

IRB PROCESS—AT A GLANCE

All research involving human subjects carried out by faculty, staff, or students of Utah Valley University is under the review and approval jurisdiction of the Institutional Review Board (IRB). Approval must be obtained *before* the research (data collection) is started, and specific IRB paperwork must be submitted to the IRB Administrator *before* research can be approved.

Before IRB paperwork is started, the researcher(s) should have been through the preparatory research stages and outlined specific plans and methodologies. This may include (but are not limited to) the development of a problem statement, research purpose, research questions or hypotheses, literature review, research design, population and sample selection, measures/instrumentation, data collection procedures, and data analysis procedures.

After these initial steps are taken, begin filling out the IRB paperwork (if possible, use the Word versions of Forms A and B and type in the information rather than handwriting on the PDF versions):

- 1. FORM A:** Review and begin completing the *RECORD OF IRB SUBMISSION*. This includes the determination of whether the project is to be submitted under an exempt, expedited, or full IRB review (see “Categories of Research” below, and the *UVU Investigator’s Handbook* for further details). In addition, this form provides a checklist of the paperwork that needs to be submitted for IRB approval.
- 2. FORM B:** Complete the *APPLICATION FOR APPROVAL FOR THE USE OF HUMAN SUBJECTS IN RESEARCH*.
- 3. INSTRUMENT:** Attach a blank copy of the final version of the research instrument you are using to gather data.
- 4. INFORMED CONSENT:** Attach a copy of the participant informed consent form or letter you intend to use (this is used to obtain the subject’s permission to willingly participate in your research).
- 5. ORGANIZATION’S PERMISSION:** If you are doing your research in specific organizations, you must attach an email or letter from the primary contact in each organization specifying that the organization agrees to participate. For example, if you are using a random sample of 100 Utah State Department of Health employees and 100 Wal-Mart employees, you need to attach a letter from a decision-maker in each organization confirming agreement to participate in the study and acknowledgment of what is expected of the organization and prospective participants (see *UVU Investigator’s Handbook* for further details).

6. COMPLETE PACKET: Complete Form A by obtaining the appropriate signatures. Next, copies of Form A and B, the instrument, and the letter of informed consent should be sent to the IRB Administrator for review. If the research is approved as exempt, then the IRB Administrator will sign Form A and send it back to the Principal Investigator for the record. If the research is categorized as expedited, then the Executive IRB will review the proposal. If approved, then the IRB Administrator will sign Form A and send it back to the Principal Investigator for the record. If the research requires full board review, then the IRB will review the proposal. If approved, then the IRB Administrator will sign Form A and send it back to the Principal Investigator for the record.

7. REQUESTED REVISIONS: After a packet is submitted, revisions may be requested. If small changes are requested, it is expected that researchers resubmit only the form in question. If minor changes are requested by IRB for expedited and full board review projects, the IRB Administrator can give his/her approval to proceed to data collection without taking the project before the Executive IRB or full IRB for a second time.

8. DATA COLLECTION: Once the IRB Administrator has approved your proposal, then you can start your research and begin to collect data!

CATEGORIES OF RESEARCH

The IRB Administrator, in conjunction with the Executive IRB and the full Board, makes the final determination of category for review. The following are general definitions for the three levels of research review (see §II of the *UVU Investigator's Handbook* for more details).

Non-IRB Regulated Research—This category includes research which does not involve human subjects, and research which does not give rise to any additional interactions with human subjects due to that research (for example, observing people in a public place without interacting with them).

Exempt Review—The exempt category is determined by the federal regulatory agencies and include research of negligible risks in the following situations:

- The study of some educational practices
- Survey interviews of adult subjects or public figures (non-sensitive topic areas, only)
- Observation of non-institutionalized adults, and minors under some circumstances
- Archival or secondary use of data or specimens with no identifiable information
- Demonstration or service projects under the “Social Security Act”

Expedited Review—Expedited review covers research that involves only minimal risk procedures such as those involving the drawing of small amounts of blood, removal of dental plaque, moderate exercise by normal volunteers, the study of individual or group behavior where the behavior is not manipulated and the subjects are not exposed to any stressful situation. Expedited review categories are designated by federal regulatory agencies.

Full Board Review—Research involving moderate or greater risk to subjects requires review by the full board. Full review covers all research not falling into the categories of exempt or expedited review.

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