

IU Kokomo IRB
Application Instructions for Research With Human Subjects

It is suggested that you use this listing as a “check-sheet” to ensure that you submit a complete application. Incomplete applications WILL result in a delay in acceptance or approval. You do not have to enclose this sheet with the application, however. Please refer to the review schedule available on the Web (site) or in KO125 The Office of Research and Sponsored Programs to allow adequate lead-time.

____ **Documentation of Review and Approval (DRA):** This is the face and signature sheet for the study. It is a part of the application form packet for ALL studies. The IU Kokomo IRB requires submission of a signed DRA.

____ **Checklist for Designated Level of Review:** This is a several page document that is different for each level of review (Exempt or Expedited. There is no “Full” checklist). The Investigator should “check” the category or categories that apply and underline the specific criteria that the proposed research study addresses.

____ **Summary Safeguard Statement (SSS) for Expedited or Full Reviews or Study Information Sheet (SIS) for Exempt Research:**

This statement provides a place for the Investigator to detail the study protocol. Do not assume that the IRB already understands the nature, purpose, procedure for, or value of your study. Explain your answer to each question carefully, keeping in mind that the IRB has to meet multiple criteria to ensure the protection of the rights and safety of human subjects. Avoid jargon, and explain your protocol in enough detail that a reader could take the IRB submission and replicate the procedure for your study. Every question on the form must be answered.

____ **Educational Requirement:** If you have not already done so, please review the educational materials about research with human subjects and take the IU Test for Investigators. Co-investigators and student investigators must also comply. Print out a verification form (one for each investigator) and attach it to the application. This material can be found at: <http://www.iupui.edu/~resgrad/Human%20Subjects/HumanSubjectsCourse.html>
If you have previously submitted this verification, please indicate this in writing with the application.

____ **Disclosure of Conflict of Interest:** With each application, the investigators will be asked to complete several questions regarding conflict of interest regarding the proposed research (regardless of funding).

____ **Documents for Study Participants:** Information sheets, informed consents, and assents should all be presented using language that is understandable to the sample (usually at an 8th grade level); and typed using easily readable font. Copies of all such documents must be included in the application. If another language is used, provide both the English and alternate version.

____ **Other Documents for Study Purposes:** Copies of all scales, instruments, tasks, and interview schedules that will be used during the study should be submitted with the application. When applicable, this includes relevant information about products or other substances that are a part of the study (package inserts, etc.).

____ **Letters from Cooperating Institutions:** Other agencies and institutions that will have a role in your research (e.g. as a sample site) must indicate, via a signed letter, their agreement to participate. If the agency requires IRB approval prior to writing a letter, then indicate this in your application. The IRB can accommodate this request using a provisional approval or acceptance process.

____ **Grant Applications:** Studies that will or may receive funding from any DHHS agency or source must submit ONE copy of the grant application and further correspondence to the IU Kokomo IRB.