



OFFICE OF RESEARCH SUPPORT & COMPLIANCE

THE UNIVERSITY OF TEXAS AT AUSTIN

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2617 Speedway #201, Austin, Texas 78712 (512) 471-8871 - FAX (512) 471-8873  
SW7 ( Mail Code A3200)

To: Graduate Advisers and Graduate Coordinators

From: Clarke Burnham, Ph.D. Chair, UT IRB  
Lisa Leiden, Ph.D., Director, Office of Research Support and Compliance

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Topic: Dissertations and Statement of Research with Human Participants

Students who submit dissertations during the summer of 2001 and thereafter must submit to the Office of Graduate Studies a "Statement of Research with Human Participants." The form may be accessed from <[www.utexas.edu/ogs/pdn](http://www.utexas.edu/ogs/pdn)>. Students are asked to indicate whether the dissertation research involves human participants. If the research does involve human participants, the student must attach forms indicating DRC/IRB approval of the research. The requirement for an ethical review of research with human subjects is mandated by the Code of Federal Regulations (45 CFR 46) and is overseen by the Office of Human Research Protection, located in the Department of Health and Human Services. Research studies conducted in countries other than the United States are subject to the same regulations as those conducted in the United States.

We are sending this memorandum to you because you are likely to know which of your doctoral students are affected by this new requirement from the Office of Graduate Studies. We urge you to ensure that all affected students are in compliance.

The purpose of this memorandum is to discuss the meaning of the phrase "research with human participants" and to describe the approval process for such research. A more complete description of this information is available at <[www.utexas.edu/research/humanresearch](http://www.utexas.edu/research/humanresearch)>. Research is defined by the federal regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." If a researcher would consider publishing his or her study in a scientific journal or presenting the results at a meeting of a scientific organization, the study is a research study. Research with human participants consists of any study in which there is a systematic observation of humans. It includes research in which there is direct intervention as well as phone or mail surveys designed to obtain generalizable knowledge. Research with humans also involves studies that are systematic investigations of non-public data or records of living individuals. It does not include the systematic investigation of publicly available records.

All research with human participants conducted by students, faculty, or staff at The University of Texas at Austin must be reviewed by a Departmental Review Committee (DRC) prior to the start of the study. The material to be submitted to the DRC by a student includes a cover sheet signed by both the student and his or her faculty supervisor, a synopsis of the study, a consent form or cover letter, a faculty supervisor's approval form, and certification of compliance with a requirement of education in the protection of human subjects. (The student and his or her supervisor as well as other key personnel in the research project must be listed on this certification which must be signed by the student and his or her supervisor.) One way to

satisfy this educational mandate is to read "Policies and Procedures Governing Research with Human Participants at The University of Texas at Austin - <[www.utexas.edu/research/humanresearch](http://www.utexas.edu/research/humanresearch)>. Some DRCs may also request other information.

Most research needs to be reviewed only by a DRC; this research is exempt from review by the Institutional Review Board (IRB). The exemption categories are available with the Cover Sheet for Exempt Application. Exempt research includes studies of instructional strategies (unless conducted with children), most surveys and interviews, most studies of psychological processes such as memory, etc.

Other research is not exempt; it must be reviewed by both a DRC and an IRB. Non-exempt research includes: (1) all research with children (minors under the age of 18) except observation of behavior in public settings; (2) research with persons confined in prisons, mental hospitals, nursing homes or other settings where the person may feel coerced to participate in the study because of the setting where the research will take place and the person's status in that setting; (3) research involving the administration of any medicine or drug including alcohol, nicotine, herbals, or over-the counter medications; (4) research involving any medical procedure including venipuncture; (5) research that poses more than minimal physical risk or that may induce more than minimal psychological stress; and (6) research in which the participant could be linked to his or her responses, such as research where the person's name is placed on a survey or research where the responses are videotaped, and disclosure of the responses outside the research context could place the participant at legal risk or be damaging to the participant's reputation.

Some non-exempt research will qualify for expedited IRB review, review by the chair and one other member of the IRB. In general, research that poses minimal risk to the participants will qualify for expedited review.

All departments or schools in which faculty and students conduct research with human participants should have a DRC. If your department or school needs to establish a DRC, contact Lisa Leiden, Director, Office of Research Support and Compliance, 471-8871 or [lisa.leiden@mail.utexas.edu](mailto:lisa.leiden@mail.utexas.edu) for information about establishing such a committee. She can also function as the DRC chair for those departments or schools in which research with humans is infrequently conducted.

If you have questions about the applicability of human subject review to studies conducted by your students or about procedures for obtaining that review, contact either Lisa Leiden or Clarke Burnham at 475-7129 or [burnham@psy.utexas.edu](mailto:burnham@psy.utexas.edu). We want to ensure that all UT faculty, students, and staff are in compliance with the federal regulations, and we want to ensure that the ethical review of research proposals is efficient and effective.