When do activities need IRB review?

In response to recommendations from research faculty, the ORI and IRB are pleased to announce a new user-friendly tool for determining what activities require review and approval from the IRB.

**When do activities need Institutional Review Board (IRB) review and approval?** provides examples and categories of what does and does not require IRB review in an easy-to-view table format. Descriptions and scenarios help clarify and provide interpretation for less distinct categories such as innovative procedures, feasibility reviews, or subject pools.

As always, contact ORI at 859-257-9428 with additional questions or to obtain an official IRB review requirement determination letter for a specific activity.

**IRB Review of Medical Device Research**

One of the last guidance documents released by the Food and Drug Administration (FDA) in 2012 was draft FDA guidance on IRB review of investigator qualifications and determinations of whether an Investigational New Drug (IND) or Investigational Device Exemption (IDE) is needed. Recently the *IRB Medical Device Form P* was updated to better categorize studies that may be exempt from IDE requirements, studies subject to abbreviated IDE requirements, and studies subject to full IDE requirements including submission of a formal IDE application to FDA.

FAQs, definitions, and scenarios to help clarify device research regulations are available in the *UK IRB Review of Medical Device Research* guidance document.

**REMEMBER**

*Download and use current versions of IRB forms for new submissions*

Form updates previously announced include:

- Updated versions of the Medical and Nonmedical Informed Consent and HIPAA Forms.
- Combined Informed Consent & HIPAA Authorization.
- Updated Form A General Information Sheet including financial disclosure question.
- Updated Form P Medical Device Form
- Deleted Financial Disclosure Form X & Y as a result of the new institutional on-line financial disclosure system [see Office of Sponsored Projects Administration website for information on the new system].

Current versions of IRB forms are available on the ORI Forms Webpage. Announcements regarding form changes are archived on the ORI ‘What’s New’ webpage.
Continuation Review Tips

It’s time to get the materials together for Continuation Review (CR)… These hints may help keep those finicky emails (about the details) out of your Inbox!

In accord with federal requirements, the IRB approval period can extend no longer than one year after the start of the approval period. When you receive your initial IRB approval it may be worth your time to take a quick look at the sample Continuation Review Form to develop a systematic plan for collecting the requested information as the study progresses. Prior to the study expiration date, ORI will provide you with a CR Form pre-populated with protocol specific information. Be sure to inform ORI of any address change so that we can ensure you receive the form. Return the competed CR Form in a timely manner to allow time for IRB review and to prevent lapse of approval. Consider these tips when completing the form.

- The CR Form will include pre-populated information, (e.g., estimated project end date, number of subjects to be enrolled, etc.) based on the information you initially provided in Form A—General Information Sheet (GIS). If you need to make changes to the information, make the changes on the CR Form rather than submitting a new Form A—GIS.
- Requested changes made to the protocol, research description, and informed consent documents that have not been previously approved by the IRB, should be underlined or highlighted for easy identification.
- The CR Form asks for the number of subjects enrolled. The IRB considers a subject “enrolled” when the subject signs a consent document. In cases where the IRB approves a waiver for the informed consent requirement or a waiver of documentation of informed consent, any individual on whom data has been collected should be counted as an “enrolled” subject.
- The CR Form includes a demographic table that requests a breakdown of the total number of subjects enrolled by ethnic/racial category and gender. The sum total number of subjects listed in the demographic table (#5c) should equal the total number of subjects recorded previously under subject enrollment (#5a). When the numbers do not match, provide a brief explanation.
- The sponsor protocol or research description (Form B) must be submitted even if there are no changes to the document.
- Before submitting copies of the signed consent forms, check the signature on the ‘name of [authorized] person obtaining informed consent’ signature line to make sure it is legible. If it is not, print the name underneath the signature on the photocopy for the IRB, (do not submit or print on an original signed consent form). This also applies to the ‘signature of investigator’ line.
- Submit one original and one copy, (both single-sided), of the completed CR Form and the requested documents.
- If a data safety monitoring plan or board are applicable to the study include any reports, literature, meeting minutes, or assessments related to safety monitoring activities even if no safety issues have been identified and the recommendation is for the research to continue.
- If the CR requires review by the full IRB, federal policy requires that all members of the board receive a summary and status report on progress of the research. You may use the most recent funding or regulatory agency progress report. If a sponsor or regulatory report is not available please provide sufficient detail on study progress and any new or relevant information, published or unpublished, since the last review.
- Upon closure of a study, a final review (FR) is conducted by the IRB. To submit a final review, complete all sections of the FR Form, include all required documentation and attach a final abstract.

Additional information is available in the ORI/IRB Continuation Review SOP or contact the following ORI Professional Associates for assistance:

- **Continuation Review for Medical IRB # 1 & 2**  
  Gail Cadwallader  
  email: gcc@uky.edu  
  phone: 859-257-6071

- **Continuation Review for Medical IRB # 3 & 6**  
  Karen Larson  
  email: karen.larson@uky.edu  
  phone: 859-257-9819

- **Initial and Continuation Review Nonmedical IRB**  
  Andrew Hedrick  
  email: andrew.hedrick@uky.edu  
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