

**WESTERN CAROLINA UNIVERSITY'S INSTITUTIONAL REVIEW BOARD
2010-11 FACT SHEET**

What is the Institutional Review Board (IRB)?

The IRB is the committee on campus that is responsible for ensuring that human research participants are treated ethically. The IRB reviews proposed and ongoing research using federal and local guidelines in order to determine that human subjects' rights are protected.

Who needs to go through review?

Most research involving people or their records requires IRB review. This research may include intervention studies, investigations using archival records, research on teaching practices (i.e., SoTL), and a variety of other studies. IRB approval is necessary regardless of the investigator's role (i.e., faculty, staff, student), the study's funding, or the location of the research.

There are some categories of scholarly activity that do not qualify as "research" for IRB purposes. We recommend that anyone planning to conduct research involving people or their records should contact the IRB Chairperson or the IRB liaison in the Office of Research Administration for advice if they are not sure whether IRB approval is necessary. It is better to check ahead of time, because IRB approval cannot be granted retroactively.

What is the review process?

Our IRB uses a primary reviewer system. Here is the typical process:

1. The investigator downloads the IRB request form (available online), completes it, and submits it to Research Administration (see contact information at the end of this document). If all investigators do not have current certification through *WCU's investigator training program (CITI)*, they complete it while planning the study or writing the IRB protocol.
2. Once the IRB protocol is completed and submitted to the Office of Research Administration it is reviewed for completeness. If complete, the protocol is routed to a designated IRB member for initial review. This screening determines which of three categories of review applies based on the nature of the study: *expedited*, *full*, or *exempt*. Most studies at WCU fit the *expedited* category.
3. If the study meets the criteria for *expedited review*, the primary reviewer completes the review independently. If conditions for approval are noted, the primary reviewer will also advise the investigator about how to resolve the conditions and will review the revised protocol to determine final approval.
4. If the study meets the criteria for *full board review*, the protocol is forwarded to the entire committee for review and will be discussed at the next scheduled IRB meeting. The investigator may be asked to provide more information either prior to or during the IRB meeting. If conditions for approval are noted by the board, the IRB chair will advise the investigator about how to resolve the conditions and will review the revised protocol to determine final approval.
5. There are a few categories of research that involve little to no risk to participants. These may qualify for *exempt* status. In these cases, the primary reviewer forwards the protocol to the IRB chairperson to confirm that it qualifies for exemption.

While the vast majority of protocols are approved through one of these methods, there may be rare circumstances in which the IRB does not approve the study because it determines the risks outweigh the benefits to participants. Western's IRB is committed to working with investigators to strengthen study procedures as necessary in order to resolve these concerns.

More information about the categories of review may be found on the IRB website. However, keep in mind that the IRB – not the investigator – determines whether a study should be exempt from review.

How long does an IRB review take?

Studies that qualify as exempt or expedited are usually reviewed within two weeks, or a little longer around breaks in the academic calendar. Review times for studies that require full review may take longer, depending on when the proposal is submitted relative to the meeting schedule. Investigators whose studies may require full review can minimize their wait time by submitting complete protocols according to the 2010-11 meeting schedule below:

Submit materials by 12 pm this date...	...for review by the full IRB on this date
September 3	September 13
September 24	October 4
October 22	November 1
November 24	December 6
January 4	January 10
January 28	February 7
February 25	March 7
March 25	April 4
April 22	May 2
*Tentative	

Proposals that are determined to be exempt or approved in the expedited category without conditions are returned to the IRB office, logged in, and forwarded to the principal investigator.

Proposals that have conditions to be met prior to approval (full or expedited categories) will be held until the investigator submits revised or amended materials to meet the conditions. The revised materials are re-reviewed to be sure all conditions have been met. The re-review of the new materials may take up to two additional weeks from the date the new materials are submitted.

Once the investigator is notified of approval, research may begin. Please keep in mind that the approval lasts for one year. If you make any changes to the basic research design, instruments, etc., you will need to file an addendum with the IRB. If you wish to collect data after the one year expiration date, you will need to file an IRB renewal request.

What else does the IRB do?

IRB members can help investigators learn more about the ethical treatment of research participants and about the IRB protocol and processes. IRB members are available to consult with individuals who are preparing their protocols in order to help maximize the likelihood of a smooth review process. The IRB also provides training to groups of faculty/staff and to classes. Contact the IRB office if you are interested in scheduling group training or one-on-one support.

Where do I learn more about the IRB?

Visit the IRB website or contact the IRB office or chairperson for more information.

IRB website: <http://www.wcu.edu/6801.asp>

IRB office contact: Paige Roberson, Research Administration
227-7212 or irb@email.wcu.edu

IRB Chairperson: Leonardo Bobadilla, Psychology Department
227-3368 or IRBChair@email.wcu.edu