

Interaction/Intervention Exemption Applications

Significant changes have been made to the application path for projects qualifying for one of the interaction/intervention exemptions (1, 2, 3, 5, and 6). This includes changes to the question sets and to the application workflow and functionality. The key changes are summarized below.

As of June 11, the eResearch application for exempt projects will undergo significant changes in both the question sets and in functionality.

Change to Application Types

The new “Human Subjects research involving interaction or intervention” application type will be used for all projects designed to collect information of biospecimens from human subjects, including projects requiring comprehensive IRB review and those qualifying for exemption.

New Exemption Screener Section

- Routes projects that do not qualify for exemption to the next section in the full IRB application
- Identifies projects that may qualify for exemption and routes them to the next section in the exemption review path

Does the research involve any of the following:

- more than minimal risk to participants?
- use of drugs or medical devices?
- target prisoners as research subjects?
- collection of biospecimens from subjects (including blood, saliva, cheek swabs)?

Yes No [Clear](#)

Some studies involving interaction or intervention with subjects meet the criteria for exemption. Select the category that best describes your research. Detailed questions to verify eligibility are found on the next page. For some studies, you will be able to issue a self-determination.

If none of these categories apply to your research select NONE. Your application will be routed for comprehensive IRB review.

Exemption Category

Exemption 1 applies to research that is:

- conducted in established educational settings (typically schools/colleges); and
- focuses on normal (accepted) educational practices (e.g. instructional techniques, curricula, classroom management methods)

May include use of educational data

Changes to Exemption Detail

Eliminated: Exempt Research Design Section (Current Section 5-3)

- Key information from the current *Research Design - Exempt Project* section will be captured in the new exempt detail page for each specific exemption category.

New: Exemption Detail Pages

- Includes qualifying questions for each interaction/intervention exemption

5-3. Research Design - Exempt Project

Completion of this section is required based on the response provided to question 1-1.1

5-3.1 Upload scientific protocol if one is available.

Name: _____
There are no items to display

5-3.2* Describe the scientific design of the project. If included in the attached protocol, please indicate the section.

5-3.3* Describe the scientific design of the project. If included in the attached protocol, please indicate the section.

Old version

Exemption 2

Completion of this section is required based on the Exemption Category selected in question 1-1.1.

Exemption 2 applies to projects that include either:

- Observation of Public Behavior; or
- Interactions with human subjects that involves collection of information ONLY using the following methods:
 - Surveys
 - Interviews (including cognitive interviews)
 - Focus Groups
 - Educational tests (cognitive, diagnostic, aptitude, achievement)
 - Observation of public behavior

Audio and/or video recording of these observations or interactions is not permitted.

This exemption does not apply if the research involves:

- Interventions/manipulations that are distinct from the collection of information
- Collection of biospecimens in conjunction with the collection of information
- Linking information collected via this exemption to other identifiable data

1* Confirm that your research involves the collection of information ONLY using one or more of the following:

- Surveys (information collected through questionnaires, in person or online)
- Interviews
- Focus Groups
- Educational Tests (cognitive, diagnostic, aptitude, achievement)
- Observation of public behavior

Yes No [Clear](#)

1.1* Does the research involve children?

Yes No [Clear](#)

New version

- A disqualifying response will move the application to the next question in the comprehensive IRB application.
- Elicits information currently captured in the exempt research design
 - Research description (or uploaded exempt protocol)
 - Subject compensation information for the Human Subjects Incentive Program (HSIP)
 - Questions regarding the use of Protected Health Information

Exemption with Limited IRB Review

- Certain Exempt 2 and 3 projects that collect information that is both sensitive and identifiable may qualify for exemption if they include adequate subject privacy and data confidentiality provisions. Defined as requiring “limited IRB review”, these projects will be routed to Section 11 to capture this required information.
- Exempt with Limited IRB Review projects require review by an expediting reviewer before the exemption can be issued.
- The IRB may require comprehensive IRB review for projects that collect information about illegal behaviors or focus on mental health, immigration status, domestic violence or other issues where there may be potential for more than informational risks to subjects.

Self-Determination

- Based on responses to each exempt qualifying question, investigators may be presented with the opportunity to generate a self-determination for certain types of exemptions at the end of the application.
- The following is required to issue a self-determination
 - A faculty advisor for investigators identifying as students
 - Active PEERRS certification for the principal investigator and faculty advisor
 - No conflict of interest disclosure

45. End of Application

Available Activities

Based on the answers provided in this application, the listed Principal Invr

Note: This letter will not generate if the PI has not completed PEERRS huma...

If you would like the IRB to review this application, the PI should click the Sub

Error Check

Submit Application

Generate Exempt Self-Determination Letter

New Template

- Investigators are encouraged to download the [Exempt Studies: Brief Protocol](#) template to describe their research.
- The Brief Protocol also includes the *Data Management and Security* questionnaire for use with Exemption #2 or #3 projects requiring limited IRB review.