Securing Institutional Review Board Approval for Research on Human Subjects:
A Guide for Anthropology Students at the University of Vermont

February 2013

Prior to conducting **research on human subjects**, all UVM students are expected to comply with the requirements set forth by the Institutional Review Board Committee on Human Research in the Behavioral Sciences at the University of Vermont. These requirements are intended to promote the ethical treatment of human research subjects and to comply with US Federal regulations and guidelines for research on human subjects.

Students in Anthropology should all familiarize themselves with the **Code of Ethics of the American Anthropological Association**:
http://www.aaanet.org/coe/Code_of_Ethics.pdf

Next, you need to **determine whether your project involves research and/or human subjects**. If your project does constitute research and does not involve human subjects, then it needs to comply with the review procedures of the UVM Institutional Review Board (IRB).

To determine whether your project will involve **RESEARCH**, please use the following flowchart:
http://www.uvm.edu/irb/inst-guide-template/not_research_determination_flow.pdf

To determine whether your project will involve **HUMAN SUBJECTS**, please see the following flowchart:
http://www.uvm.edu/irb/inst-guide-template/flowchartnotH.S.for forms page.pdf

Note for students conducting research on **human remains** from deceased individuals who are not identifiable with regard to personal identity: IRB review is not required if specimens were not obtained from LIVING individuals. For IRB purposes, they are considered under the same rules as those applied to autopsy specimens. It is not considered human subjects research.

If your project does involve research on human subjects, you should begin by completing UVM's online **human subjects tutorial**, including reading through the tutorial, taking the quiz at the end, and retaining a copy of your completion certificate:
http://www.uvm.edu/irb/tutorial/index.html

All student research on human subjects at UVM must be conducted under the formal **supervision of a UVM faculty member:**
http://www.uvm.edu/~irb/?Page=education/facultysponsorshipintro.htm

Your next step is to locate a faculty member with related interests and ask them if they would be willing and able to supervise and sign off on your research. For a list of faculty in the Anthropology Department, please see this website to identify faculty for you to **inquire about research supervision**:
http://www.uvm.edu/~anthro/?Page=faculty/faculty.php

Once you have found a faculty member who has the time and expertise to supervise you and has agreed to do so, you should **give them a copy** of your human subjects **tutorial completion certificate.**

Next, you need to **familiarize yourself with the types of student research on human subjects** and what **kinds of IRB procedures are required for each type.**

For an overview of the **types of and requirements** for **student research** on human subjects from the **UVM Research Manual**, please review the material at the following link: http://www.uvm.edu/irb/researchmanual.htm#SEC6astudents

Student research on human subjects under faculty supervision may be considered exempt or non-exempt human subjects research. **Exempt** research poses little or no risk to human subjects and requires filling out a brief form to request confirmation from the IRB Administrative Staff that they agree that your project meets the criteria for exempt research. **Non-exempt** research has the possibility of posing more than minimal risk to human subjects and thus requires filling out more forms and providing supplementary documentation. Non-exempt research will undergo either expedited review by one or two IRB Committee members or full review by a quorum of the full IRB Committee. Whether exempt or non-exempt, student research may be an **assignment in a course** involving research or **independent study or thesis research**.

Each of these kinds of research requires its own set of IRB forms and approvals, as outlined below.
http://www.uvm.edu/irb/?Page=m1_forms.php&SM=humanmenu1.html

	Exempt	Non-Exempt	
Type of Research	Confirm Exemption	Expedited Review	Full Review
An Assignment in a Course	***Instructor's Assurance Form*** *and* ***Protocol Exemption Review and Determination Form***	***Protocol Form*** and ***Common Protocol Cover Form*** *and supplementary documentation*	***Protocol Form*** and ***Common Protocol Cover Form*** *and supplementary documentation*
Independent Study or Thesis Research	***Instructor's Assurance Form*** *and* ***Protocol Exemption Review and Determination Form***	***Protocol Form*** and ***Common Protocol Cover Form*** *and supplementary documentation*	***Protocol Form*** and ***Common Protocol Cover Form*** *and supplementary documentation*

Exempt Research:

Exempt research conducted by a student **under an Instructor's Assurance**: The faculty member supervising the student or students conducting research on human subjects should fill out an Instructor's Assurance Form and secure approval from the IRB for students to proceed. Research conducted under an Instructor's Assurance should be of a nature exempt from IRB committee review. Exempt research involves little or no risk to human subjects. As outlined in the UVM Research Manual, the six types of exemptions include the following: (http://www.uvm.edu/irb/researchmanual.htm#SEC6astudents):

Categories of Exempt Research: Apply to IRB to Request Exemption

Exemption #1. Research conducted in established or commonly accepted educational settings, involving normal educational practices.

Exemption #2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior. EXCEPT when identifiers are recorded and any disclosure of the responses outside the research could place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. (Note: This exemption does not apply to research involving minors except for research involving educational tests or observation of public behavior when the investigator(s) do not participate in the activities being observed.)

Exemption #3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior where the human subjects are elected or appointed officials or candidates for public office or the personally identifiable information is kept confidential.

Exemption #4. Research involving the collection or study of existing data, documents, records. EXCEPT when the material is not publicly available or when identifiers are recorded. Note: This may not constitute "human subjects research" if the investigators/collaborators will not have access to the identities of the subjects. See guidance on Research Involving Coded Private Information or Biological Specimens, Attachment I.

Exemption #5. Research and demonstration projects which are conducted by or subject to the approval of the Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise exam: public benefit or service programs.

Exemption #6. Taste and food quality evaluation and consumer acceptance studies.

Excerpted from the UVM Research Manual

Even with Exempt Research, forms must be filed with the IRB to request an exemption. The **Instructor's Assurance Form** and the **Protocol Exemption Review and Determination Form** that are required can be found under the section entitled Student Research part way down the page at the following link:
http://www.uvm.edu/irb/?Page=m1_forms.php&SM=humanmenu1.html

Non-Exempt Research Requiring Expedited or Full Review:

For **non-exempt research**, there are two categories: **expedited** and **full review**. (http://www.uvm.edu/irb/researchmanual.htm#SEC6astudents):

Examples of Expeditable Research – Apply to IRB for Expedited Review

1. Voice or image recordings or photographs of individuals made for research purposes, such as investigations of speech defects.
2. Research on individual or group behavior or characteristics of individuals, such as studies

of perception, cognition, game theory, or test development, where the investigator does not modify subject's behavior and the research will not involve stress to subjects.
3. The study of existing documents, data, records or diagnostic specimens which are not publicly available.
4. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. This category also includes such procedures as weighing, testing sensory acuity, EKG, EEG, thermography. (However, exposure to electromagnetic radiation outside the visible range -- e.g. x-rays, microwaves -- requires FULL REVIEW.)

Excerpted from the UVM Research Manual

Examples of Research that would require Full Committee Review – Apply to IRB for Full Review

Any research involving the following populations and procedures most likely will require a full committee review. The Committee on Human Research in the Behavioral Sciences strongly discourages research in these categories by undergraduates.
1. Vulnerable populations:
   Children (persons under 18 yrs)
   Mentally disabled/incompetent
   Pregnant Women
   Prisoners
2. Physically invasive procedures - Drugs, devices, x-rays, strenuous exercise, etc.
3. Psychologically or emotionally distressing situations
4. Manipulation of behavior - Deception, hypnosis, etc.
5. Collection of sensitive data - Criminal behavior, illicit drug or alcohol abuse, sexual habits (where identifiers are attached).

Excerpted from the UVM Research Manual

For non-exempt research requiring expedited for full committee review, the forms that need to be completed include a **Protocol Form** and a **Common Protocol Cover Form,** together with additional forms referred to in those two forms. These forms can be found part way down the page at the following link:
http://www.uvm.edu/irb/?Page=m1_forms.php&SM=humanmenu1.html.

For qualitative research involving medical procedures (e.g., interviewing and taking blood specimens) or for quantitative research (e.g., administering survey questionnaires), you need to fill out the generic Protocol Form. For qualitative research not involving medical procedures, you should fill out the **Qualitative Research Protocol Form** instead of the generic Protocol Form. However, whether you fill out the generic or qualitative protocol form, you will also need to fill out the **Common Protocol Cover Form**. The Common Protocol Cover Form will feel repetitive in many places with what you have already filled out on whichever version of the Protocol Form (generic or qualitative) that you completed. However, the Common Protocol Cover Form is still required because it provides the committee with a standardized abbreviated version which puts all of the key information in the same place across all project applications.

Together with your Protocol Form and Common Protocol Cover Form, you may also need to fill out additional forms or to consult additional templates, such as: **Request for Waiver of Informed Consent/ Authorization/Documentation** or the **Informed Consent Template**. These are all found at the following link:
http://www.uvm.edu/irb/?Page=m1_forms.php&SM=humanmenu1.html.

Expedited and full review of non-exempt research also require submission of copies of various forms of **supplementary documentation** to the IRB Committee. Precisely what supplementary documentation will be required depends on your project. Examples include a list of your planned interview questions, a copy of your planned observation protocol, a copy of subject recruitment materials, and so on. Please see the Protocol Form and Common Protocol Cover Form for examples to see what may be relevant to your project.

Committee schedule and submission guidelines can be found here. Anthropology students should check the **CHRBS** committee schedule (behavioral sciences IRB committee, rather than the CHRMS medical IRB committee).
http://www.uvm.edu/irb/?Page=m1_forms.php&SM=humanmenu1.html

If you have any **questions**, please do not hesitate to **contact the UVM Institutional Review Board Staff**. They are happy to answer questions or to give you feedback, clarification, or guidance. Normally, the **first point of contact** in the IRB Office for students and their faculty supervisors will be the **Research Review Administrator** for the Behavioral Sciences Committee (CHRBS). Currently this would be **Gale Weld** at Gale.Weld@uvm.edu. Additional IRB contacts can be found at the link below:
http://www.uvm.edu/~irb/?Page=contacts.html

If you and your faculty supervisor are having **further difficulties** that cannot be resolved by reading the documentation provided above and/or contacting the Research Review Administrator for the Behavioral Sciences Committee (see above), it may be helpful to contact the **Anthropology Department's IRB Liaison** (currently Jeanne Shea at Jeanne.Shea@uvm.edu) for a consultation.

Once approval or exemption is secured from the UVM Institutional Review Board Committee on Human Research in the Behavioral Sciences, the student may begin research. **Student research on human subjects can only begin after receiving an exemption from or approval by the IRB**.

Note: Since the IRB frequently updates its content (e.g., research manual, forms, guidelines, and templates), this Human Subjects Research Guide for Anthropology Students focuses on providing web links to relevant sections of the IRB website. If you find that some of the links provided are no longer working, go to the homepage of the IRB at http://www.uvm.edu/~irb/ and search there for the content that you are seeking.

Compiled by Jeanne Shea, Department of Anthropology, University of Vermont