

**FORM A**  
**GUIDELINES AND APPLICATION INSTRUCTIONS**

**For Certification for Exemption from IRB Review  
for Research Involving Human Subjects**

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**OVERVIEW**

In the most recent revisions to the human subjects regulations ([45 CFR 46](#)), the US Department of Health and Human Services (DHHS) exempted certain types of research from review by Institutional Review Boards (IRB). The government placed the judgment of whether or not a given piece of research required full review in the hands of the institution, namely, UT. In our assurance of compliance to DHHS, the University stated it would certify, by an appropriate procedure, that every exempt research project involving human participants indeed met the requirements for exemption of review by the full IRB.

Therefore, all research involving human participants conducted by UT faculty, staff, or students or making use of UT facilities must either be reviewed by the IRB or be certified as exempt from IRB review by the Departmental Review Committee. In this document, we will explain what types of research qualify for exemption, what responsibilities you have in carrying out exempt research, and what procedures you must follow to receive your certification of exemption. At the end of this document is a sample copy of IRB Form A, the brief form you fill out to receive certification of exemption. Altogether, this information should put you in a position to file successfully a Form A.

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**RESEARCH EXEMPT FROM REVIEW BY THE IRB**

The forms of research that regulations exempt from **formal** review have all been found to present no greater than minimal risk to the subjects. "Minimal risk" is defined as "the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." For research activities which are, or will be, externally funded, final approval must come from Research Compliance Services of the Office of Research. Research activities in which the only involvement of the

human participants will be in one or more of the following categories are exempt from IRB review and need only be certified as such by the appropriate UT Departmental Review Committee:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

- research on regular and special education instructional strategies, or
- research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures\*, interview procedures or observation of public behavior, **unless**:

- information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and**
- any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

\* **PLEASE NOTE:** *An exemption cannot be used when children are involved for research involving survey or interview procedures or observations of public behavior, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed. [45 CFR 46.401(b)]*

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

- the human subjects are elected or appointed public officials or candidates for public office; **OR**
- Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

- public benefit or service programs;
- procedures for obtaining benefits or services under those programs;
- possible changes in or alternatives to those programs or procedures; **OR**
- possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminants at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the US Department of Agriculture.

The degree of liability or sensitivity is a matter of judgment, and the UT Departmental Review Committee may require that an investigator submit his/her proposal to the IRB on a Form B in order to assist in the judgment.

With respect to item #4 above (the collection or study of existing data, documents, etc.), please be sure that you have legal access to the materials in question, even if you record the data without identifiers. Some records are by nature confidential (e.g., many types of school records) and others are the property of clients only held in trust by an institution (e.g., patient records). These types of records do not qualify for exemption. They fall under a classification for **expedited review**, which requires the submission of a Form B. Special provisions are needed to legally access data within these records.

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## CONDUCTING EXEMPT RESEARCH

One common misperception about research that is exempt from IRB review is that the research is exempt from the provision of the human subjects regulations. **ALL** research involving human participants must follow the provisions of applicable regulations regardless of whether or not IRB review is required.

Good research design dictates careful consideration of risks, protections, and benefits, even if detailed review by the IRB does not occur. Moreover, the research design should meet applicable research ethics standards of the investigator's professional association or society. In all cases, the standards of respect for persons, beneficence, and justice enumerated by the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the **Belmont Report**) apply to research involving human subjects, whether reviewed or certified as exempt from review.

Full compliance with regulations includes securing informed consent from all participants of research prior to the conduct of the research activity involving the subject. A thorough discussion of informed consent also appears in the Research Compliance Services document, **Basic Elements of Informed Consent**.

Normal informed consent procedures call for a written consent document and the signature of the participant. If the only document linking the identities of the participants to the research is the informed consent document, then the requirement for written consent may be waived upon request and justification within Form A or Form B. Verbal consent is still required after providing the subject with a fair and reasonable explanation of the research, the participant's role in it, anticipated risks and protection measures, and a statement that the participant is free to withdraw at any time without penalty. The potential subject should understand that his/her participation is voluntary, and he/she should have an opportunity to ask questions about the research. These requirements apply to all direct contacts with subjects and to such research methods as telephone surveys.

With mail questionnaires and drop-box surveys, where the respondent remains anonymous, the researcher should provide a similar explanation about the purpose of the research and the procedures for completing the questionnaire. This material may be contained in the cover letter accompanying the questionnaire or at the head of the questionnaire itself. The explanation should close with a statement to the effect that "return of the questionnaire will constitute your informed consent to participate."

If the respondent does not remain anonymous -- that is, if the investigator can initially identify each return with a subject, as is often the case where follow-up questionnaires may be sent -- this fact should be revealed to the subject and written consent procedures used.

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## **DETERMINING IF A RESEARCH PROJECT IS EXEMPT**

The UT system of review and certification of exemption makes use of resources within the investigator's department. The first step in this determination involves consultation with the departmental review committee to elicit a consensus judgment on whether the research is exempt and should be submitted on a Form A. If you or the Departmental Review Committee remain uncertain after consultation about the exempt status of a proposed project, contact the Compliance Officer in the Office of Research at (865) 974-3466.

If you and your unit agree that the research is exempt from review, complete a Form A. This form provides a brief description of the project, its purposes, the subjects, and their involvement in the research. More detailed instructions for filling out a Form A appear below. Submit the completed form, with the original signatures of the principal investigator, co-principal investigator (if applicable), and in the case that the principal investigator is a student, the advisor, to the Departmental Review Committee (DRC). If the DRC agrees that the project is exempt from review, the DRC Chair will obtain the signature of the Head of the department or unit, thus completing the certification. The DRC will return a copy of the fully signed form to you and a copy will be submitted to Research Compliance Services for entry into the Institutional Review Board's database.

However, the DRC Chair may determine that IRB review is necessary, in which case he/she will notify you to submit a Form B. In reaching this determination, the DRC Chair may consult with members of Research Compliance Services or IRB for advice.

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## **EXAMPLES FOR DETERMINATION**

Part of the determination of whether a project may be certified as exempt may rest upon the nature of the instruments used in conducting the research. Therefore, include a copy of all instruments with the Form A. If qualitative or phenomenological research is proposed, include the questions to be asked.

If the project will make use of the facilities of another institution or a business, obtain letters (on their letterhead) of permission or cooperation to use them and to interact with personnel there. If the institution is one that also must review research involving human participants, you must submit your project on their forms to its IRB. In such cases, you should note the submission on your Form A to UT and provide a copy of the approval (along with any project modifications the external institution may require) for your UT file.

A graduate student who submits a Form A for thesis or dissertation research must follow these same general procedures. On page 4 of the UT Graduate School Guide to the Preparation of Theses and Dissertations, 1994, 8th Edition, page 4, "...The Graduate School requires every student to verify that they have complied with the appropriate approval procedures prior to initiation of the thesis- or dissertation-related research, if approval is relevant to the research." Thesis- or dissertation-related research has two additions to the Form A or Form B:

- The student investigator should consult initially with his/her advisor, who should also sign the Form A in the proper place. The advisor's signature certifies that the student's thesis plan has been approved or the dissertation committee has approved the dissertation prospectus.
  - If an informed consent form or information sheet is to be employed in the research, a statement should be added in the "Purpose of the Study" that the research is being conducted in partial fulfillment for a master's thesis or doctoral dissertation.
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## FILLING OUT A FORM A

This document will assist you in determining that all requirements are included in your protocol before submitting it to the departmental review committee for approval. The following notes may aid you in answering the small set of questions on Form A. Your goal is to provide answers that assist the DRC in determining that the proposed research is indeed exempt from review.

The Form A may be reproduced on a personal computer and printed on a high quality printer (e.g., LaserJet or DeskJet) or a typewriter may be used on the form itself. Form As generated on personal computers are not restricted to the one-page length of the form. The entries on Form A should together provide the DRC with a brief but complete and coherent picture of the research project. Excessive brevity may delay certification by requiring requests for further detail.

1. **Objectives:** Briefly state the purpose of the research, with special reference to and emphasis upon the exact procedures in which human subjects will be involved. If the research occurs in a larger context, such as a training program, emphasize the research component, using the remainder of the work to be done as the context of the research.

2. **Subjects:** Briefly describe the participants, the criteria of selection or exclusion, the population from which they will be selected, the duration of involvement, and any special characteristics they have or must have relative to the research. Form A research is restricted to normal adults only ( $\Rightarrow$ 18 years of age). If you make use of a control group as well as an experimental group, be sure to specify the selection methods and source populations for both.

3. **Methods or Procedures:** Briefly enumerate, using non-technical language, the research methods that will involve the use of human subjects. List any potential risks to the subjects along with the protective measures you will apply to minimize those risks. If there are no risks, explain why there are none. If the subjects will remain anonymous, describe how you will accomplish this. Describe how you will secure the confidentiality of the data and the subject identities (if applicable), and note where materials with names will be stored, along with the names of the persons who will have access to the names and data.

In this section, also mention what appropriate method of obtaining informed consent you will use. If consent is to be waived, provide a short justification either in the space available or on an attached sheet.

4. **Category:** Referring to the earlier part of this document or to the list of exempt categories of research on the reverse side of Form A, cite the paragraph number that you deem entitles your research project to exemption from review by the IRB. If uncertain which paragraph applies to the proposed research, consult with Chair of the Departmental Review Committee or the OR Coordinator of Research Compliance Services.

By signing a Form A, you commit yourself to abiding by the regulations governing research involving human subjects, including those provisions specifying the means of obtaining informed consent. In addition, you commit yourself to abiding by the applicable ethical standards of your discipline and those found in the Belmont Report.

Processing a Form A varies between departmental review committees. The process of completing Form A is fairly simple and straightforward and should not take long if you are completely familiar with your proposed project and can summarize salient points readily. The system of certification of exemption used by UT is as painless as we can make it.

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## **RENEWAL AND TERMINATION**

Certification of exemption from review is **not subject to annual review and approval**. Unless your research takes off in a new direction (e.g., major changes in the objectives or involvement of human participants), your department will have responsibility for reviewing and approving changes in your research and determining whether the changes will affect the current status of the project or will require a Form B to be submitted for IRB review.

One last step is very important. When you complete your research, file a Form D and check the termination box. This will allow the departmental review committee and Research Compliance Services to close your file and three years later to discard it. The longer the delay in terminating a project, the longer we must keep out-of-date paper on file.

These are the essentials of the Form A, Certification of Exemption from IRB Review for Research Involving Human Subjects. If you have further questions, contact the Chair of your Departmental Review Committee or any staff member in Research Compliance Services of the Office of Research by phone, (865) 974-7697, e-mail, or in person (404 Andy Holt Tower).

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## **SELECTED REFERENCES**

The following reference material is available in paper form from Research Compliance Services as well as on the Internet:

**Form B: Application and Instructions**

**Form D: Changes and Modifications to Approved Form B**

**The Human Subject Research Review System**

**Application Due Dates for Full IRB Review**

**Departmental Review Committee Guidelines**

**[The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research](#)**

**[Federal Regulations for the Protection of Human Subjects, Title 45, Code of Federal Regulations, Part 46 \(45 CFR 46\)](#)**

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