

Online Application Orientation: Screening questions – which application? (1)

The screenshot displays the '4. Screening Questions' section of an online application. On the left, a navigation menu lists sections: General Information, Project Personnel, Funding Sources, and Screening Questions. Below the menu are buttons for Home, Application Status, Submit, and Delete Submission. The main content area shows question 1.1: 'Is your project Human Subjects Research (HSR) that requires IRB review and approval (e.g., clinical trial, identifiable survey)? Select "No" if either you are unsure or you would like documentation that your project does not require IRB approval. *'. Below this is a sub-header: 'The following questions will help build the remaining components of your IRB application.' Five additional questions (A-E) follow, each with 'Yes' and 'No' radio buttons. A dashed arrow points from the text below to the 'Yes' radio button for question 1.1. At the bottom, there are 'Save and Continue' and 'Clear Responses' buttons, along with a note: '* Required. To navigate the Application, press continue or any link in the Item List to your left.'

Your response to Screening Question 4.1 will determine the shape of your entire application. If you already know that your application constitutes human subjects research, you will be asked to refine your answer.

Online Application Orientation: Screening questions – which application? (2)

IRBIS Office of Human Research Ethics

HOME | COMMITTEE REVIEWS | ADMIN | GENERAL MANAGEMENT | HELP | LOGOUT

Logged in as David Tegner

Item List click on section name to expand

General Information

- ✓ 1. General Information
- ✓ 2. Project Personnel
- ✓ 3. Funding Sources
- 4. Screening Questions

Home

Application Status

Submit

Delete Submission

>> 4. Screening Questions

Current Application: [Quick View](#) [PDF for Printing](#) [View FAQ](#)

1. Is your project **Human Subjects Research (HSR)** that requires IRB review and approval (e.g., clinical trial, identifiable survey)? Select "No" if either you are unsure or you would like documentation that your project does not require IRB approval. *

Yes No

The following questions will help you determine if your project will require IRB review and approval.

A. Is your project or activity a systematic investigation? This would typically mean that the same procedure(s) will be used to gather data about more than one person ("systematic"), in order to test a hypothesis or answer questions ("investigation"). *

Yes No

B. Will your study help develop or contribute to generalizable knowledge? This would not typically describe projects that are intended solely for internal assessment purposes, such as quality improvement/assurance, or program evaluations. *

Yes No

C. Do you intend to publish or present results from your study to an audience outside of UNC-CH, with the intent of drawing scientific conclusions or increasing the body of scientific knowledge? *

Yes No

D. Will you be using information (data, records or human biological specimens) that is currently existing or will be collected in the future for purposes other than this proposed research (e.g., medical records, ongoing collection of specimens for a tissue repository)? *

Yes No

E. Will you be collecting information about a living individual through direct intervention or interaction with that individual? This includes any contact with subjects including surveys, questionnaires, interviews, focus groups, observations, treatment intervention(s), etc. *

Yes No

F. Will the information be individually identifiable? This means that the identity of the subject is or may readily be ascertained by the investigator or associated with the information. *

Yes No

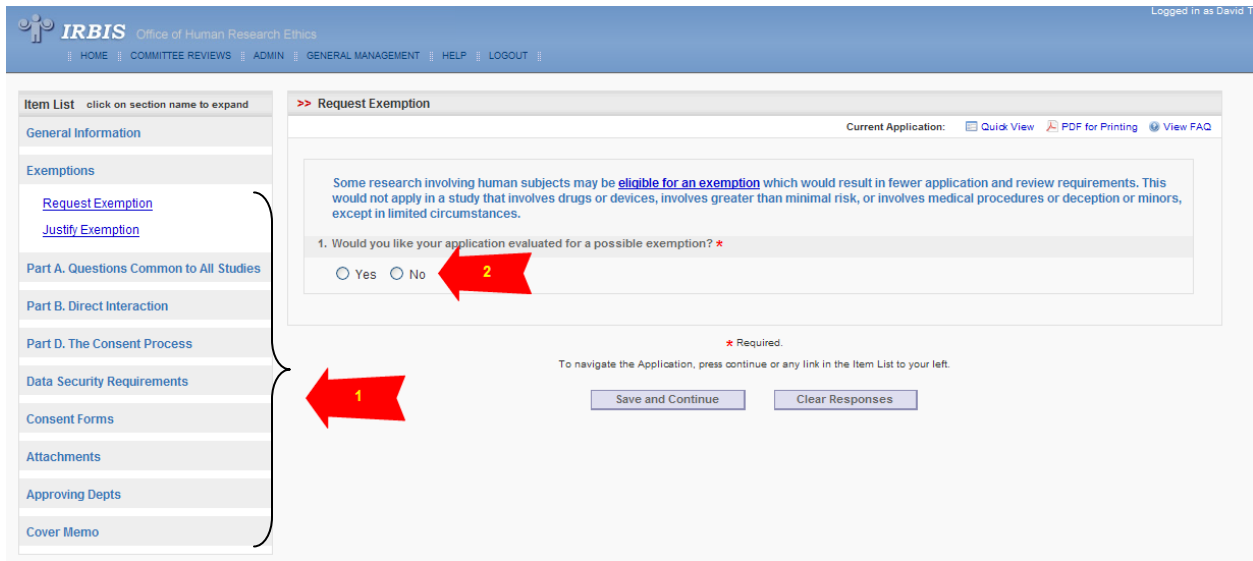
G. Will the information be private? This includes information about behavior that occurs in a context where an individual can reasonably expect that no observation or recording is taking place, or which the individual can reasonably expect will not be made public (e.g., a medical or school record). *

* Required.

To navigate the Application, press continue or any link in the Item List to your left.

If you know that your study does NOT constitute human subjects research, or if you are uncertain, a "no" response to 4.1 will prompt a set of additional questions that will help make this determination.

Online Application Orientation: Screening questions – which application? (3)



The screenshot displays the IRBIS Office of Human Research Ethics website. The left sidebar contains an 'Item List' with various sections. A red arrow labeled '1' points to the 'Request Exemption' link. The main content area is titled '>> Request Exemption' and contains a question: '1. Would you like your application evaluated for a possible exemption? *'. Below the question are two radio buttons: 'Yes' and 'No'. A red arrow labeled '2' points to the 'Yes' radio button. At the bottom of the main content area, there are two buttons: 'Save and Continue' and 'Clear Responses'.

Investigators whose responses to the screening questions result in a determination of “human subjects research” will automatically be directed to the full IRB application--note the expanded **Item List** (1). However, before commencing, you will first be asked (2) whether you would like to apply for an exemption (see [Requesting an Exemption](#)).

Online Application Orientation: Screening questions -- which application? (4)

The screenshot displays the IRBIS (Office of Human Research Ethics) online submission interface. The top navigation bar includes links for HOME, COMMITTEE REVIEWS, ADMIN, GENERAL MANAGEMENT, HELP, and LOGOUT. The main content area is titled 'A.9. Identifiers' and contains a list of identifiers to be checked. The left sidebar shows a navigation menu with sections like General Information, Exemptions, Part A. Questions Common to All Studies, NHSR, Consent Forms, Attachments, Approving Depts, and Cover Memo. A red arrow points to the 'A.9. Identifiers' link in the menu. The main content area lists various identifiers with checkboxes, including Names, Telephone numbers, Dates, Geographic subdivisions, Fax numbers, Electronic mail addresses, Social security numbers, Medical record numbers, Health plan beneficiary numbers, Account numbers, Certificate/license numbers, Vehicle identifiers, Device identifiers, Web universal resource locators (URLs), Internet protocol (IP) address numbers, Biometric identifiers, Full face photographic images, and Any other unique identifying number.

Item List click on section name to expand

General Information

Exemptions

Part A. Questions Common to All Studies

[A.9. Identifiers](#)

NHSR

Consent Forms

Attachments

Approving Depts

Cover Memo

Home

Application Status

Submit

Delete Submission

>> A.9. Identifiers

Current Application: [Quick View](#) [PDF for Printing](#) [View FAQ](#)

1. Check all of the following identifiers you will be receiving. This does not apply to information on consent forms.

- Names
- Telephone numbers
- Any elements of dates (other than year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death. For ages over 89: all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 and older
- Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes, except for the initial three digits of a zip code
- Fax numbers
- Electronic mail addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers (VIN), including license plate numbers
- Device identifiers and serial numbers (e.g., implanted medical device)
- Web universal resource locators (URLs)
- Internet protocol (IP) address numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any comparable images
- Any other unique identifying number, code, or characteristic, other than dummy identifiers that are not derived from actual identifiers and for which the re-identification key is maintained by the health care provider and not disclosed to the researcher

If your responses to the Screening Questions result in a determination of “Not Human Subjects Research (NHSR),” you will be guided through an abbreviated application—note the much abbreviated **Item List**, missing application sections B and D.