

Exemption: Requesting an exemption

The screenshot shows the IRBIS (Office of Human Research Ethics) online submission interface. The page title is "Request Exemption". The left sidebar contains an "Item List" with sections: General Information, Exemptions (with "Request Exemption" selected), Part A. Questions Common to All Studies, Part B. Direct Interaction, Part D. The Consent Process, Data Security Requirements, Consent Forms, Attachments, Approving Depts, and Cover Memo. Below the sidebar are buttons for Home, Application Status, Submit, and Delete Submission. The main content area has a header "Request Exemption" and a sub-header "Current Application: Quick View PDF for Printing View FA". A text box explains that some research involving human subjects may be eligible for an exemption, but not if it involves drugs, devices, greater than minimal risk, medical procedures, deception, or minors. The first question is "1. Would you like your application evaluated for a possible exemption? *". The "Yes" radio button is selected. Below it is the question "Will your study either involve prisoners as participants or be FDA-regulated?". The "No" radio button is selected. A red asterisk indicates a required field. At the bottom, there are instructions to navigate the application and two buttons: "Save and Continue" and "Clear Responses".

You may request consideration for exemption, but NOT if your study involves prisoners as subjects or is regulated by the FDA.

Exemption: Justifying a request

The screenshot shows the IRBIS Office of Human Research Ethics interface. The main content area is titled '>> Justify Exemption'. It contains three categories of questions:

- Category 1:** 'Check all of the following that apply to this study.'
 - The research is to be conducted in established or commonly accepted educational settings.
 - The research will involve normal educational practices, such as:
 - Research on regular and special education instructional strategies.
 - Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
 - Explain: [Text area]
- Category 2:** 'Does your study involve minors under the age of 18?'
 - Yes No
 - The research involves the use of one or more of the following:
 - Educational tests (cognitive, diagnostic, aptitude, achievement).
 - Survey procedures.
 - Interview procedures.
 - Observation of public behavior.
 - And either or both of the following is true:
 - The information to be obtained will be recorded in such a manner that participants cannot be identified, directly or indirectly through identifiers linked to the participants.
 - Any disclosure of the participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.
 - Explain: [Text area]
- Category 3:** 'Research involves the use of one or more of the following:'
 - Educational tests (cognitive, diagnostic, aptitude, achievement)

The left sidebar contains a navigation menu with items like 'General Information', 'Exemptions', 'Part A. Questions Common to All Studies', etc. The bottom navigation bar has buttons for 'Home', 'Application Status', 'Submit', and 'Delete Submission'. A dashed arrow points from the text below to the 'No' radio button in Category 2.

Federal regulations allow for exemption in six specific circumstances (categories). To justify a request for exemption, respond to questions specific to one or more of these categories.

Note, for example: under Category 2, you may not qualify for an exemption if you intend to enroll minors as subjects (see next page).

Exemption: Justifying a request -- Category 2

Approving Depts

Cover Memo

Home

Application Status

Submit

Delete Submission

2. Category 2: Does your study involve minors under the age of 18?

Yes No

The research involves the use of one or more of the following

Educational tests (cognitive, diagnostic, aptitude, achievement).

Survey procedures.

Interview procedures

Observation of public behavior.

And either or both of the following is true:

The information to be obtained will be recorded in such a manner that participants cannot be identified, directly or indirectly through identifiers linked to the participants.

Any disclosure of the participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

Explain

To qualify for an exemption under Category 2:

- Subjects must be adults.
- Data collection must employ at least one or more of four specified methods.
- Data must be gathered in such way that subject cannot be identified AND/OR risk to subjects is minimal.

Exemptions: Applying for an exemption

The screenshot displays the IRBIS (Office of Human Research Ethics) online submission interface. A yellow alert box at the top center reads: "EXEMPTION ALERT: Based on your responses you may be eligible for an exemption. Please complete the following abbreviated application." Below the alert is an "OK" button. The main interface features a sidebar on the left with an "Item List" containing sections like "General Information", "Exemptions", "Part A. Questions Common to All Studies" (with sub-sections A.1 through A.10), "Part B. Direct Interaction", "Data Security Requirements", "Attachments", "Approving Depts", "Cover Memo", and "Application Cover Memo". The main content area shows a text editor with a toolbar and a note: "Please review the FAQ section for Tips and Techniques on using the HTML Editor." At the bottom, there are "Save and Continue" and "Clear Responses" buttons. A red asterisk indicates a required field.

If it is determined that you qualify for IRB review under rules governing exemption, you will be presented with an abbreviated application form. You will therefore NOT be required to complete the following online application sections:

- Part A.2: Subjects
- Part A.3: Inclusion/exclusion criteria
- Part A.5: Benefits to subjects and/or society
- Part A.7: Data and data safety monitoring
- Part A.8: Data analysis
- Part B: Direct Interaction

However, you will be asked to attach all supporting materials, including recruitment scripts and flyers, surveys and questionnaires, and consent forms and scripts, etc.

Note: Even if your study qualifies for exempt review, the IRB must thoroughly examine your application and supporting materials before making its determination.