

Decision Tool: Does this study qualify as Exempt 1, 2, 3, or 4?

This guide provides:

1. Definitions of the 4 Exempt categories as defined by the revised Common Rule
2. Bullet points to highlight new criteria for qualifying for a specific category
3. Questions that will be in the “Initial Screening Questions” section of the IRB application for each category, along with advisements (**in bolded red and black**) that will appear for specific answers. Many of the advisements indicate that a study does not meet the specified Exempt criteria, and provides instructions for how to proceed.

Important: You must **read and follow the instructions** in the **bolded red and black** advisements to ensure you are filling the application out correctly. Otherwise, the IRB will send the application directly back to you for correction, without review.

Category 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.

- Prisoners can be enrolled only incidentally, cannot be an intentionally targeted study population
- No interventions allowed
- Minors can be enrolled

Question	* Does the research intend to enroll prisoners as a targeted population?
Answer	Yes No
Advisement	(if yes) If being a prisoner is an inclusion criteria, change your answer in 4.6 from 'Exempt' to 'Expedited.' Research can only qualify as Exempt if the research is aimed at a broader population that only incidentally may include prisoners. (if no, proceed)

Question	* Does the research involve <u>interventions</u> ?
Answer	Yes No
Advisement	(if yes) Research using interventions does not qualify under Exempt Categories 1, 2, and 4. If the research includes interventions, change your answer in 4.8 to Exempt Category 3 or change the review level in 4.6 from 'Exempt' to 'Expedited.' (if no, proceed)

Question	* Will study be conducted in a commonly accepted educational or training setting (including professional meetings)?
Answer	Yes No
Advisement	(if yes, proceed) (if no) The research does not qualify as Category 1 Exempt. Change your response in 4.8 to Exempt Category 2. If the scope of work does not meet the criteria for Exempt Category 2, change the review level in 4.6 from 'Exempt' to 'Expedited.'

Question	* Are the following activities involved (check all that apply):
Answer	<input type="checkbox"/> Research on instructional / training strategies <input type="checkbox"/> Research on effectiveness of instructional techniques, curricula, or classroom management methods <input type="checkbox"/> Research comparing different instructional / training techniques
Advisement	(if any boxes are checked, proceed) (if none of the boxes are checked) If the research does not involve any of these activities, it doesn't qualify as Exempt Category 1. You should change it to Exempt Category 2 or change the Review Level in 4.6 to 'Expedited.'

Question	* Does the research specifically involve 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:
Answer	Yes No
Advisement	(if yes, proceed) (if no) The research does not qualify as Category 1 Exempt. Change your response in 4.8 to Exempt Category 2. If the scope of work does not meet the criteria for Exempt Category 2, change the review level in 4.6 from 'Exempt' to 'Expedited.'

Category 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).

- Prisoners can be enrolled only incidentally, cannot be an intentionally targeted study population
- No interventions allowed
- Minors can be enrolled only if:
 - No identifiers are recorded, **and**
 - The only procedures are educational tests or observation of public behavior (i.e., minors cannot participate in survey or interview procedures under this category), **and**
 - If it is an observation study, the PI does not participate in the activity being observed

Question	* Does the research intend to enroll prisoners as a targeted population?
Answer	Yes No
Advisement	(if yes) If being a prisoner is an inclusion criteria, change your answer in 4.6 from 'Exempt' to 'Expedited.' Research can only qualify as Exempt if the research is aimed at a broader population that only incidentally may include prisoners. (if no, proceed)

Question	* Does the research involve interventions ?
Answer	Yes No
Advisement	(if yes) Research using interventions does not qualify under Exempt Categories 1, 2, and 4. If the research includes interventions, change your answer in 4.8 to Exempt Category 3 or change the review level in 4.6 from 'Exempt' to 'Expedited.' (if no, proceed)

Question	* Are any of the subjects under 18 years old?
Answer	Yes No
Advisement	(if yes, proceed) (if no, proceed)

Question Only asked if enrolling minors	* Will the research with subjects under the age of 18 only involve: <ul style="list-style-type: none"> • Educational tests; or • Observation of public behavior?
Answer	Yes No
Advisement	(if yes, proceed) (if no) The research does not qualify as Exempt Category 2. Scroll up to the Initial Screening Questions section and change the review level in 4.6 from 'Exempt' to 'Expedited.'

Question Only asked if not enrolling minors	* Does the research only include interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording): (REQUIRED)
Answer	Yes No
Advisement	(if yes, proceed) (if no) The research does not qualify as Exempt Category 2. Change the review level in 4.6 from 'Exempt' to 'Expedited.'

Question	* Does the research (check all that apply):
Answer	<input type="checkbox"/> Record information in such a manner that the identity of the human subjects CAN readily be ascertained, directly or through identifiers linked to the subjects? ('identifiable') <input type="checkbox"/> Record the information in such a manner that the identity of the human subjects CANNOT readily be ascertained, directly or through identifiers linked to the subjects ('de-identified'); <input type="checkbox"/> Ensure that 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; or <input type="checkbox"/> None of the above
Advisement	<p>(if 'Identifiable' 1st box and including minors) This type of research does not permit the inclusion of subjects under the age of 18. If subjects under the age of 18 are part of the research change the review level in 4.6 from 'Exempt' to 'Expedited.'</p> <p>(if 'Identifiable' 1st box and not including minors) This study will receive limited IRB review. You will be asked to answer additional questions about privacy and confidentiality later in this form.</p> <p>(if minors are included and the 'de-identified' 2nd box <u>isn't</u> checked) For research involving subjects under 18, the second box must be checked to qualify as Category 2 Exempt. If the second box doesn't apply to your study, change the review level in 4.6 from 'Exempt' to 'Expedited.'</p> <p>(if 2nd or 3rd box, proceed)</p> <p>(if 'None of the above') The research does not qualify as Category 2 Exempt. Change the review level in 4.6 from 'Exempt' to 'Expedited.'</p>

Question Only asked if enrolling minors	* If the research involves observation, will the investigator participate in the activities being observed?
Answer	Yes No
Advisement	(if yes) The research does not qualify as Category 2 Exempt. Change the review level in 4.6 from 'Exempt' to 'Expedited.' (if no, proceed to the next question)

Category 3:

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.

- Benign behavioral intervention is defined as “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” ([HHS](#)).
- Minors can NOT participate in Exempt 3 research

Question	* Does the research intend to enroll prisoners as a targeted population?
Answer	Yes No
Advisement	(if yes) If being a prisoner is an inclusion criteria, change your answer in 4.6 from 'Exempt' to 'Expedited.' Research can only qualify as Exempt if the research is aimed at a broader population that only incidentally may include prisoners. (if no, proceed)

Question	* Are any of the subjects under 18 years old?
Answer	Yes No
Advisement	(if yes) Research involving minors under 18 does not qualify under the Exempt 3 category. Please scroll up to 4.6 and select 'Expedited' instead of 'Exempt.' (if no, proceed)

Question	* Does the research (check all that apply):
Answer	<input type="checkbox"/> Record information in such a manner that the identity of the human subjects CAN readily be ascertained, directly or through identifiers linked to the subjects? ('identifiable') <input type="checkbox"/> Record the information in such a manner that the identity of the human subjects CANNOT readily be ascertained, directly or through identifiers linked to the subjects ('de-identified'); <input type="checkbox"/> Ensure that 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; or <input type="checkbox"/> None of the above
Advisement	(if 1 st or 2 nd box, proceed) (if 'Identifiable' 3 rd box) This study will receive limited IRB review. You will be asked to answer additional questions about privacy and confidentiality later in this form. (if 'None of the above,' proceed)

Question	* Will the research:
Answer	<input type="checkbox"/> only involve benign behavioral interventions; <input type="checkbox"/> only include the collection of information from subjects through verbal or written responses (including data entry) or audiovisual recording; and <input type="checkbox"/> obtain agreement (e.g. consent) from the subject prior to the intervention and information collection
Advisement	(if yes, proceed) (if no) The research does not qualify as Category 3 Exempt. Change the review level in 4.6 from 'Exempt' to 'Expedited.'

Question	* Will the research include deceiving the human subjects regarding the nature or purpose of the research?
Answer	Yes No
Advisement	(if yes, proceed) (if no, proceed)

Question Only asked if "yes" to deception	* If this study involves deception, does the informed consent document(s) disclose to the human subject that he/she will be unaware or misled regarding the nature or purposes of the research:
Answer	Yes No N/A
Advisement	(if yes, proceed) (if no) Deception is only allowed in Exempt research if the subjects prospectively agree to deception in the consent form. Either change your answer to 'Yes' and ensure the consent form includes a statement about deception OR change the Review Level in 4.6 from 'Exempt' to 'Expedited.'

Category 4:

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens

- Data can be existing or collected prospectively
- Research involving subject contact does not qualify for Exempt 4
- Minors can be enrolled

Question	* Does the research intend to enroll prisoners as a targeted population?
Answer	Yes No
Advisement	(if yes) If being a prisoner is an inclusion criteria, change your answer in 4.6 from 'Exempt' to 'Expedited.' Research can only qualify as Exempt if the research is aimed at a broader population that only incidentally may include prisoners. (if no, proceed)

Question	* Does the research involve interventions ?
Answer	Yes No
Advisement	(if yes) Research using interventions does not qualify under Exempt Categories 1, 2, and 4. If the research includes interventions, change your answer in 4.8 to Exempt Category 3 or change the review level in 4.6 from 'Exempt' to 'Expedited.' (if no, proceed)

Question	* Does the research (check all that apply):
Answer	<input type="checkbox"/> Use identifiable private information or identifiable biospecimens that are publicly available; <input type="checkbox"/> Use information, which may include information about biospecimens, that 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; <input type="checkbox"/> Only collect and analyze 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); or <input type="checkbox"/> Qualify as research conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities. <input type="checkbox"/> None of the above
Advisement	(if any of the first 4 boxes are checked, proceed) (if ‘None of the above’) This research does not qualify as Exempt Category 4. Change the Review Level in 4.6 to 'Expedited.'