

Overview of Human Subject Research
Guidelines for faculty and students in the Department of Anthropology
Compiled by Gail E. Wagner, Chair of Ethics Committee, Sept. 2009

All faculty and graduate students who work with humans (e.g., interviewing, observing, compiling data from records) need to be certified for Human Subject Research by taking the free, online 5-hour course and passing the quizzes with an 80% or better score. Additionally faculty and graduate students need to apply for and receive Institutional Review Board (IRB) approval for their study. Undergraduate students who conduct simple interviews for a class do not need to do the above unless the results will be made public or unless children or other disadvantaged people will be included in the study. A study becomes public if you present it in poster or paper form at a conference (such as Discovery Day) or other public venue (such as the web) or publish it (including a senior thesis).

The university office and web page under which you will find all the following information is the Office of Research Compliance, at <http://www.orc.research.sc.edu/> If you don't have this site bookmarked, you can find it again by typing "research compliance" in the USC web site search box. The Office of Research Compliance has posted in pdf an Investigator's Handbook that is a must-read for anyone contemplating human subject research. You will find it at: <http://www.orc.research.sc.edu/pdf/InvestigatorIRBHandbook.pdf>

When you are formulating your research plan, not only should you plan to meet all USC requirements for human subject research, but also you should be well acquainted with the ethics statements and guidelines posted by the American Anthropological Association (AAA) at: <http://aaanet.org/profdev/ethics/> In particular, be sure to review the Resource for Working with Institutional Review Boards. You may also find useful advice under the Ethics Committee > Draft Briefing Papers on Common Dilemmas Faced by Anthropologists Conducting Research in Field Situations (several written by Kingsolver and by Wagner!).

Several large issues you will need to address include, but are not limited to: the informed consent process, how you will target or sample informants, whether you will deal with minors or others who need legal guardian consent, how you will disseminate your research results, and how you will protect the confidentiality of your informants/records. On the AAA Ethics web page under Working with IRBs you will find actual case studies that dealt with confidentiality and storage of data issues.

In the following guidelines, I briefly touch upon what research does not require IRB review, then I outline the procedure for obtaining or renewing certification for human subject research, followed by an outline of the procedure for applying for IRB approval to conduct human research.

What needs IRB review?

The AAA Ethics page clarifies the sort of research that requires IRB review, but basically ethnographic research does require IRB review. What research does NOT require IRB review? The following is taken from the *eIRB Electronic Institutional Review Board User Guide*, by Research Development, USC, Aug., 2008, page 4. I've highlighted the sentence that refers to when student work for class requires IRB approval.

“Non-Research Activities (IRB review not required)

Certain activities have the characteristics of research but do not meet the definition of research for IRB review. These activities do not require review by the IRB. Examples of data collection or observation activities that do not require review include:

- Data collection for internal departmental or other University administrative purposes (e.g. teaching evaluations, student evaluations, and “customer service” surveys), and
- Program evaluation carried out under independent contract for an external agency that is for their internal purposes only. Examples include personnel studies, human cost benefit analysis, treatment effectiveness studies, and customer satisfaction studies. Course related activities (e.g. research methods instruction) that involve the use of human participants but have no connection with research beyond the instructional function preclude the need for IRB review. **However, efforts that lead to presentation outside of the classroom and/or the publicizing of the student-prepared documents in any manner are considered research.** Instructors of research courses are encouraged to consult with their IRB Liaison or IRB staff to determine the appropriate procedures for assuring that student projects conform to ethical guidelines.”

CITI online certification course

The online course is called CITI Course, which is an abbreviation of Collaborative IRB Training Initiative. You can reach the CITI online course through the Office of Research Compliance web page: <http://www.orc.research.sc.edu/>

The University of South Carolina states the following policy:

“Our Federalwide Assurance (FWA #00000404), on file with the federal oversight agency called the Office for Human Research Protections (OHRP), mandates that all USC investigators (faculty, staff and/or students) conducting research involving human subjects, or using data or biological specimens derived therefrom, regardless of funding source or status, be trained in the protection of human subjects. IRB approval for pending projects will be withheld until such time as training requirements have been verified by the Office of Research Compliance.” **Refresher training is required every three years.**

Within the CITI course are a number of options: Group 1, Biomedical Researchers; Group 2, Social and Behavioral Researchers; Group 3, Data and Specimens Only; Group 4, IRB members; and Groups 5-6, Student Education Groups. A person who conducts general, run-of-the-mill anthropological interviewing will need to be certified in Group 2, Social and Behavioral Researchers. The following link leads you to a pdf file with a description and overview of the CITI course, guidelines on how to complete the course, and answers to frequently asked questions. You need to read through this page before you apply to take the CITI course. The document also supplies a link to the actual CITI site.

http://www.orc.research.sc.edu/PDF/USC_HS_RCR_Training_rvd_081409.pdf

In addition to Human Subject (HS) training, CITI offers training in Responsible Conduct of Research (RCR). Although USC does not require that researchers complete this training, some granting agencies such as NSF and NIH may. CITI has training specifically for students (Groups 5-6), although I recommend that you have your students NOT take the student training, but instead take the regular training, which they can list on their resume. When you register for CITI training, you can opt to also be registered at other, listed universities such as Clemson. This option is especially useful if you are collaborating on a project with someone at another university. Also, other universities have modules available that are not listed on the USC CITI course. You can add or drop your listing with other universities, allowing you to add a university and see what other modules are available through them.

My recommendation for taking the online CITI course is to open a module (in order) and print it. Then you can exit the module and read through your printout, and even have the printout in hand when you take the quiz for that module. The first modules are long and complex, but succeeding modules may be much easier and shorter, and you will find that

certain questions are repeated. If you do not score well on a module, take it over again before you complete the course.

Institutional Review Board applications

The following is a very useful web page that answers frequently asked questions, such as what categories of research qualify for exempt review: <http://orc.research.sc.edu/irb.html> It also lists the dates for full review board meetings. It supplies an overview of getting started, the IRB, policies and procedures, and the consent process (including templates for informed consent forms).

The Office of Research Compliance has instituted a new (as of 2009) electronic IRB routing and review system called eIRB. Your earlier projects may have been submitted electronically under USCeRA, which is being phased out. Your continuing reviews for project submitted under USCeRA will continue to be reviewed under USCeRA until the entire switch has been made. The new system was developed with Health Science South Carolina (HSSC) partners and allows USC applicants to use their IRB applications at other HSSC institutions. All new IRB applications must be submitted through eIRB:

http://www.orc.research.sc.edu/eIRB_migration_info.html

You must begin by registering with eIRB. During registration you are asked simple, basic questions about yourself, not about your project. You may have to wait up to 24 hours after registration before you are able to enter the system to begin IRB application. You will need to remember your username and password! All team members must be CITI certified before you can submit an application. A Quick Reference Guide for using the eIRB system (scroll down to see the one written for investigators in the USC System) has been posted as a pdf file on the above-referenced web page. A booklet guide is also available on the same site: <http://eirb.healthsciencessc.org/HSSC/Doc/0/QIHEIL7EM7VKRD4S0SNB0E3027/USC%20eIRB%20User%20Guide.pdf>

Since all my IRB applications have been through USCeRA and I have not yet used eIRB, I rely heavily upon this pdf for the following information. Only Principal Investigators may submit a new IRB. Like the old system, you can upload documents, including your informed consent forms. Notification of review will be posted both in the Personal Workspace within eIRB and an email will be sent to all members of the study team that you identified in your application.

From reading through the full user's guide, it appears you will need to have the following information prepared to submit an application via eIRB: Full title, short title, and a brief study summary (a non-technical description in 3-10 sentences). The program will prompt you for required documents, such as informed consent forms or consent scripts, depending on the type of application you make.

IRB applications are made in one of the following three kinds of applications: exempt, expedited, and full review. If you will interview only adults about innocuous things, you may be able to obtain exempt status. Exempt status means your approval is a one-time deal: you do not need to be reviewed again unless you experience an adverse effect. You will probably need to submit a consent script that will be read to each participant in your study. You may or may not choose to also have an informed consent form. With an expedited approval, you undergo a yearly review and an informed consent form is required. Both of these types of studies can usually obtain approval in 24-36 hours. A full review can take weeks, or until the next meeting of the full review board. If you will interview children, for example, you must have at least an expedited review. For a full explanation of the process, refer to the Investigator's Handbook <http://www.orc.research.sc.edu/pdf/InvestigatorIRBHandbook.pdf>

If you are beginning a multi-year project in which targeted informants and/or data collection methods will be evolving and changing, it is ok to apply for IRB approval of just the first (or next) stage of research, and then re-apply later on when your project methodology is slated to change. Please feel free to consult with the chair of the departmental Ethics Committee, who can direct you to the resource best suited for answering your questions.