

Tips on Completing the IRB Protocol Request for Exempt/Flexible Review form Research projects

The following are some tips on completing the IRB Protocol Request for Exempt/Flexible Review form. I will start at the beginning of the form and work my way through it. The goal is to have it in the best shape so when the IRB reviews the form, there are no requests for clarification, no requests for revisions thus facilitating approval of the project. Requests for clarification will only slow the process.

Please Note: All sections/questions need a response. If a section/question does not apply, state 'Not applicable'; do not leave it blank.

NOTE: This is for the IRB form version v2026-01.

Basic Information	
Title of Study:	
Principal Investigator Name:	
Principal Investigator's Department/Unit:	

- Principal Investigator's Department/Unit should be College of Nursing.

Funding Information

For some projects, there is no funding. If you have no funding and are giving compensation to participants such as a gift card or raffle for a gift card, the source of the funds needs to be stated or the IRB will ask the source of the funds. Suggest checking 'Other' and for 'Name of funding source' state Gift card(s) will be self-funded by the PI. If you have funding, be careful what is checked, especially if it asks for an institutional proposal or award number and it has not been routed through Sponsored Projects. This will cause a delay when submitted in eIRB.

Eligibility for Exempt/Flexible Review

Check any items that apply to your study. Please note the instructions in red. If you check any of the items, this is not the appropriate form to complete. Stop and proceed with the appropriate IRB Protocol form.

Note: If any of the items are checked, DO NOT use this form. Proceed with the standard IRB application. For more information on the items below, please review the [HSPP guidance documents](#).

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| <input type="checkbox"/> Activities posing greater than minimal risk (i.e., the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life) |
| <input type="checkbox"/> Multisite study with the UA IRB providing IRB oversight to external research team members and/or outside institution |

<input type="checkbox"/> Investigating a drug, device, software as a medical device, or biologic (i.e., FDA regulated). See HSPP guidance, <i>Software as a Medical Device</i>
<input type="checkbox"/> Clinical trial as defined by the NIH and the FDA
<input type="checkbox"/> Prisoners as participants
<input type="checkbox"/> Collecting identifiable, sensitive research data requiring limited IRB review (information is considered <i>sensitive</i> if the loss of confidentiality, integrity, or availability could be expected to have a serious adverse effect on individuals—such as data related to abuse, trauma, grief, sexual history, mental health, substance use, illegal behavior, or other stigmatizing or private experiences).
<input type="checkbox"/> Actively recruits Native Americans or Indigenous populations for enrollment or categorizes these populations within the study's statistical analyses or research objectives
<input type="checkbox"/> Accessing medical records or protected health information (PHI)

Summary of Activities

1. Provide a concise description of the purpose of the project

Include a purpose statement. Include specific aims, hypotheses, and/or research questions if applicable.

2. Describe the proposed methods and study procedures:

Include a detailed description of the study procedures. This can include the recruitment process and consent process in addition to a detailed description of the study procedures.

3. Select the study population:

<input type="checkbox"/> Healthy adults	<input type="checkbox"/> Non-English-speaking individuals
<input type="checkbox"/> Non-healthy adults	<input type="checkbox"/> UA staff/faculty
<input type="checkbox"/> Children (under 18 years old)	<input type="checkbox"/> UA students
<input type="checkbox"/> Pregnant women, neonates, and/or fetuses	<input type="checkbox"/> Banner employees
<input type="checkbox"/> Refugees	<input type="checkbox"/> Other – please explain:
<input type="checkbox"/> Adults unable to consent (i.e., adults with cognitive impairments)	

4. Recruitment:

<p>Confirm that potential participants will not be cold-contacted (i.e., contacted directly by the research team without a prior relationship or appropriate access mechanism):</p> <p><input type="checkbox"/> Yes, I confirm that no potential participants will be cold-contacted by the research team. See HSPP guidance, <i>Recruitment and Advertising</i>.</p> <p><input type="checkbox"/> N/A</p>
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5. Select the consent method(s) to be used:

<input type="checkbox"/> Informed Consent – written, electronic, online or verbal
<input type="checkbox"/> Parental Permission – written, electronic, online or verbal
<input type="checkbox"/> Assent (participants under 18) – written, electronic, online or verbal
<input type="checkbox"/> Debriefing Script or Form – document used to properly inform participants of the study’s purpose when intentionally deceived or incomplete disclosure in the consent.
<input type="checkbox"/> Other – please explain: Click to enter text.

6. Describe all physical, psychological, social, legal, and/or economic risks that could be associated with participation in this research. Be sure to address any risks related to audio/video recording and possible breaches of confidentiality.

If there are risks, state them. If there are no risks, state no risks. The risk of loss of confidentiality should be considered. However, if the data will be anonymous and no identifiers will be collected, this may not be a risk. Risks stated here should also be stated in the consent document.

7. Select where study data will be stored:

<input type="checkbox"/> Box@UA	<input type="checkbox"/> Department Office
<input type="checkbox"/> Box@UA Health	<input type="checkbox"/> Encrypted Drive
<input type="checkbox"/> Password Protected Drive	<input type="checkbox"/> External Drive (hard drive, USB, disk)
<input type="checkbox"/> Cloud Server (Qualtrics, Google, Dropbox, etc.), specify the server name below	<input type="checkbox"/> REDCap
<input type="checkbox"/> Department Drive	<input type="checkbox"/> Other, specify: Click to enter text.
Describe the security measures in place to protect research data. If audio or video recordings are collected, specify when they will be transcribed and when the original files will be destroyed, if applicable.	

Remember to complete the second part of this section – description of the security measures that will be in place to protect the research data.

Exempt Categories

Please select the most applicable exemption category for this study.

TIP: If the study is not funded, select *Flexible Review, Minimal Risk 2018*. If the study is federally funded, select a category from 1–6 below.

NOTE: If none of these categories apply, STOP - the submission does not qualify for Exempt/Flexible Review.

<p><input type="checkbox"/> Unfunded Study: Flexible Review, Minimal Risk 2018: This category is not found in the federal regulations but has been created for projects that do not directly meet a specific exemption category according to 45 CFR 46.104 but still considered low risk. These projects will be reviewed using an approval process identical to that used for exempt research under 45 CFR 46.104.</p>
<p>Funded Study Selections</p>
<p><input type="checkbox"/> (1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. Site Authorization is required for research occurring in a school setting.</p>
<p><input type="checkbox"/> (2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if <u>at least one</u> of the following criteria is met:</p> <p>(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;</p> <p>(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation. Research involving children can be classified as exempt under these categories if the research involves only educational tests and/or observation of public behavior where the investigator does <u>not</u> participate in the activities and the research meets the other conditions of the exemption category.</p>
<p><input type="checkbox"/> (3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and <u>at least one</u> of the following criteria is met:</p>

<p>(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or</p> <p>(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.</p> <p>(3)(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.</p> <p>(3)(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.</p> <p>This exemption category cannot be used for research involving children.</p>
<p><input type="checkbox"/> (4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if <u>at least one</u> of the following criteria is met:</p> <p>(i) The identifiable private information or identifiable biospecimens are publicly available;</p> <p>(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; or</p> <p>(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b).</p>
<p><input type="checkbox"/> (6) Taste and food quality evaluation and consumer acceptance studies:</p> <p>(i) If wholesome foods without additives are consumed, or</p> <p>(ii) 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.</p>

If none of these categories apply, STOP - the submission does not qualify for Exempt/Flexible Review.

Checklist for Investigators

Review the additional items below that may be required for approval (select all that apply):

<input type="checkbox"/> Advisor approval (if the PI is a student or medical resident)*
<input type="checkbox"/> Scientific/Scholarly review approval *
<input type="checkbox"/> RAP/Banner feasibility (if the study uses any Banner Health resources)*
<input type="checkbox"/> SRC approval (if the study is cancer-related – see Scientific Review Committee)*
<input type="checkbox"/> eDoc number (if the study is industry funded – see Fees for Human Subject Research)*
<input type="checkbox"/> School district approval* and principal approval (if the study takes place within a school setting)
<input type="checkbox"/> Site Authorizations
<input type="checkbox"/> Current PI CV, biosketch, or resume
<input type="checkbox"/> Consent Form(s)
<input type="checkbox"/> Recruitment Material
<input type="checkbox"/> Data Collection Materials
<input type="checkbox"/> Completion of Human Subjects CITI training for all members of the study team
NOTE: All investigators must complete their study-specific COI disclosure before IRB approval is released. For unfunded studies, COI certifications are automatically generated upon eIRB submission. <i>After</i> submission, all research team members must log into eDisclosure to complete their COI certification.

* If any applicable items marked with an asterisk are missing, your submission will be **returned** unreviewed.