IRB Frequently Asked Questions

1. What is the Institutional Review Board (IRB)?
The Institutional Review Board (IRB) is a standing university committee established under federal regulations to protect the rights and welfare of all human subjects who volunteer to participate in research studies conducted under the partnership of the University of Southern Indiana. It oversees institutional compliance with all federal, state, and University guidelines relating to research with human subjects.

The IRB is responsible for reviewing all research involving human subjects, insuring the equitable selection of research subjects, ensuring that potential research-related risks are minimized, and that there is full disclosure so that volunteers can make an informed decision to participate.

2. How do I know what IRB Application Form to use?
IRB Review Category explanations are on the OSPRA website (www.usi.edu/ospra).

- Type 1 Research (Exempt studies) should use IRB Application Form A.
- Type 2 Research (Expedited studies) should use IRB application Form B.
- Type 3 Research (Full Board studies) should also use IRB application Form B.
- IRB Application Form C should be used to make a modification to already approved studies.
- IRB Continuing Review Form should be used to conclude a project or renew an application for an additional amount of time.

All forms can be found in IRBNet (www.irbnet.org) under the Forms and Templates tab.

Please note: Type 1 Research (Exempt) studies must still submit application to IRBNet for review. A determination of "exempt" does not mean that it does not need IRB review, but that it is exempt from the requirements of 45 CFR 46.

3. My research doesn’t involve human subjects. I’m using already existing data. Do I need to go through the IRB?
Yes. The IRB is responsible for reviewing research that involves the use of private data previously collected about individuals even if there is no additional interaction or intervention with those individuals planned. Depending on the nature of the data and the reason for their initial collection, such studies are often either determined exempt from IRB review or may be reviewed via the expedited process. IRB Policy on secondary
data can be found on the OSPRA website (www.usi.edu/ospra).

4. **How long will it take for my application to be reviewed?**
   The IRB will only review complete applications*. This means that a signed application with all supporting documents (i.e. survey, interview questions, informed consent document, assent document, verification letter, etc.) and CITI training certification are submitted to IRBNet (www.irbnet.org).

   - Type 1 Research (Exempt) Applications have a review period of 7 business days.*
   - Type 2 Research (Expedited) Applications have a review period of 10 business days.*
   - Type 3 Research (Full Board) Applications must be reviewed during a monthly scheduled IRB meeting during the fall and spring semesters. The IRB must receive the application and all supporting documents at least **two weeks*** before the IRB is scheduled to meet. Any Type 3 Research (Full Board) Application received after the two week deadline will be reviewed at the next scheduled meeting.

   *Please note that any time delays due to incomplete applications and/or required modifications are not part of the above review time periods.

   For the IRB meeting schedule, please see the OSPRA website (www.usi.edu/ospra).

5. **How long is my project approved for?**
   The IRB determines the length of approval for all projects. Approval will not be granted for periods longer than 12 months. For projects running past their project expiration date, a Continuing Review form must be submitted via IRBNet (www.irbnet.org). The continuing review form must be submitted before the initial approval period is over. Any applications that need to be renewed but do not submit a continuing review form before the project expiration date must submit a new application and begin the review process.

6. **What happens after the IRB reviews my application? How can I find out the status of my application?**
   The Office of Sponsored Projects and Research Administration will contact the principal investigator and faculty sponsor (if applicable) through IRBNet (www.irbnet.org) to notify of any requested revisions or approval.

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The principal investigator and/or faculty sponsor can contact the Office of Sponsored Projects and Research Administration by email at rcr@usi.edu or phone 812-228-5149 to inquire about an application status.

7. **What is my role as investigator?**

Investigators are responsible for obtaining IRB approval before beginning any human subjects research. Investigators are responsible for providing the IRB with sufficient information and related materials about the research (e.g., grant applications, research protocols, sample consent documents, ethics training certifications). Along with meeting the specific requirements of a particular research study, investigators are responsible for ongoing requirements in the conduct of approved research that include: obtaining and documenting informed consent of subjects prior to participation in the research, obtaining prior approval from the IRB for any modifications of the previously approved research, providing the IRB prompt reports of any unanticipated problems involving risks to subjects or others and proper storage and disposal of all collected data.

8. **What is the role of my faculty sponsor?**

The University requires that the faculty sponsor assume meaningful supervision for each student researcher listed on the application form. The faculty sponsor must be reasonably available to assist in the resolution of and reporting of any problems that may arise during the course of the research. Faculty sponsors are responsible for imparting to students an understanding of the ethical principles of human research to which the University adheres. If a student is conducting research or a class activity that falls within the IRB’s purview, the faculty sponsor must ensure that the student completes appropriate training and secures IRB approval before beginning the study or activity. The faculty sponsor also has primary responsibility for overseeing the conduct of the research in its entirety and for ensuring that student adheres to the approved protocol. The duty of the faculty member is to assess, and, if prudent, veto, activities proposed by a student to fulfill a class assignment should more than minimal risk for harm to either the participants or the student exist.

9. **What is informed consent?**

Informed consent is the process by which a fully informed research subject can determine whether they wish to enroll in a research study. It is based on the legal and ethical rights of humans to make voluntary and autonomous decisions about whether they wish to be a research subject. Informed consent can only be obtained from individuals over the age of 18. Minors (age 7-17) must complete an assent document AND have a parent or guardian complete an informed consent document.
Informed consent is required for all research studies unless the investigator specifically requests a waiver from the IRB. In order to participate in a research study, human subjects must understand that they are part of a research project, that participation is voluntary, and that they may withdraw at any time without penalty. They must also understand the procedures involved, time commitment, benefits and risks, and the extent to which confidentiality is maintained. This information is presented to prospective subjects in consent forms.

Investigators are required to keep all signed informed consent documents.

Please note: The University of Southern Indiana IRB requests that all informed consent documents and assent documents follow the templates provided on the OSPRA website (www.usi.edu/ospra).

10. How is the consent process handled for Internet-Based research?
For Internet-based surveys, it is sometimes appropriate to use implied informed consent. Participants would still need to be presented with the consent information, but would be informed that their consent is implied by submitting the completed survey.

11. What is CITI Training and is it necessary?
Yes. All investigators and research staff much successfully complete the CITI Program for training in the ethical conduct of research with human participants. Certification is valid for three years upon completion. Approvals for IRB applications will be not be granted until this training has been completed and training certificates have been submitted to IRBNet (www.irbnet.org).

- Type 1 Research (Exempt) Applications must complete either the IRB Exempt training modules or the IRB Expedited/Convened training modules.
- Type 2 or Type 3 Research (Expeditied/Full) Applications must complete the IRB Expedited/Convened training modules. **Any RCR training modules will not be accepted for IRB applications.**

CITI training can be accessed at www.citiprogram.org.

12. What if I want to make changes to an already approved study?
Any modifications to ongoing studies that have already been approved must submit IRB Application Form C via IRBNet (www.irbnet.org).

13. What happens if I don’t apply for IRB approval for my project before doing research?
Engaging in human subject research without IRB approval has serious ethical implications and violates university and federal policies. Students, faculty, and staff are required to submit IRB applications before embarking on any data collection. There is no
provision in the federal regulations that allow for IRB approval of research that has already been conducted.

If it is discovered that research is being conducted without IRB approval, the investigator must immediately stop, appropriately discard all collected data and submit an application for IRB approval through IRBNet (www.irbnet.org).

NOTE: Most academic journals now require proof of IRB approval before an article can be accepted for publication.