“Off-Site Research”: why does the IRB need to know?

The term “off-site research” is used to describe activities conducted at sites that:
- are not owned or operated by the University of Kentucky (UK);
- are geographically separate from UK; or
- do not fall under the UK IRB’s authority.

Cooperative research is defined as research conducted in cooperation with and at a performance site of an institution or facility (domestic or international) that is not affiliated with UK or that does not fall under the UK IRB’s authority.

The UK IRB application asks questions regarding off-site and cooperative research in order to establish and define roles and responsibilities of facilities, IRBs and personnel involved.

- Research procedures should not be initiated at an off-site location prior to IRB review of the appropriate documentation for that site.

This may include standard of care procedures IF done as part of the research protocol!

The requirements that apply to off-site research vary with each protocol, but the IRB will consider the following in performing their review:

Does the “off-site” facility approve of the conduct of the research?
To validate approval, the investigator must provide the IRB with a letter from the appropriate administrator of the non-UK institution addressing: 1. agreement for the study to be conducted at the site; 2. appropriateness for the facilities population and adequacy of the facility to perform research associated procedures; and 3. confirmation that facility personnel have the appropriate expertise to carry out any procedures as reviewed and approved by the IRB.

Is the “off-site” facility “engaged” in the research activity?
An institution is “engaged” in research when employees or agents, intervene or interact with living individuals or obtain individually identifiable private information for research purposes.

In some cases, the agents from the off-site facility are “involved” but not “engaged”. For instance, staff at a facility who perform a non-collaborative, commercial service would not be engaged as long as the activity doesn’t merit professional recognition or result in a publication and they are not involved in obtaining informed consent or administering any study intervention (i.e., a survey firm hired to conduct a survey or a clinic posting a flyer advertising a study).

If an off-site facility is “engaged”, the investigator must provide assurance that personnel from the facility who are involved in data collection have appropriate training in human subject research protection.

Is more than one IRB Involved?
Off-site research may involve more than one IRB responsible for research oversight. The investigator, ORI, and the IRB work together to determine the relied upon IRB for each engaged site. In some situations, an IRB Authorization Agreement (IAA) or an Individual Investigator Agreement (IIA) is needed 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.

Is an assurance mechanism required for “engaged” sites?
If the research is supported 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 institution must be approved by the Office for Human Research Protections (OHRP).

Are their Cultural Considerations for Geographically Separate Off-Site Locations?
Whether the research is to be conducted at a geographically separate facility or “in the field” where there is no cooperating institution or facility, the investigator must provide the IRB with information on subject populations, the cultural context, and the languages understood by the human subjects. If the IRB membership does not have the appropriate expertise for conducting the review, a cultural consultant will be identified to review consent forms, provide verification of translations, and provide guidance on any cultural issues or considerations.

Coordinating a plan for approval and oversight of off-site research at the front end can clarify roles and improve communications during the research. For additional information on off-site research and associated requirements, see the guidance documents at http://www.research.uky.edu/ori/IRB-Survival-Handbook.html#Offsite
GOT KIDS?: Enrolling children in your protocol doesn’t always mean the protocol will require “Full” review by the Convened IRB

Whether or not a protocol meets the regulatory definition of “minimal risk” is the first litmus test for determining what type of IRB review a protocol will require. Second, all of the activities involved in a minimal risk research protocol must fit at least one of the regulatory categories in order to qualify for Exempt Review or Expedited Review.

A common misperception is that research with children would never qualify for one of these review mechanisms. While federal regulations for vulnerable subjects provide additional protections for research involving children, and there are limitations to which categories apply, some minimal risk research may fit either the Exempt or Expedited review categories.

The research activities involving children that may fall under exemption are those involving educational tests or observation of public behavior where the investigators do not participate in the activity being observed. To be exempt, these activities must also meet the condition that the data are recorded without individual identifiers unless disclosure of the recorded responses would not place the subjects at risk of criminal or civil liability or be damaging financially or to their reputation or potential employability. Exempt category 2, (research involving surveys, interviews, or tests of minors) does not apply to research with children. Refer to the Issues to be Addressed when Conducting Exempt Review document for guidance.

Fortunately most Expedited review categories will apply to research with children. There are some qualifying limitations such as amount and frequency of blood collection based on age, weight, health status, etc. For guidance on Expedited review categories see the Issues to be Addressed when Conducting Expedited Review document.

The IRB ultimately makes the determination regarding which review mechanism is applicable and appropriate. Regardless of the review type, other regulations such as the Family Educational Rights and Privacy Act (FERPA) or the Health Insurance Portability and Accountability Act (HIPAA) may apply.

The UK IRB also offers policy guidance regarding ethical and regulatory issues and potential safeguards for children, K-12 students, and university students. IRB Form W mirrors the federal regulations and prompts compliance with the risk category classifications, and associated protections including parental permission, assent of a minor subjects, and other safeguards. The Office for Human Research Protections (OHRP) provides answers to frequently asked questions for research with children at http://answers.hhs.gov/ohrp/categories/1570.