for conducting the review, ORI staff and/or the PI assists the IRB in identifying cultural consultants following procedures outlined in the IRB Standard Operating Procedures (SOPs) (see “Initial Full Review,” “Expedited Initial Review,” and “IRB Member and Consultant Conflict of Interest.”). The PI may supply the name of an appropriate consultant in **Form N**.

Questions about the University of Kentucky IRB Off-Site policies may be addressed to:

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