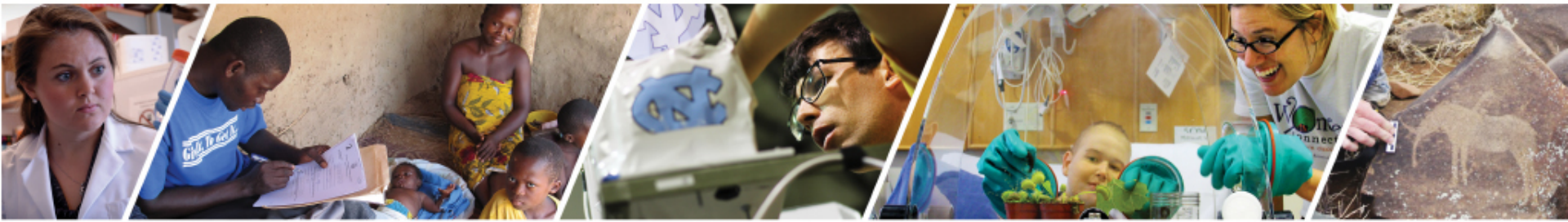


Recruitment

Completing the IRB Application

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UNC
RESEARCH

Recruitment SOPs

SOP 2.4.10

Recruitment is often the 1st step in the consent process.

Advertisements must clearly state that the project is a “research study”

Using lay language

Briefly describe the purpose

Summarize the procedures, location, and time commitment.

If the study involves an investigational device or drug, it must be described as *investigational*.

Recruitment SOPs

Advertisements should **NOT**:

- ❑ State or imply favorable outcome or benefits
- ❑ Include exculpatory language (e.g., By agreeing to participate, you waive any possibility of compensation for injuries that may occur.)
- ❑ Emphasize compensation by such means as a typeface that is large, bold, or colorful or a special placement

Recruitment SOPs

Direct Solicitation -- Researcher may not solicit by direct appeal to students employees or trainees in an effort to recruit subjects as this may be construed as coercive.

“Dear Colleague” letters – Intended to solicit help of professional peers in recruiting subjects

Recruitment by external researchers –May require collaboration of UNC investigator (e.g., subjects are UNC students or UNC HC patients)

The IRB approves the advertisement, not placement. You must obtain permission from gatekeepers: Local departments, clinics, external institutions or other sites.

Recruitment SOPs

Cold calls –It is preferable for patients to first hear about a research study from someone they would recognize as having a reason to know about their medical condition or other eligibility. (e.g., Letter of introduction by primary healthcare provider)

When this is not practicable (e.g., large number of subjects), the IRB may allow researchers to contact subjects directly.

Recruitment SOPs

Recruitment letters should begin with one of the following:

We are contacting you because you were seen by UNC Health Care since 2004.

Your records in the UNC Health Care System indicate you may be eligible to participate in our research study entitled “xxxxxxxxxx”. We are contacting people who have either an xxxx (lab value) or xxxxx (specific inclusion criteria)

Based on your medical history, you may be eligible to participate in this study.

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Section B.1.1.: Methods of Recruiting

1. Check all the following means/methods of subject recruitment to be used:*

- In person
- Participant pools
- Presentation to classes or other groups
- Letters
- Flyers
- Radio, TV recruitment ads
- Newspaper recruitment ads
- Website recruitment ads
- Telephone script
- Email or listserv announcements
- Follow up to initial contact (e.g., email, script, letter)
- Other

If other, please specify

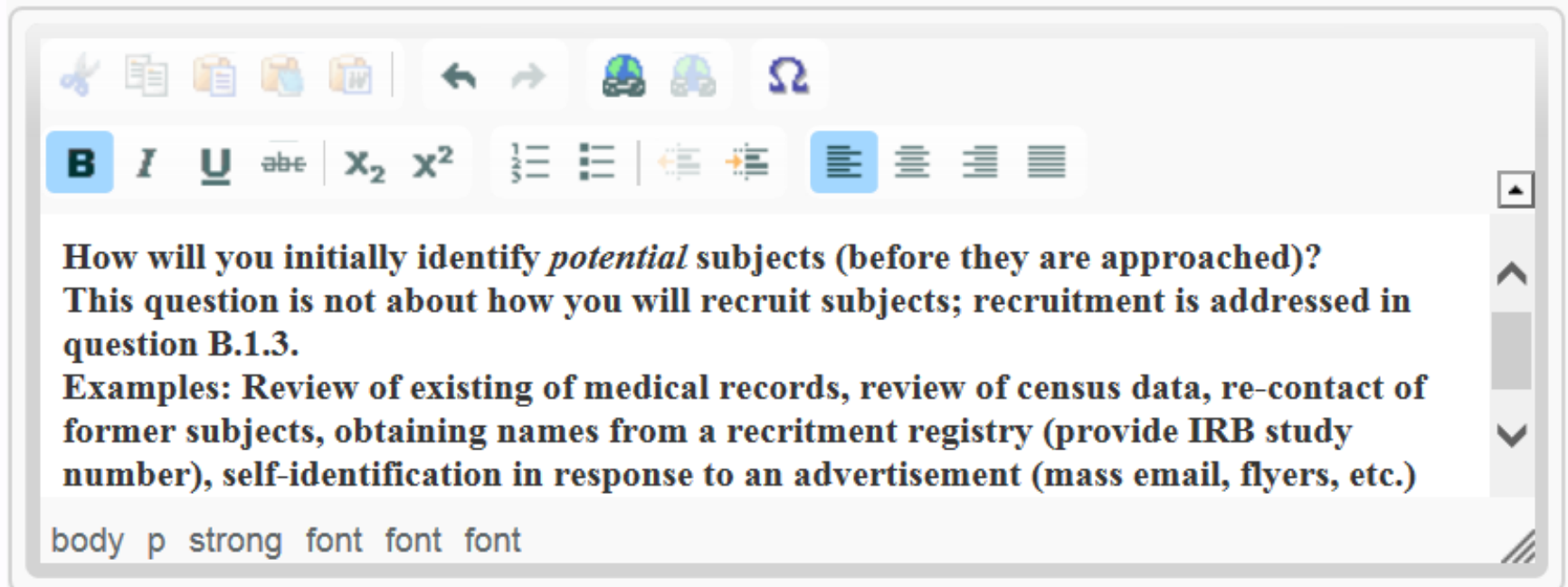
If using "Join the Conquest", select "Other" and then describe here.
Check "not yet available/not applicable" for required document in the Attachments section.

Check all that apply. If you plan to recruit in person (e.g., during clinic) and later follow-up with potential subjects via email or phone, select In person AND Follow-up to initial contact.

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Section B.1.2.: Identifying Subjects

2. Describe how subjects will be identified *



The screenshot shows a rich text editor interface for an IRB application. The toolbar includes icons for undo, redo, bold, italic, underline, text color, background color, bulleted list, numbered list, link, unlink, and a table icon. The text area contains the following content:

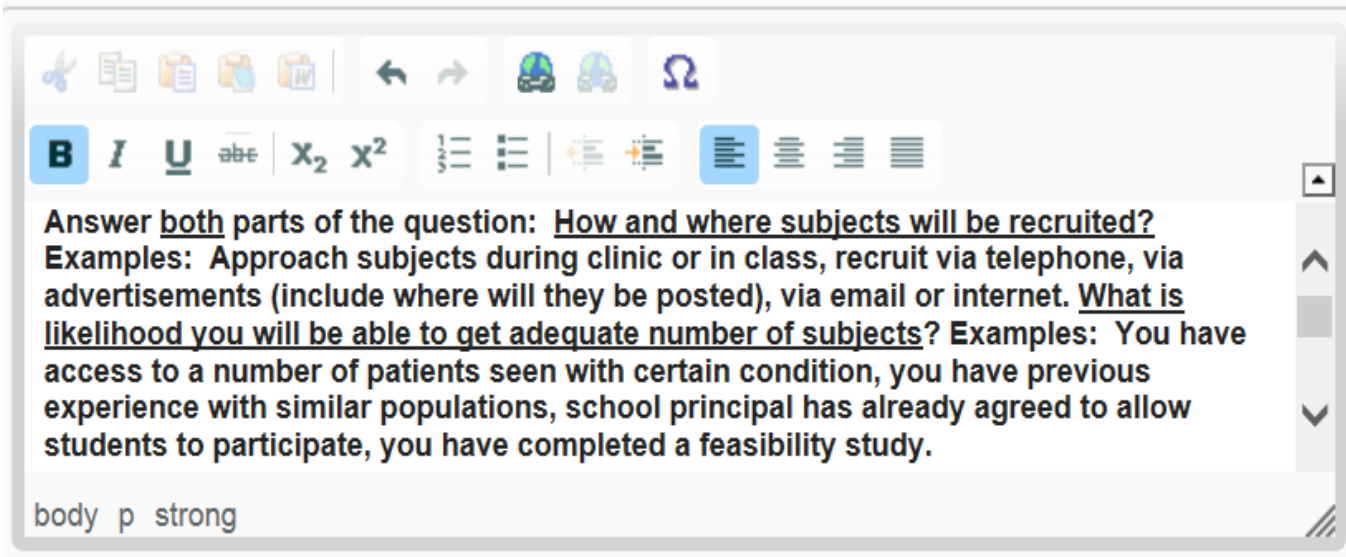
How will you initially identify *potential* subjects (before they are approached)?
This question is not about how you will recruit subjects; recruitment is addressed in question B.1.3.
Examples: Review of existing of medical records, review of census data, re-contact of former subjects, obtaining names from a recruitment registry (provide IRB study number), self-identification in response to an advertisement (mass email, flyers, etc.)

body p strong font font font

Completing the IRB Application

Section B.1.3.: How and Where Subjects Are Recruited, Access to Projected Number of Subjects

3. Describe how and where subjects will be recruited and address the likelihood that you will have access to the projected number of subjects identified in A.2. *




The screenshot shows a rich text editor interface. At the top, there is a toolbar with icons for undo, redo, link, unlink, and search. Below the toolbar is a second toolbar with text formatting options: bold (B), italic (I), underline (U), text color (abc), subscript (x₂), superscript (x²), bulleted list, numbered list, indent left, indent right, and a blue button with a list icon. The main text area contains the following text:

Answer both parts of the question: How and where subjects will be recruited? Examples: Approach subjects during clinic or in class, recruit via telephone, via advertisements (include where will they be posted), via email or internet. What is likelihood you will be able to get adequate number of subjects? Examples: You have access to a number of patients seen with certain condition, you have previous experience with similar populations, school principal has already agreed to allow students to participate, you have completed a feasibility study.

At the bottom left of the text area, there is a small text box containing the words "body p strong".

Completing the IRB Application

Section B.1.4.: Protecting Privacy During Recruitment

4. Describe how you will protect the privacy of potential subjects during recruitment * 



Describe methods for protecting privacy of potential subjects while recruiting (prior to enrollment). This question is not about confidentiality of the data.

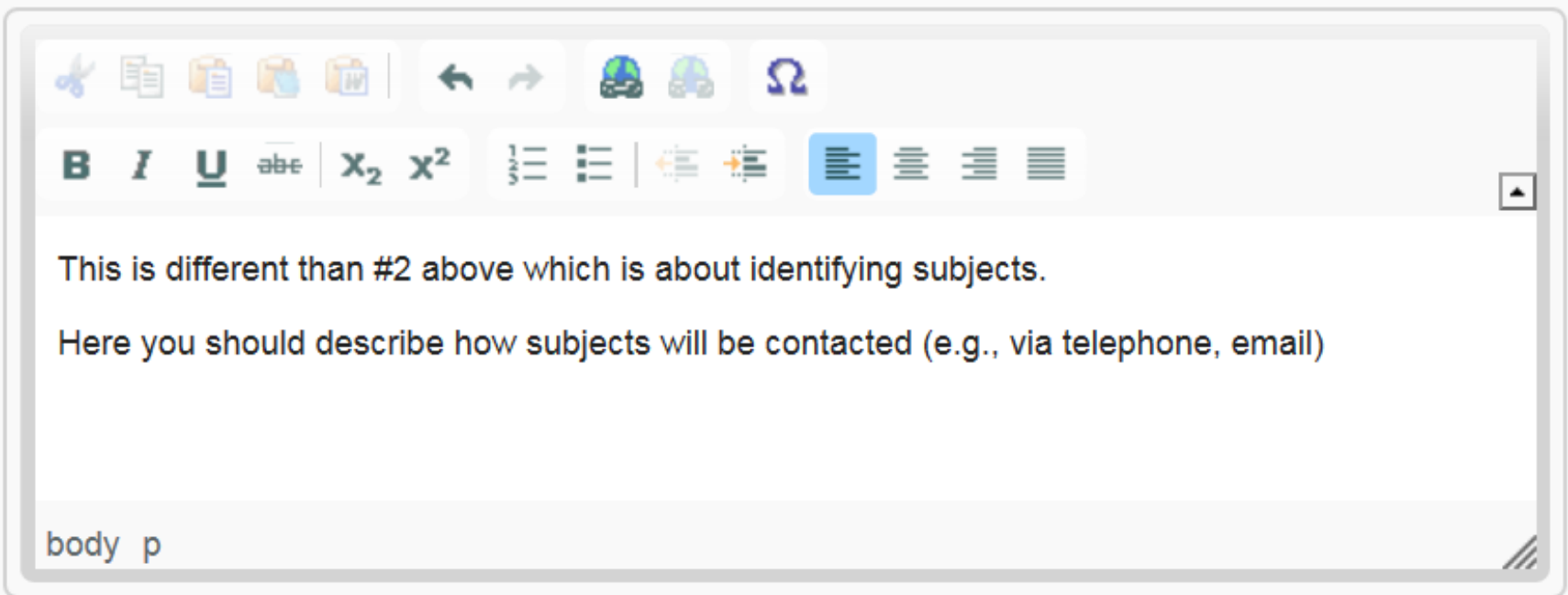
Examples: Taking potential subject to private area to discuss the study, making recruitment calls from private areas, using discretion when contacting subjects (not identifying the department on the envelope), sending mailing to home address only (i.e., not to place of employment).

body p font font font strong

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Section B.1.5.: Contacting Subjects

5. Describe how subjects will be contacted, if not addressed above *



The screenshot shows a rich text editor interface. At the top, there is a toolbar with icons for undo, redo, link, unlink, and refresh. Below the toolbar is another set of icons for bold, italic, underline, text color, background color, subscript, superscript, bulleted list, numbered list, indent, and outdent. The text area contains two paragraphs:

This is different than #2 above which is about identifying subjects.

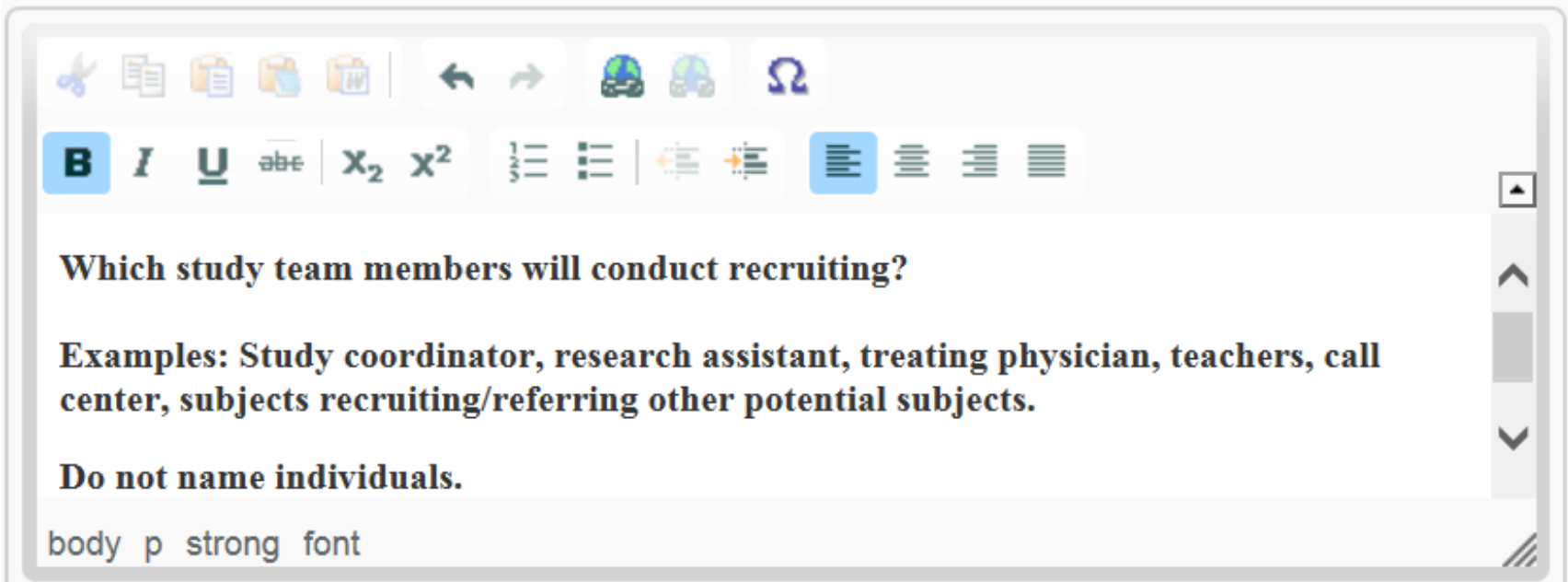
Here you should describe how subjects will be contacted (e.g., via telephone, email)

body p

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Section B.1.6.: Who will recruit?

6. Describe who (by role) will do the recruiting *

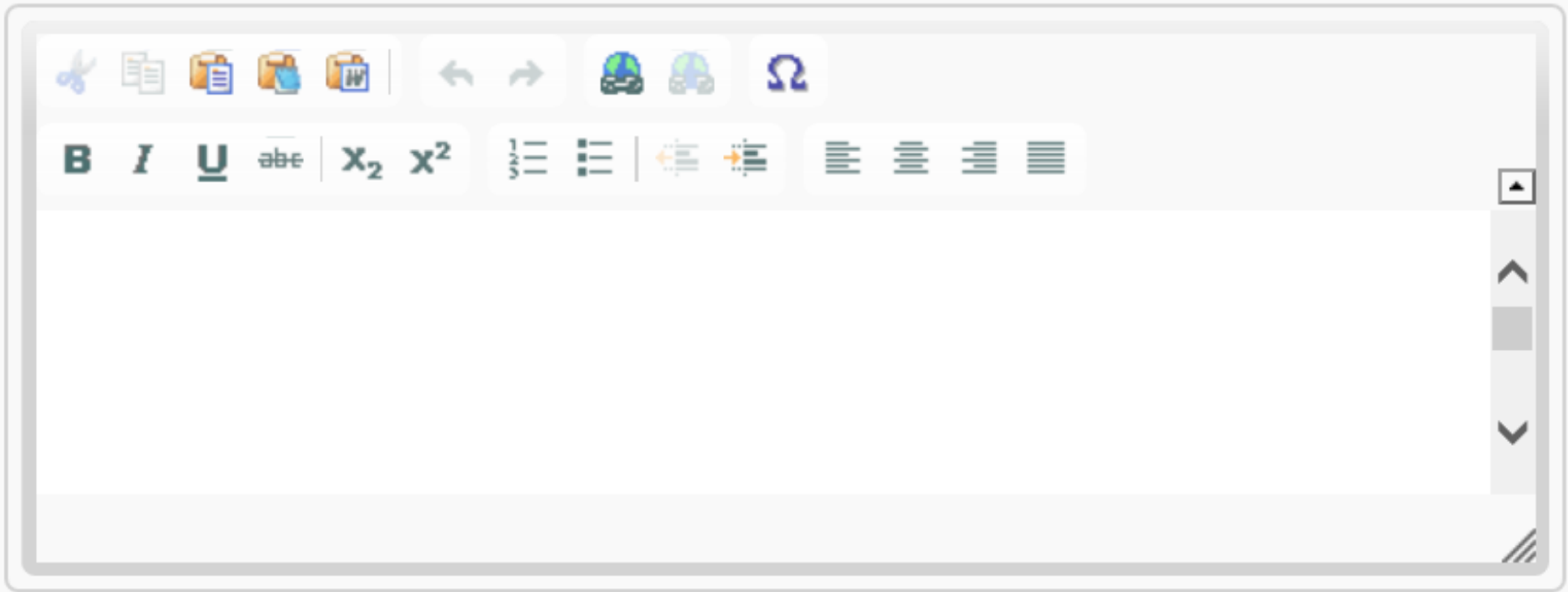


The screenshot shows a rich text editor interface. At the top, there is a toolbar with icons for undo, redo, bold, italic, underline, strikethrough, subscript, superscript, bulleted list, numbered list, indent, and outdent. Below the toolbar, the text reads: "Which study team members will conduct recruiting?" followed by "Examples: Study coordinator, research assistant, treating physician, teachers, call center, subjects recruiting/referring other potential subjects." and "Do not name individuals." At the bottom, there is a text input field with the placeholder text "body p strong font".

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Section B.1.6.: Participation of Women and Minorities

7. Describe efforts to ensure equal access to participation among women and minorities *



The image shows a screenshot of a rich text editor interface. The top toolbar contains icons for cut, copy, paste, undo, redo, link, unlink, and help. Below the toolbar is a second row of icons for bold, italic, underline, strikethrough, subscript, superscript, bulleted list, numbered list, indent, and outdent. The main editing area is currently empty. On the right side, there is a vertical scrollbar with up and down arrows and a diagonal refresh icon at the bottom right corner.

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Section B.2.1.: Requesting a Limited HIPAA Waiver (1 of 2)

1. Are you requesting a limited waiver of HIPAA authorization?

If you need to access Protected Health Information (PHI) to identify potential subjects who will then be contacted, you will need a [limited waiver of HIPAA authorization \(see SOP 29.3\)](#). This does not apply to situations where you will never contact subjects directly (e.g., retrospective chart review), in which case you should request a full waiver under section D. *

Yes No

Will you access the records of 50 or more patients under this limited waiver? *

Yes No

If you access the records of fewer than 50 patients under this waiver, submit a copy of your IRB approval letter and a completed [Research Disclosure Form](#) to Health Information Management (HIM). Do not submit this information to the IRB. For additional information about this process, you should contact HIM directly at 919-966-5655 or 919-966-1225 or 919-966-5580.

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Section B.2.1.: Requesting a Limited HIPAA Waiver (2 of 2)

Please provide a response to each of the following questions:

Under this limited waiver, you are allowed to access and use only the minimum amount of PHI necessary to review eligibility criteria and contact potential subjects. Describe the information you are planning to collect for this purpose *

Be specific. Example: Name, DOB, home phone number, diagnosis, results of last A1C within past one year.

Describe how confidentiality/privacy will be protected prior to ascertaining the patient's willingness to participate *

This question pertains to protection of the PHI that you obtained under the limited waiver of HIPAA.
How will you protect the data (e.g., secure, password protected University

Describe when and how you will destroy the contact information if an individual declines participation *

If potential participant says no or can't be contacted, when and how will you destroy the data?

Recap

- Read SOP #2.4.10 (Recruitment) before submitting recruitment materials.
- Be sure you describe your ENTIRE recruitment plan.
- Do not list individual names in Section B.1.6 (who will recruit). If you add names here and later change study personnel, you need to remember to delete from both places.
- Recruitment letters should include an *opt out* phone number.
- Provide adequate justification for Limited Waiver of HIPAA (e.g., minimum PHI that will be collected).

Questions?

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