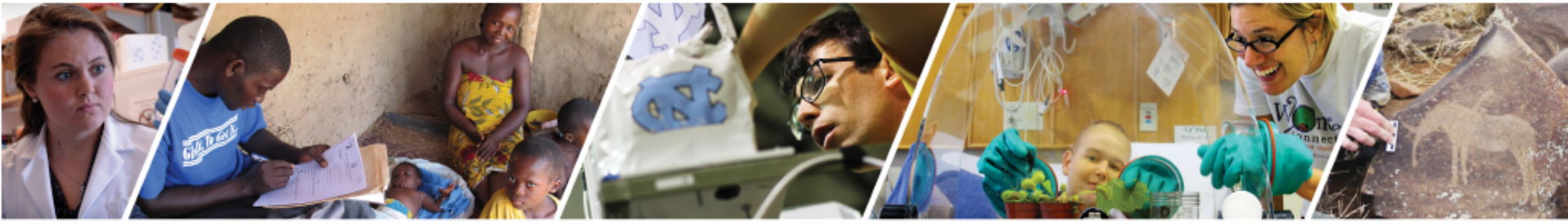
Recruitment

Completing the IRB Application

August 29, 2017



Office of Human Research Ethics
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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

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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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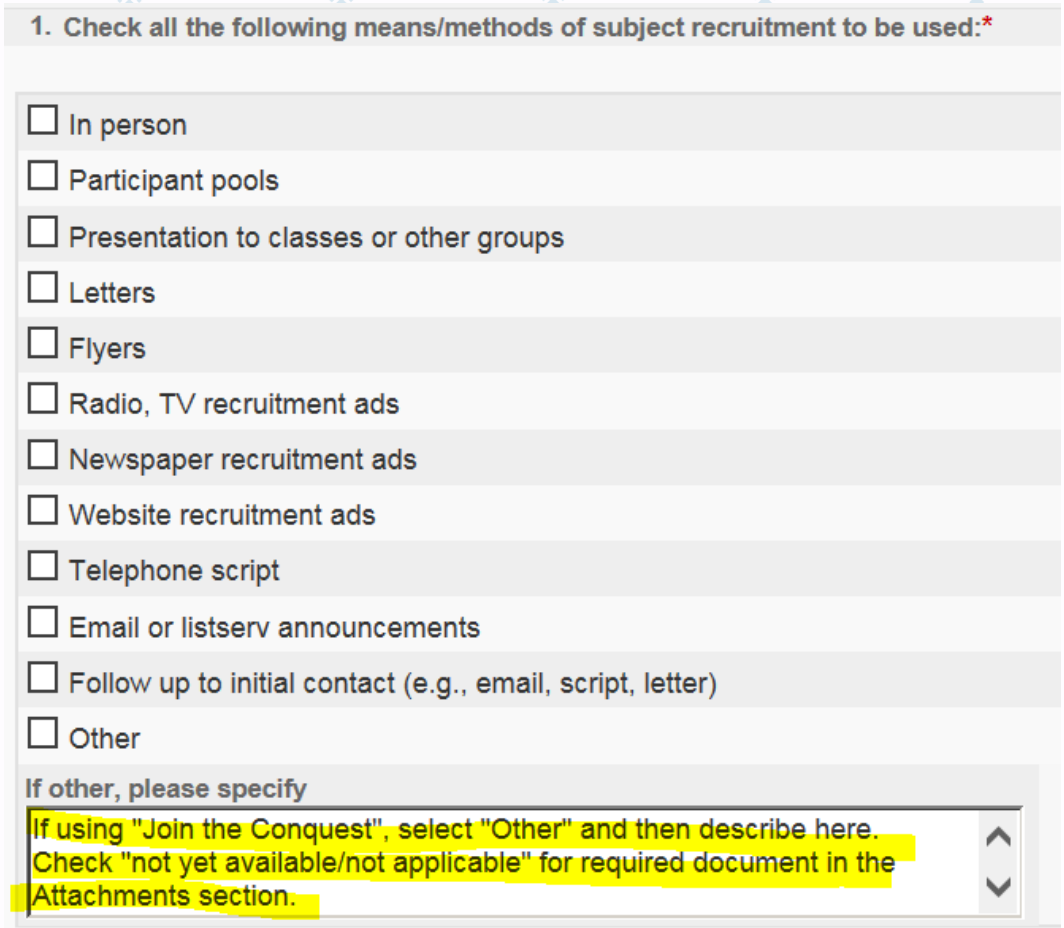
Section B.1.1.: Methods of Recruiting



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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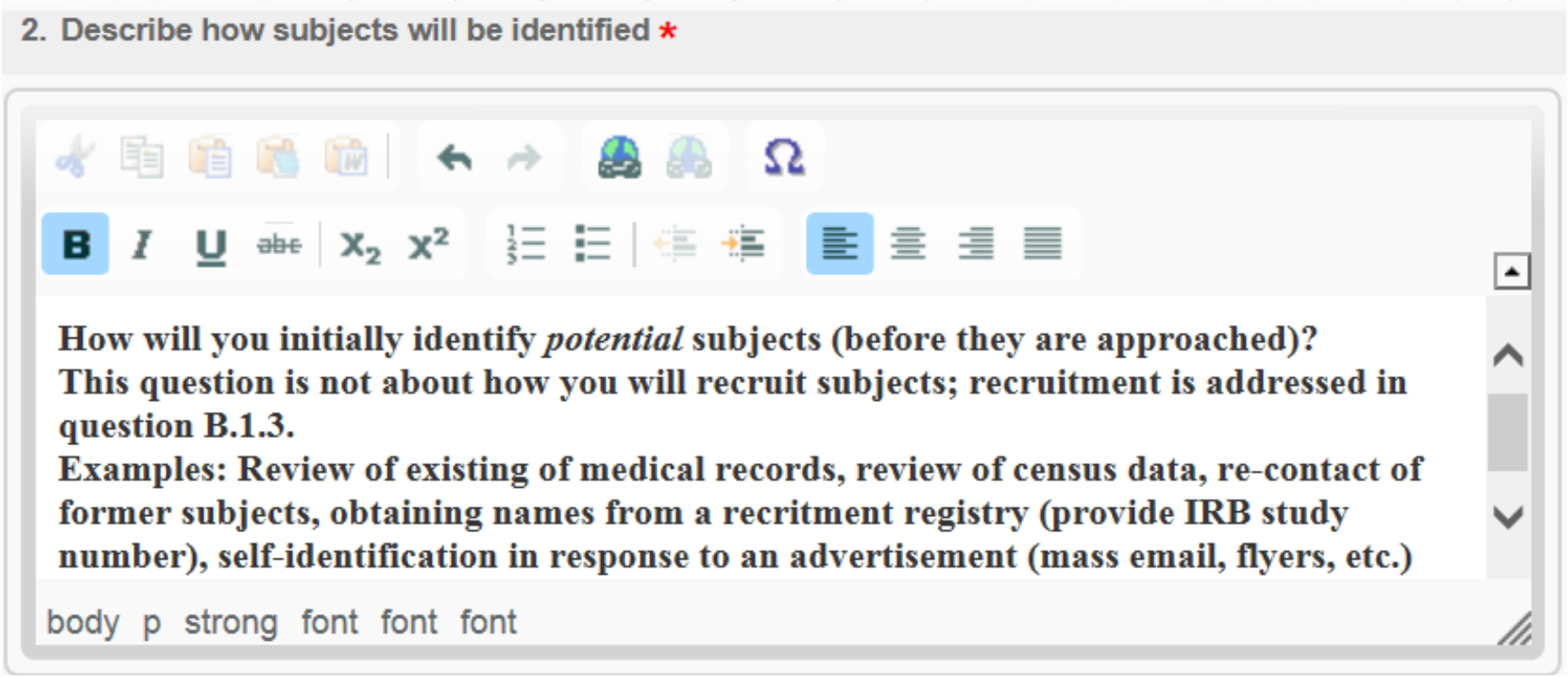
Section B.1.2.: Identifying Subjects



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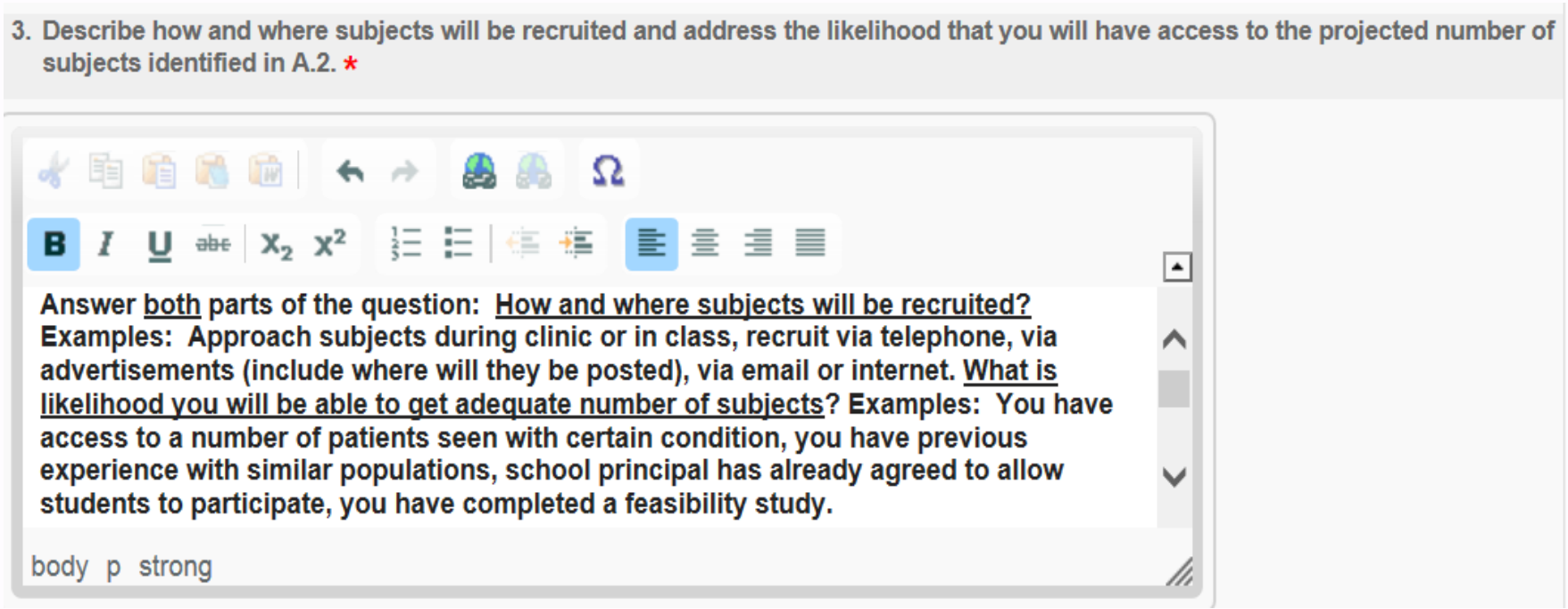
Section B.1.3.: How and Where Subjects Are Recruited, Access to Projected Number of Subjects



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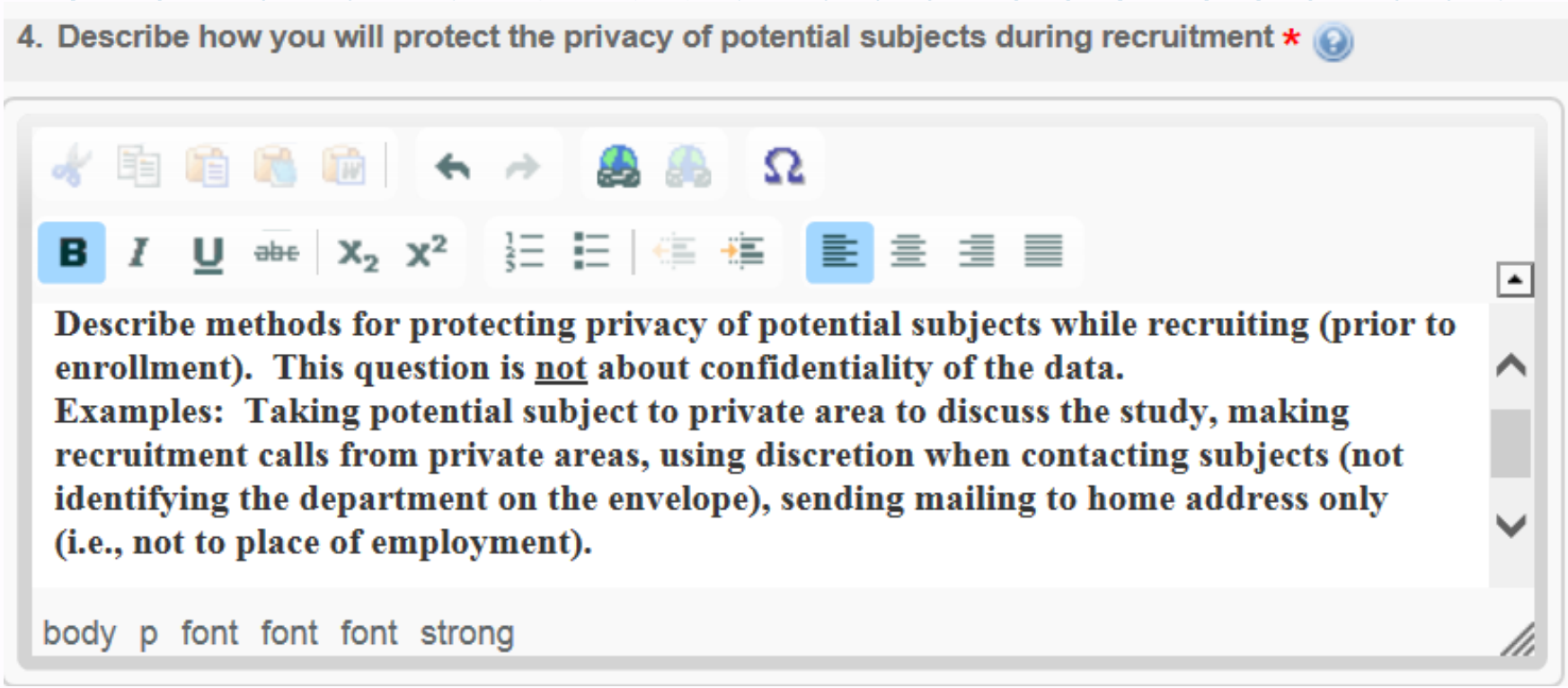
Section B.1.4.: Protecting Privacy During Recruitment



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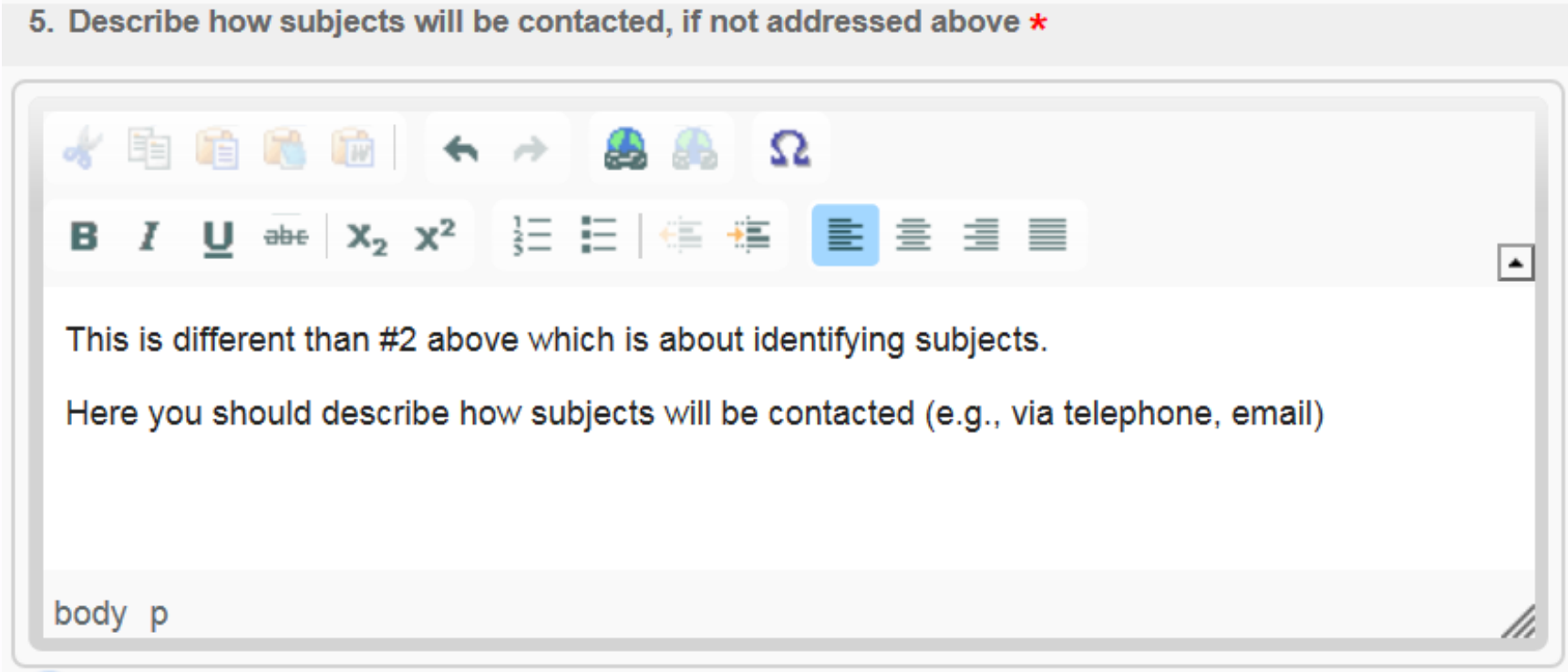
Section B.1.5.: Contacting Subjects



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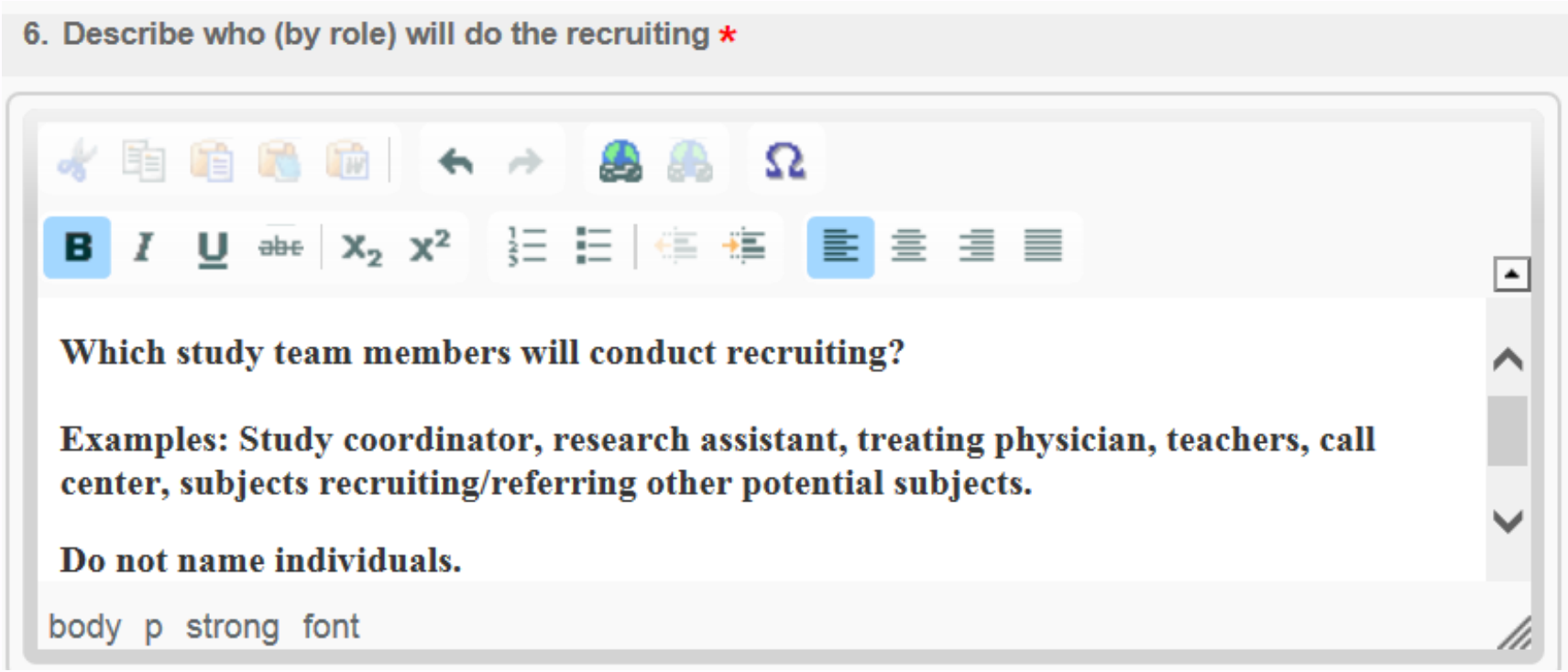
Section B.1.6.: Who will recruit?



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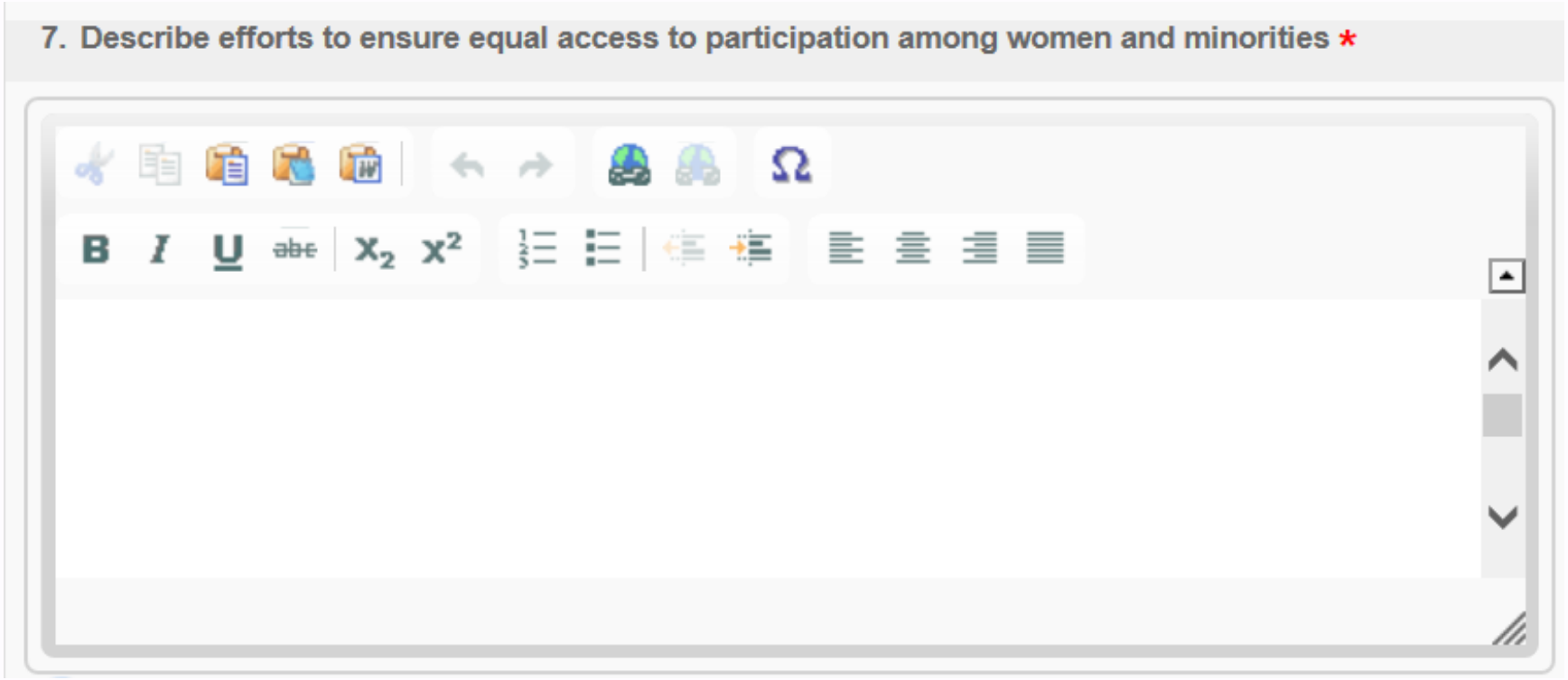
Section B.1.6.: Participation of Women and Minorities



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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 nee
   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 For additional information about this process, you should contact HIM directly at 919-966-5655 or 919-966-1225 or 919 595-5580.

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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?

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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).

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Questions?

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