Institutional Review Board Materials

Guidelines for Research Involving Human Participants

A. What is the purpose of the Institutional Review Board (IRB) review?

The U.S. Department of Health and Human Services requires that all research projects involving human participants be screened to confirm that the participant's rights, privacy, welfare, and civil liberties are protected. The IRB is responsible for reviewing all research projects involving human participants conducted by individuals affiliated with Drury University.

B. What terminology is important to understand when conducting research involving human participants?

(Taken from the *Code of Federal Regulations*, Title 45, Part 46, Subpart A)

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Human participant means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information.

IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Vulnerable populations are groups of individuals who require additional measures to ensure that rights, privacy, welfare, and civil liberties are protected. These groups include children, prisoners, pregnant women, and people with mental, physical, and/or intellectual disability. People with intellectual disability are not officially considered a vulnerable population in the current code of federal regulations as there is no subpart devoted to this group. They are included here as their inclusion appears to be consistent with the spirit of the regulations. Refer to the current code of federal regulations for additional information concerning vulnerable populations.

C. Are there any research activities that do not require IRB review?

No. All research involving human participants must be reviewed by the IRB. However, the IRB may determine that a project qualifies for exempt status.

D. What criteria will the IRB use to determine if a research project receives exempt status?

The following criteria for a project to be considered exempt were taken directly from the *Code of Federal Regulations,* Title 45, Part 46, Subpart A. You will be allowed to explain on the application form why you believe your project fits the exempt status criteria; however, the final determination for exempt status is made by the IRB.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) 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: (a) information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and (b) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

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 (2) of this section, if: (a) the human participants are elected or appointed public officials or candidates for public office; or (b) 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 participants cannot be identified, directly or through identifiers linked to the participants.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs, (b) procedures for obtaining benefits or services under those programs, (c) possible changes in or alternatives to those programs or procedures, or (d) 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, (a) if wholesome foods without additives are consumed or (b) 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 contaminant 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 U.S. Department of Agriculture.

E. What criteria will determine if a project may be reviewed by the IRB through an expedited review procedure?

The Department of Health and Human Services has established that the IRB may use an expedited review procedure to review either research involving no more than minimal risk or for minor changes in approved research. Taken from the Notice in the Federal Register, research involving no more than minimal risk includes research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. See the code of regulations for a list of other types of research involving only minimal risk.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviews designated by the chairperson from among the members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the

reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in the code of regulations. Each IRB that uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals that have been approved under the procedure.

F. What elements of the research protocol will be very important in the IRB review process?

To help ensure a favorable review, our records suggest that the IRB evaluates research protocols with an eye toward certain elements. These elements are presented to aid in the development of the research protocol and application.

1. All data are recorded anonymously or identifying information deleted at the end of the study. The coding system to protect participants' identity does not use participant initials, ID numbers (such as social security numbers or student ID numbers), mailing addresses, etc., in place of the participant's name. Instead, assignment of unique or random numbers to participants is recommended. In cases where follow-up is important, a master key could be maintained with the participant's name and contact information. However, only the number is placed on test materials. When final analyses are completed and no follow-up is planned, this key is destroyed.
2. When required, participant/parental permission must always be provided in a written format that is returned to the researcher.
3. When conducting research with vulnerable populations, additional protections are delineated and aligned with the code of regulations for that population.
4. If a control group is used as part of the treatment-type study, the advantages derived from the research should be made available to the control group or the control group told of the advantages.
5. Results are generally given to the participant in aggregate or group form; individual results are generally not reported back to the participants.
6. Services are not to be terminated or negatively affected if an individual refuses to participate or withdraws from the study.
7. A cover letter is provided to all research participants. The following information should be included in the cover letter:
    a. The researcher's affiliation with Drury University.
    b. An overview of the project that includes a description of what the participants will be asked to do. The description should be written in terms laypersons can easily understand and should avoid the use of jargon, technical terms, or medical terms or phrases.
    c. A statement of the voluntary nature of the project.
    d. A statement of anonymity/confidentiality of the participant's data.
    e. The contact information for the researcher so that participants can request details of the research study, ask follow-up questions, or express concerns.
8. All research participants are asked to read and sign an informed consent form. The informed consent form must include the following elements stated in language the participant can easily understand.
    a. An explanation of:
        - the purpose of the research and the expected duration of the individual's participation,
        - a description of the procedures to be followed,
        - and identification of any procedures that are experimental.
    b. A description of any reasonably foreseeable risks or discomforts to the participant.
    c. A description of any benefits to the participants or to others which may reasonably be expected from the research.
    d. A disclosure of appropriate alternative procedures or courses of treatment (if any) that might be advantageous to the participant.
    e. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained.

f. An explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
g. An explanation of whom to contact for answers to pertinent questions about the research and research participant's rights, and whom to contact in the event of a research-related injury to the participant.
h. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled and that participation may be discontinued at any time without penalty or loss of benefits to which the participant is otherwise entitled.
i. For phone surveys or interviews, participants should be informed of items 8a-h.

9. In addition, to the general items provided in 8 a-h, the Informed Consent Form must include the following paragraphs verbatim:

   This project has been reviewed and approved by the Drury University Institutional Review Board (IRB). The IRB has determined that the research procedures adequately safeguard the participant's privacy, welfare, civil liberties, and rights. The chair of the IRB may be reached at Drury University, 900 North Benton Avenue, Springfield, MO 65802. The telephone number is 417-873-7_ _ _.

   I have read the material above, and any questions I asked have been answered to my satisfaction. I agree to participate in this activity, realizing that I may withdraw without penalty or prejudice at any time.

   _____ _____
   Signature of Participant or Authorized Representative *Date (mm/dd/yyyy)*

   _____
   Printed Name of Participant or Authorized Representative

10. When preparing the research protocol and application, please note that the IRB must review and approve all cover letters, informed consent forms, scripts, instructions to the participants, introductory remarks, survey materials, etc.

G. Research Utilizing Electrical or Psychophysiological Equipment

All electrical/psychophysiological equipment connected to a participant (such as EEG, EKG, or polygraph equipment) or that the participants come in contact with should be checked by a qualified technician within one month prior to testing and on a regular basis during testing (i.e., normally one month intervals). Assurance of this should be included on the application form.

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Application to Conduct Research with Human Participants

For IRB OFFICE Use Only:
Project Identification Number: Year_____ ID#_____

Project Director or Investigator: **Date (*mm/dd/yyyy*):**

Institution: **Department:**

Mailing address:

Phone: **Email:**

Project or Grant Title:

Project Status: _____ New Project _____ Revision to an Existing IRB-Approved Project

_____Periodic Review of an IRB-Approved Continuing Project

Anticipated Project Start and End Dates:

Where will the research be conducted?

Project Type (Check the option that best applies.)

_____ Faculty research

_____ Student research (under faculty direction)

_____ Student class project* (under faculty direction)

*Provide course number: _____

_____ Federal grant application -- List source:

_____ Nonfederal grant application – List source:

_____ Thesis or dissertation

_____ Other, please specify:

Does your project involve participants or individuals from special/vulnerable populations?

_____ Yes _____ No (If "Yes," check all that apply.)

_____Children under 18 years of age
_____Individuals with intellectual disabilities
_____Prisoners
_____ Other; please specify: _____

_____ Pregnant women
_____ Individuals with physical disabilities
_____ Economically disadvantaged

Who are your proposed research participants? Check all categories that apply, and provide an estimate of the total number of individuals in each relevant category on whom you will be collecting data for your project or study:

_____ College Students
_____ Faculty
_____ Staff
_____ General Public
_____ Children and Youth under 18
_____ Other (provide category and specific number of individuals)

Comments: (optional)_____

Research Protocol/Project Checklist (Respond to each question by placing an "X" on YES or NO.)

YES	NO	
____	____	1. Does this project or study involve collection of data that identifies individuals (e.g., cohort databases that include SSN# information on individuals or surveys/ interviews identifiable by name or student number)?
____	____	2. Will data identifiable by individual be shared with anyone (such as in a performance report for a funding source, conference presentations, published articles and reports, etc.)?
____	____	3. Are the participants being offered one or more of the incentives to participate (such as money, extra credit for the class, etc.)? If so, describe the incentive(s):
____	____	4. Is participation in this project or study voluntary for the individuals participating in the program or study?
____	____	5. Will participants be fully informed about the benefits and any risks?
____	____	6. Will participants be videotaped during the project or study?
____	____	7. Will participants' privacy and personal information be protected? Briefly explain how privacy and information will be protected.
____	____	8. Will participants be debriefed following completion of the project or study?
____	____	9. Will participants, prior to the project, indicate informed consent to participate by completing and signing a written form? Is a sample form included? Yes No
____	____	10. Does the funding source have any potential for financial or professional benefit from the outcome of this study or project? If yes, please explain.
____	____	11. Are data sources clearly identified (such as interviews, survey, existing project data, to include services received, reports, grades, existing school records, focus group, etc.)?

Narrative for Research Protocol

I. **Abstract Describing Project and Purpose:** Briefly describe (a) the project or study and (b) what human participants will experience during the proposed study or project. Describe all strategies or experimental methods to be used, design and program activities. Indicate what data, measures, or observations will be collected and used in the study or for the project. If any questionnaires, tests, or other instruments are to be used, include a brief description and **one copy** of the instruments. **Note to Grant Projects Directors:** In the case of educational or training grants, data collected about the participants served, assessment testing, pre- and post-testing and other aspects of project evaluation plans are critical. (Use additional pages if necessary)

II. **Methodology:** Specify who the project participants or research subjects will be. Indicate how they will be solicited, recruited, or contacted. Include any recruitment letters and materials with this document. State how much time will be required of each participant or subject. Describe procedures to which subjects will be subjected. Use additional pages if necessary.

III. **Voluntary Participation:** Specify the steps that will be taken to insure that each individual's participation is voluntary. State what, if any, inducements will be offered for their participation.

IV. **<u>Confidentiality of Data and Privacy Protection</u>:** Describe the methods to be used to safeguard the privacy of your participants and ensure the confidentiality of data obtained, including plans for publication, disposition and destruction of data, including that of computer, print, videotape, and audio materials.

V. **<u>Informed Consent</u>:** Attach a copy of all consent forms to be signed by the participants and/or any statements to be read to or provided to the participant.

VI. **<u>Risks to Participants</u>:** a) Describe any potential risks to participating individuals—physical, psychological, social, legal, or other; b) include all known and anticipated risks to the participants such as side effects, risks of placebo (inert) treatments, etc.; and c) in research that proposes substantial risk to human participants, list emergency backup procedures that are in place such as medical or counseling interventions.

VII. Benefits: a) Describe the benefits and/or any compensation that the participating individuals can expect and (b) describe the gains in knowledge that may result from the project or research study.

VIII. Human Participant Research Protection Exemption Categories:

Federal law 45 CFR 46.101(b) identifies the six (6) EXEMPT categories listed on the following pages using the language found in the legislation. *Check all that apply to your project or study and explain why you believe your proposed project or study falls into the category.*

NOTES:

1) The exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

2) Explanations for exempt status should be provided in sufficient detail to allow the IRB to determine if the study can be classified as exempt under Federal Regulations 45 CFR 46.101(b).

Special Note to Grant Project Directors:

In most cases, your grant projects are not what we traditionally think of as research studies. Nevertheless, the participant data, pre- and posttests of student learning, and other information you generate, compile, analyze, and report on in carrying out project activities and project evaluation are now considered Human Subjects Research by federal funding agencies. As you review the exemption categories listed below, think about the data you are collecting and reporting for the participants you serve and other data you will be using for project evaluation purposes.

EXEMPTION CATEGORIES:

_____ (1.) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
Please provide an explanation as to how your research falls into this category:

_____ (2.) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND (ii) 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 provide an explanation as to how your research falls into this category:

_____ (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: (i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
Please provide an explanation as to how your research falls into this category:

_____ (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.
Please provide an explanation as to how your research falls into this category:

_____ (5.) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: a) public benefit or service programs; b) procedures for obtaining benefits or services under those programs; c) possible changes in or alternatives to those programs or procedures; or d) possible changes in methods or levels or payment for benefits or services under those programs.
Please provide an explanation as to how your research falls into this category:

_____ (6.) Taste and food quality evaluation and consumer acceptance studies, a) if wholesome foods without additives are consumed or b) if a good 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 contaminant 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 Inspective Service of the U.S. Department of Agriculture.
Please provide an explanation as to how your research falls into this category:

Attachments: (Check the items you have included with your application, and attach all that apply.)

_____ Cover letter for participants

_____ Informed consent form(s)

_____ External support proposal or award letter

_____ Letters of approval from cooperating entities

_____ Research methods (research design, data source, sampling strategy, etc)

_____ Questionnaires, surveys, or other data-gathering forms

_____ Letters, flyers, questionnaires, etc., that will be distributed to participants

_____ Copy of thesis/dissertation, approved proposal, or prospectus

_____ If the research is part of a research proposal submitted for federal, state, or external funding, submit a copy of the FULL proposal

Signature of Principal Investigator: Date: (*mm/dd/yyyy*)

Printed Name:

Email: **Phone:**

Approval by Faculty Sponsor: I confirm the accuracy of this application. I accept responsibility for the conduct of this research, the supervision of human participants, and the maintenance of informed consent documentation as required by the IRB.

Signature of the Faculty Sponsor: Date: (*mm/dd/yyyy*)

Printed Name:

Email: **Phone:**

DRURY UNIVERSITY

General Agreements, Signatures, and IRB Decision

Project Title _____

In making this application, I(we) certify that:

1) I(we) agree to comply with federal, state, and local laws regarding the protection of human participants in research.
2) I(we) will submit any future changes to the research project to the IRB for review and approval prior to implementation, as these may alter the exempt status of the project.
3) I(we) agree that any new findings that develop during the course of this study that may affect the risks and benefits to participants will be promptly reported to the IRB in writing.
4) I(we) agree that any adverse events that occur in the course of this study will be promptly reported to the IRB in writing.
5) I(we) agree and understand that records of the participants will be kept for at least three (3) years after the completion of the research.
6) I(we) may begin research only after the IRB gives notice of its approval.

Signatures of all researchers/project directors are required (attach additional pages, if necessary).

_____ _____
Signature Date

_____ _____
Signature Date

_____ _____
Signature Date

_____ _____
Signature Date

Faculty Advisor or Departmental Advisor:

_____ _____
Signature Date

♦ ♦ ♦

The request for approval submitted by the above researcher(s) was considered by the Drury University Institutional Review Board on _____(*mm/dd/yyyy*). The application was ❑ approved ❑ not approved by the IRB. Special conditions ❑ were ❑ were not set by the IRB. (Any special conditions are described on the reverse side.)

_____ _____
Chair, Institutional Review Board Date
Drury University