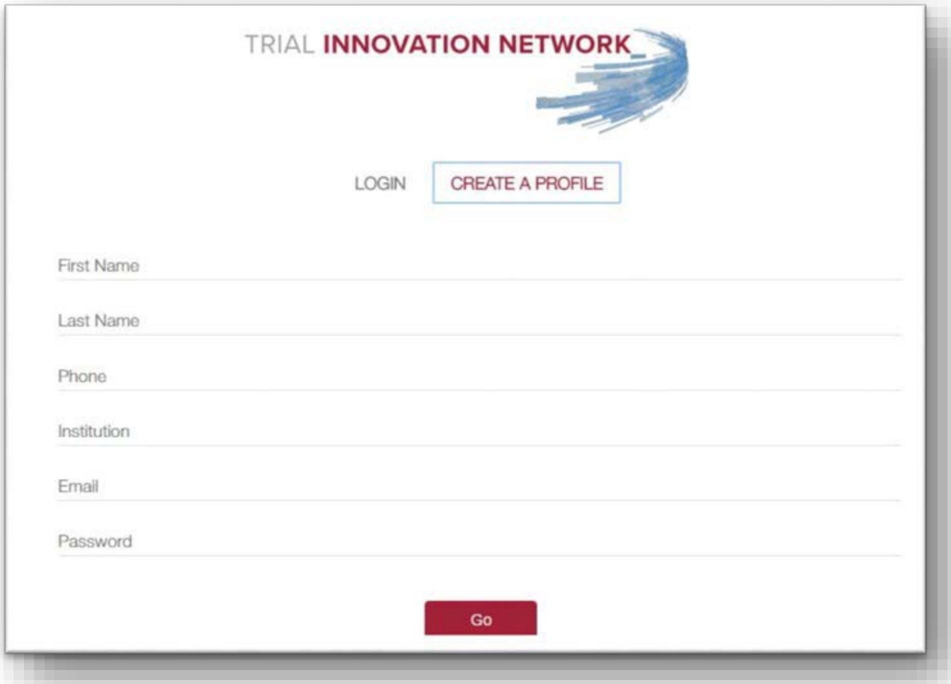
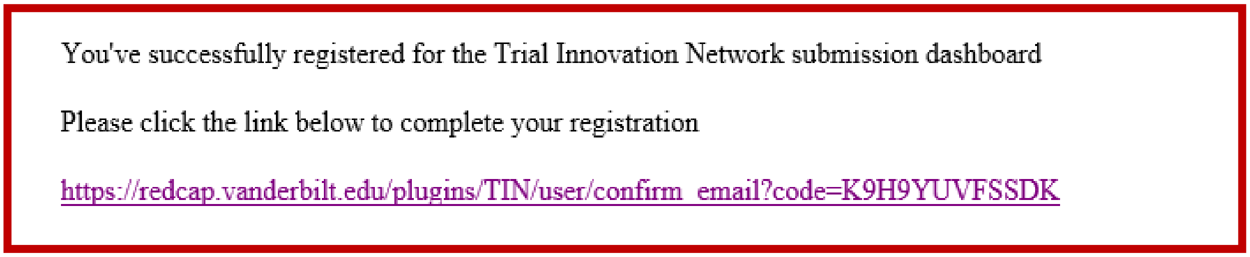
Create A Profile Before You Submit

- All first-time applicants will be required to create a profile before being granted access to the Network Dashboard
- Please answer all questions on the “Create a Profile” page.
- You will be sent an email. The e-mail will contain a link that will direct you back to the login screen.
- This will complete the registration process.

Create A Profile:



E-mail Confirmation: If you do not see the e-mail confirmation in your mailbox, please check your junk folder in case it was marked as spam.



You've successfully registered for the Trial Innovation Network submission dashboard

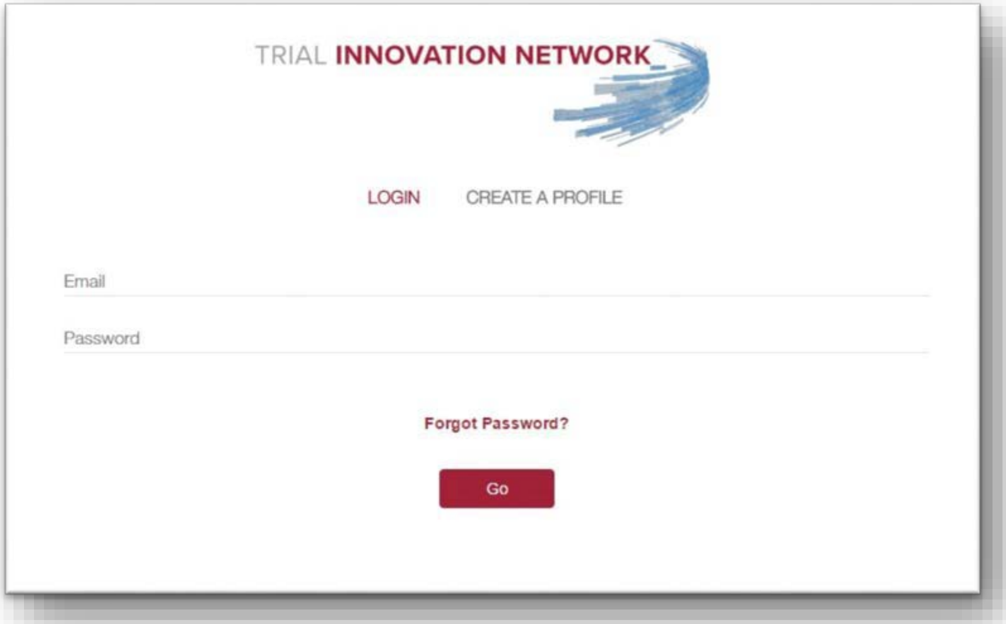
Please click the link below to complete your registration

https://redcap.vanderbilt.edu/plugins/TIN/user/confirm_email?code=K9H9YUVFSSDK

Log In To Access Your Dashboard

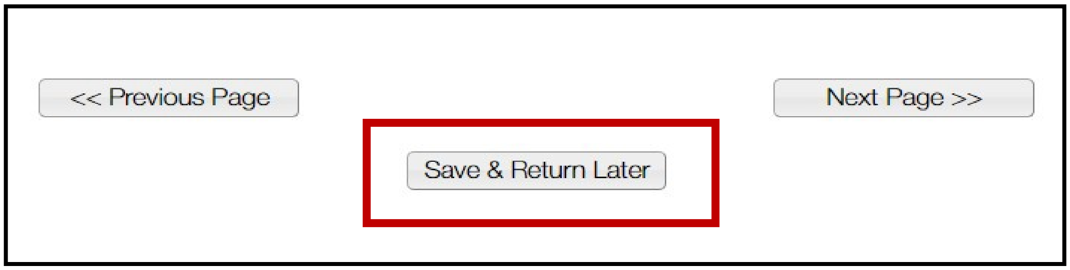
The e-mail address and password submitted to create your profile will be the Login information needed to sign in and submit a proposal. The same Login information applies when returning to check on the status of a proposal or to submit a new proposal.

Login:



Submit Your Proposal

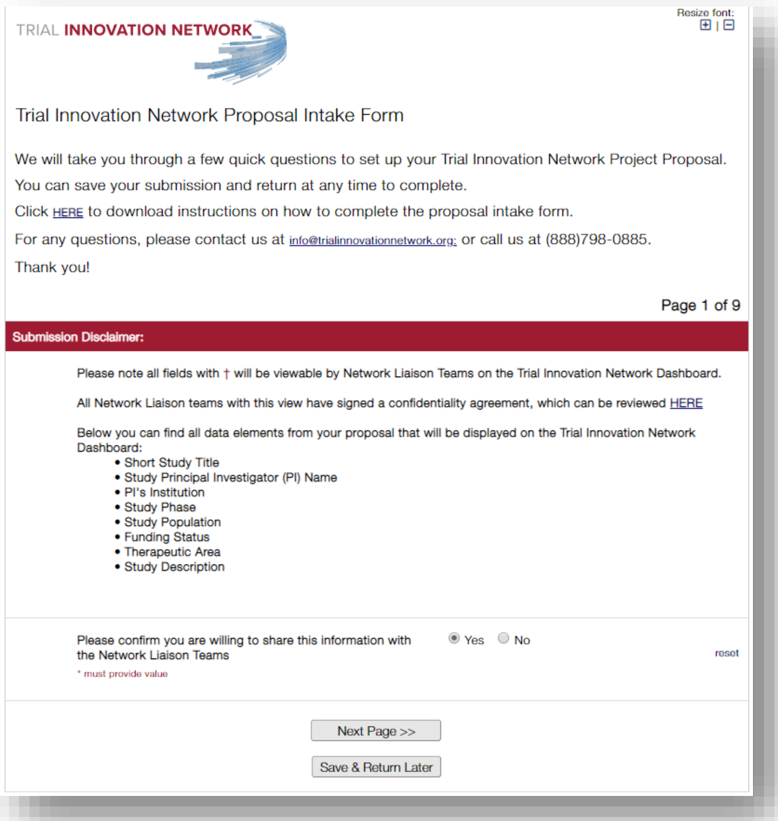
- Throughout the submission process, you will be prompted to complete questions related to the study.
- Questions containing an asterisk with “must provide value” are required in order to move forward with the submission.
- If at any time you need to step away from the submission process, you may click the “Save & Return Later” button at the bottom of the page to save current progress. Your information will automatically be saved when you click “next page”.



Page 1

Page 1 of the proposal intake form includes the following information/resources:

- Link to download instructions on how to complete the proposal intake form
- Provides contact information in case of any questions
- Includes a submission disclaimer that asks the user for consent on sharing the bulleted data elements with CTSA Liaison Teams. Please note the user is not required to consent in order to submit a proposal.



Trial Innovation Network Proposal Intake Form

We will take you through a few quick questions to set up your Trial Innovation Network Project Proposal.

You can save your submission and return at any time to complete.

Click HERE to download instructions on how to complete the proposal intake form.

For any questions, please contact us at info@trialinnovationnetwork.org; or call us at (888)798-0885.

Thank you!

Page 1 of 9

Submission Disclaimer:

Please note all fields with † will be viewable by Network Liaison Teams on the Trial Innovation Network Dashboard.

All Network Liaison teams with this view have signed a confidentiality agreement, which can be reviewed HERE

Below you can find all data elements from your proposal that will be displayed on the Trial Innovation Network Dashboard:

- Short Study Title
- Study Principal Investigator (PI) Name
- PI's Institution
- Study Phase
- Study Population
- Funding Status
- Therapeutic Area
- Study Description

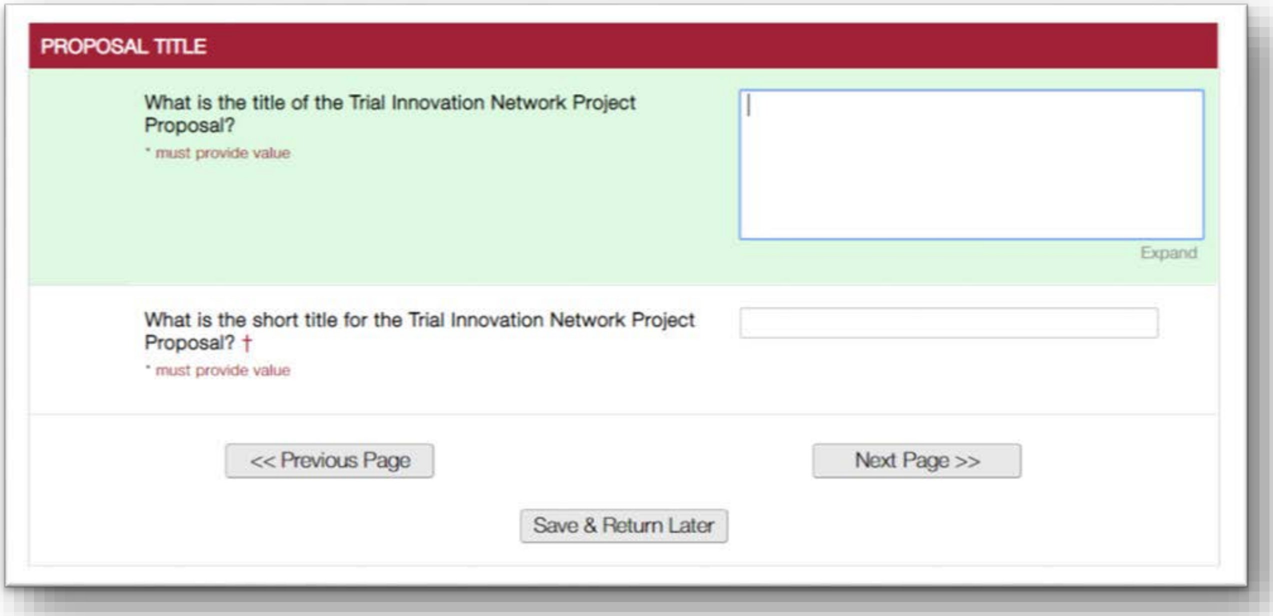
Please confirm you are willing to share this information with the Network Liaison Teams ● Yes ○ No

* must provide value

Submit Your Proposal

Page 2

Page 2 of the proposal intake form will direct you to complete basic information about the proposal.



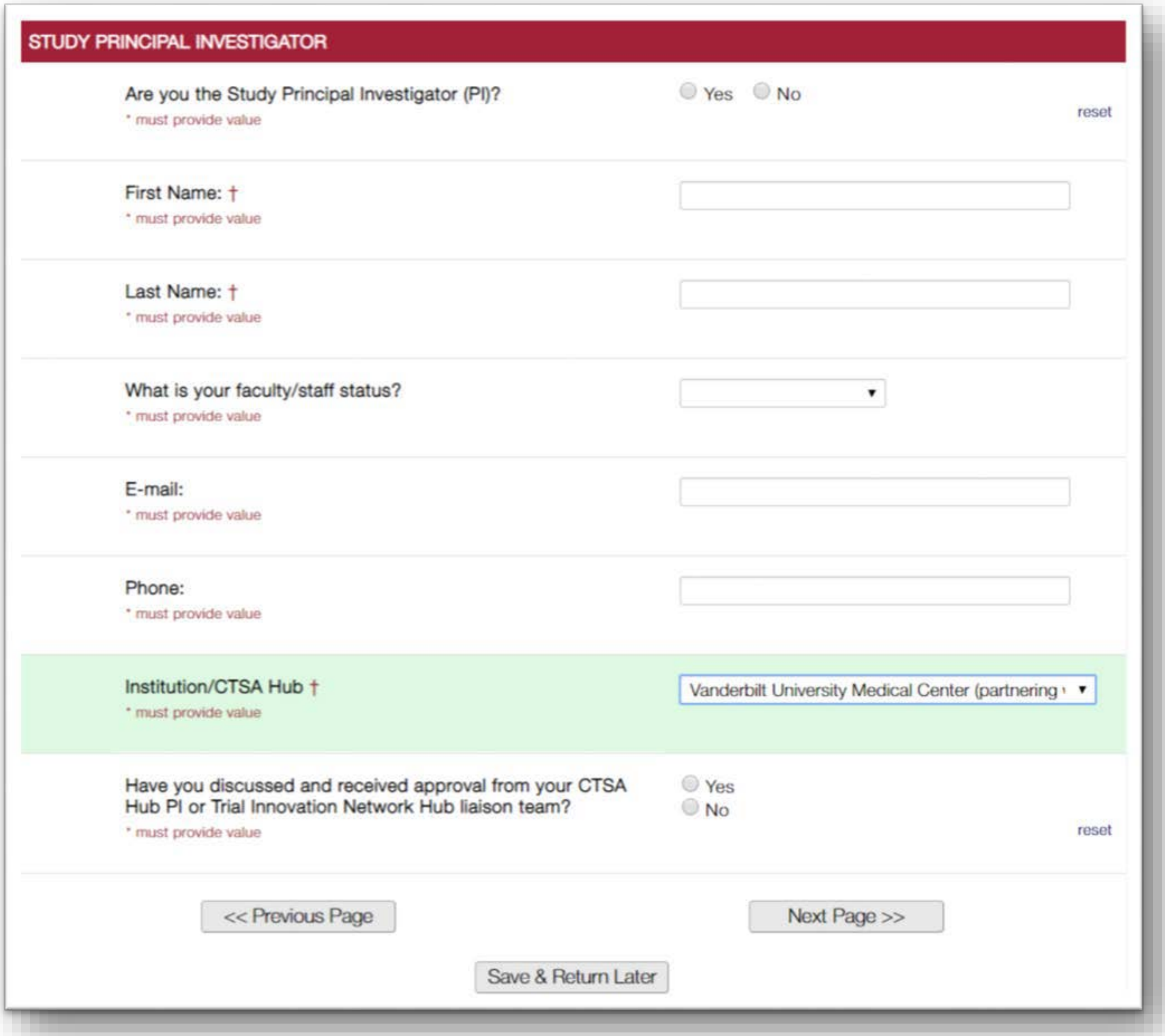
PROPOSAL TITLE

What is the title of the Trial Innovation Network Project Proposal?
* must provide value

What is the short title for the Trial Innovation Network Project Proposal? †
* must provide value

Page 3

- On page 3 of the proposal intake form, you will be asked for information about the Study Principal Investigator (PI).
- If you are submitting on behalf of a Study PI, please make sure to fill out the Study PI's information.
- Please note: If the Study PI is at a CTSA site, you will have to receive approval from the CTSA PI prior to submission. You will not be able to complete the submission process without attaching documentation indicating CTSA PI support for your submission.



STUDY PRINCIPAL INVESTIGATOR

Are you the Study Principal Investigator (PI)? ○ Yes ○ No
* must provide value

First Name: †
* must provide value

Last Name: †
* must provide value

What is your faculty/staff status?
* must provide value

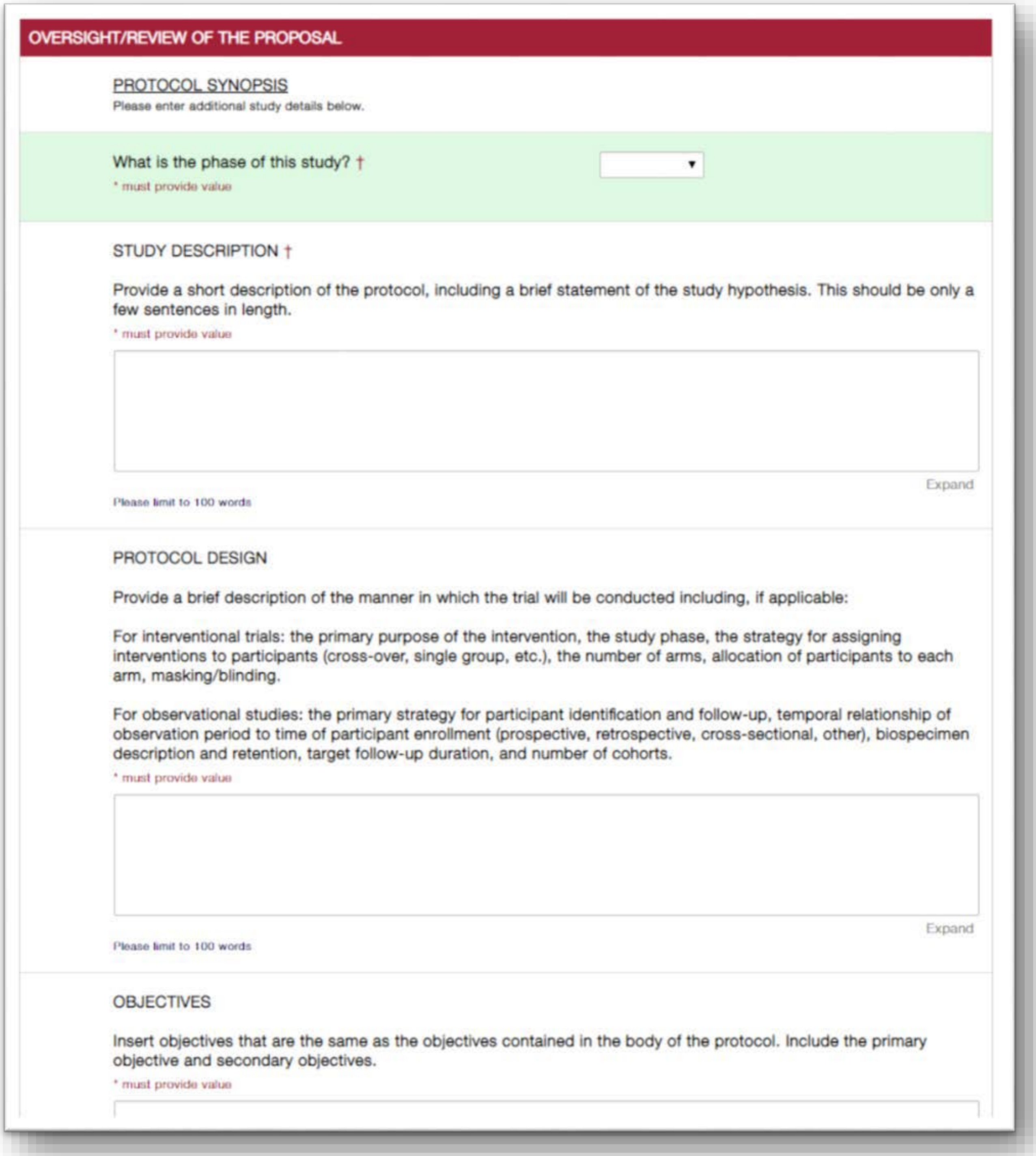
E-mail:
* must provide value

Phone:
* must provide value

Institution/CTSA Hub † Vanderbilt University Medical Center (partnering
* must provide value

Have you discussed and received approval from your CTSA Hub PI or Trial Innovation Network Hub liaison team? ○ Yes ○ No
* must provide value

- Please note that most questions/sections of the proposal are required.
- If you have charts or tables that pertain to this section, please attach those supporting documents at the end of the proposal intake form on page 9.



OVERSIGHT/REVIEW OF THE PROPOSAL

PROTOCOL SYNOPSIS

Please enter additional study details below.

What is the phase of this study? †

* must provide value

STUDY DESCRIPTION †

Provide a short description of the protocol, including a brief statement of the study hypothesis. This should be only a few sentences in length.

* must provide value

Please limit to 100 words

PROTOCOL DESIGN

Provide a brief description of the manner in which the trial will be conducted including, if applicable:

For interventional trials: the primary purpose of the intervention, the study phase, the strategy for assigning interventions to participants (cross-over, single group, etc.), the number of arms, allocation of participants to each arm, masking/blinding.

For observational studies: the primary strategy for participant identification and follow-up, temporal relationship of observation period to time of participant enrollment (prospective, retrospective, cross-sectional, other), biospecimen description and retention, target follow-up duration, and number of cohorts.

* must provide value

Please limit to 100 words

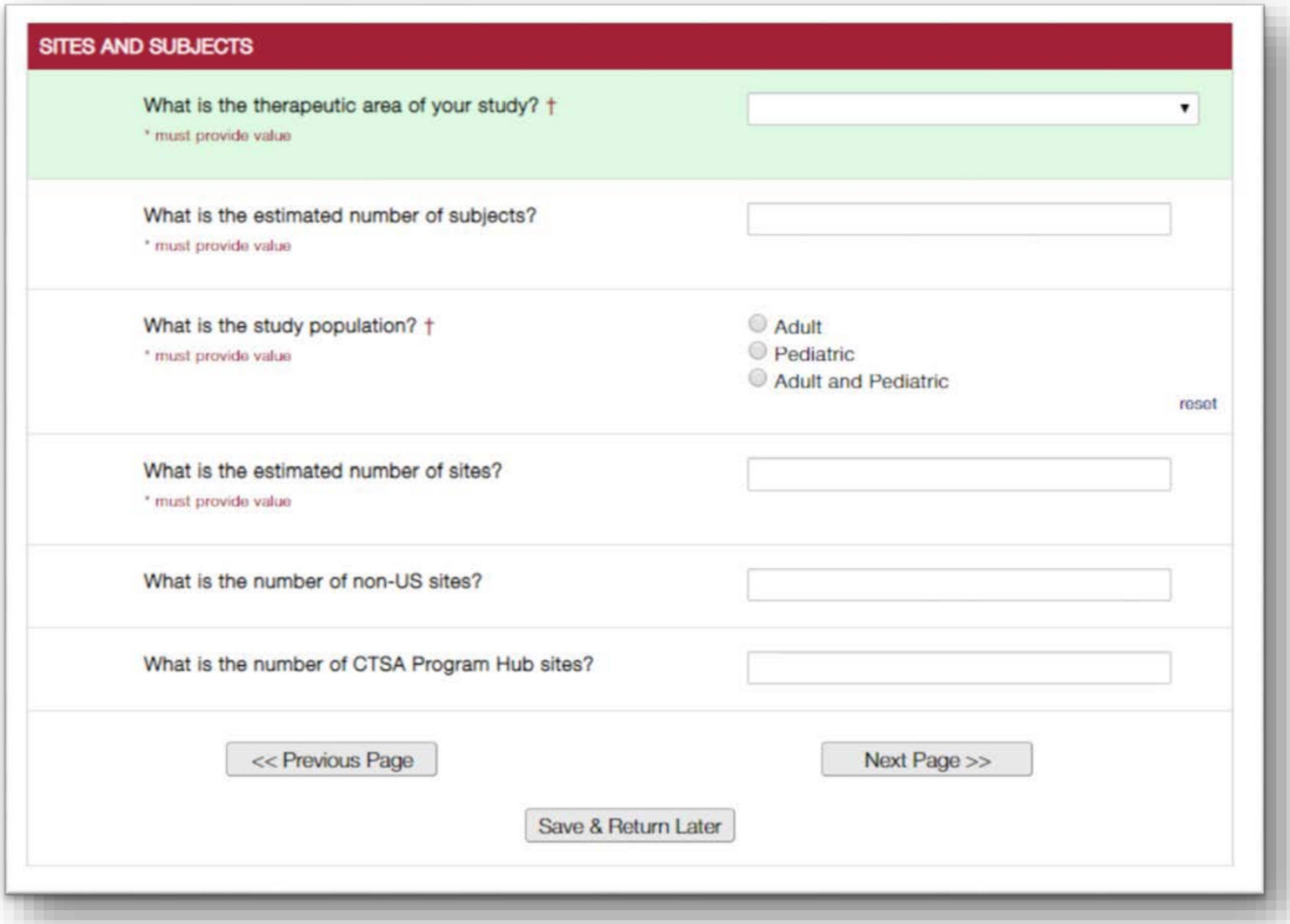
OBJECTIVES

Insert objectives that are the same as the objectives contained in the body of the protocol. Include the primary objective and secondary objectives.

* must provide value

Page 5

- On page 5 of the proposal intake form, you will be asked questions related to the Sites and Subjects of the study.
- Please answer all required questions and non-required (if possible).
- The Trial Innovation Network currently only supports multi-center trials and studies.
- The proposal intake form will automatically give a warning notification if the number of subjects or sites is less than two.
- Please provide an estimated number in all the required fields, even if you think the number may change in the future.



SITES AND SUBJECTS

What is the therapeutic area of your study? †
* must provide value

What is the estimated number of subjects?
* must provide value

What is the study population? †
* must provide value
○ Adult
○ Pediatric
○ Adult and Pediatric

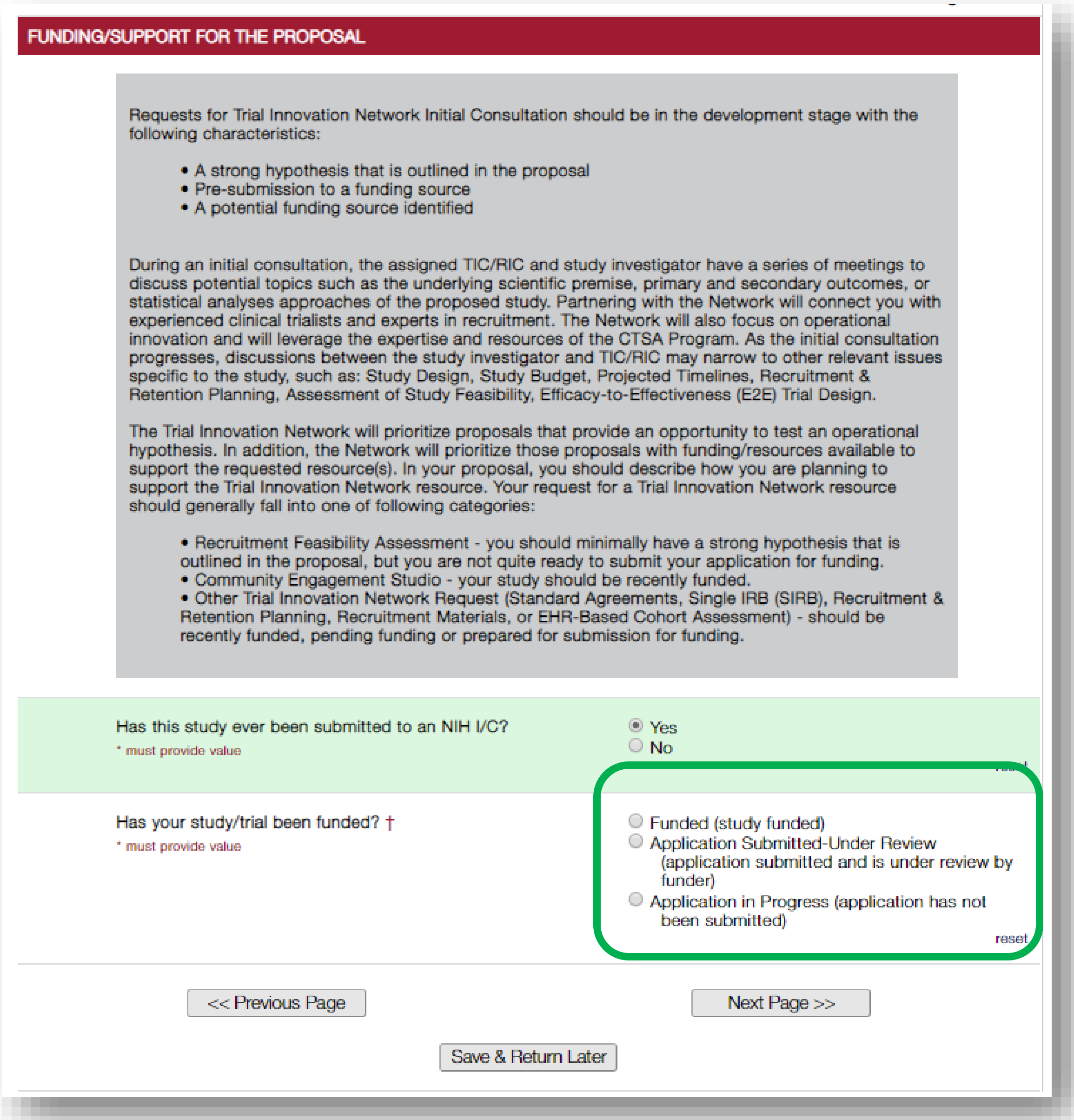
What is the estimated number of sites?
* must provide value

What is the number of non-US sites?

What is the number of CTSA Program Hub sites?

Page 6

- On page 6 of the proposal intake form, you will be asked questions related to the funding status of the proposal. Depending on your response to the first question, you will be asked a series of follow-up questions.
- On the following pages, you can see screenshots of what follow-up questions will be asked depending on your funding status. Please note there are several required fields on this page. Please answer all required questions to the best of your ability, even if the information you provide is only an estimate.



FUNDING/SUPPORT FOR THE PROPOSAL

Requests for Trial Innovation Network Initial Consultation should be in the development stage with the following characteristics:

- A strong hypothesis that is outlined in the proposal
- Pre-submission to a funding source
- A potential funding source identified

During an initial consultation, the assigned TIC/RIC and study investigator have a series of meetings to discuss potential topics such as the underlying scientific premise, primary and secondary outcomes, or statistical analyses approaches of the proposed study. Partnering with the Network will connect you with experienced clinical trialists and experts in recruitment. The Network will also focus on operational innovation and will leverage the expertise and resources of the CTSA Program. As the initial consultation progresses, discussions between the study investigator and TIC/RIC may narrow to other relevant issues specific to the study, such as: Study Design, Study Budget, Projected Timelines, Recruitment & Retention Planning, Assessment of Study Feasibility, Efficacy-to-Effectiveness (E2E) Trial Design.

The Trial Innovation Network will prioritize proposals that provide an opportunity to test an operational hypothesis. In addition, the Network will prioritize those proposals with funding/resources available to support the requested resource(s). In your proposal, you should describe how you are planning to support the Trial Innovation Network resource. Your request for a Trial Innovation Network resource should generally fall into one of following categories:

- Recruitment Feasibility Assessment - you should minimally have a strong hypothesis that is outlined in the proposal, but you are not quite ready to submit your application for funding.
- Community Engagement Studio - your study should be recently funded.
- Other Trial Innovation Network Request (Standard Agreements, Single IRB (SIRB), Recruitment & Retention Planning, Recruitment Materials, or EHR-Based Cohort Assessment) - should be recently funded, pending funding or prepared for submission for funding.

Has this study ever been submitted to an NIH I/C?
* must provide value

● Yes
○ No

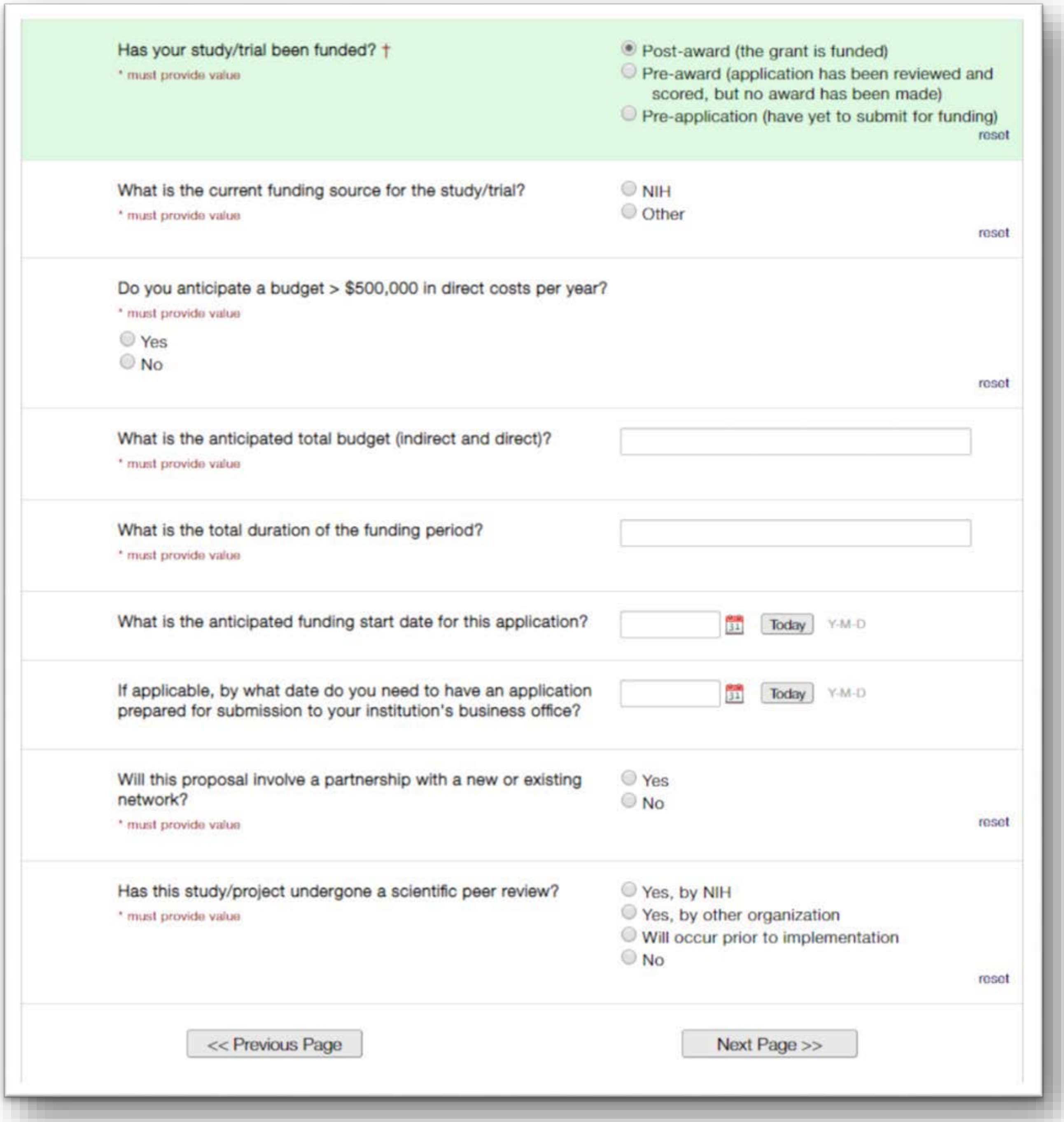
Has your study/trial been funded? †
* must provide value

○ Funded (study funded)
○ Application Submitted-Under Review (application submitted and is under review by funder)
○ Application in Progress (application has not been submitted)

Page 6 (continued)

If you respond “Post-award (the grant is funded)” Your response page will look like this:

Please note: depending on responses to some questions, you may be required to fill in additional information.



Has your study/trial been funded? †
* must provide value

● Post-award (the grant is funded)
○ Pre-award (application has been reviewed and scored, but no award has been made)
○ Pre-application (have yet to submit for funding)

What is the current funding source for the study/trial?
* must provide value

○ NIH
○ Other

Do you anticipate a budget > $500,000 in direct costs per year?
* must provide value

○ Yes
○ No

What is the anticipated total budget (indirect and direct)?
* must provide value

What is the total duration of the funding period?
* must provide value

What is the anticipated funding start date for this application? Y-M-D

If applicable, by what date do you need to have an application prepared for submission to your institution's business office? Y-M-D

Will this proposal involve a partnership with a new or existing network?
* must provide value

○ Yes
○ No

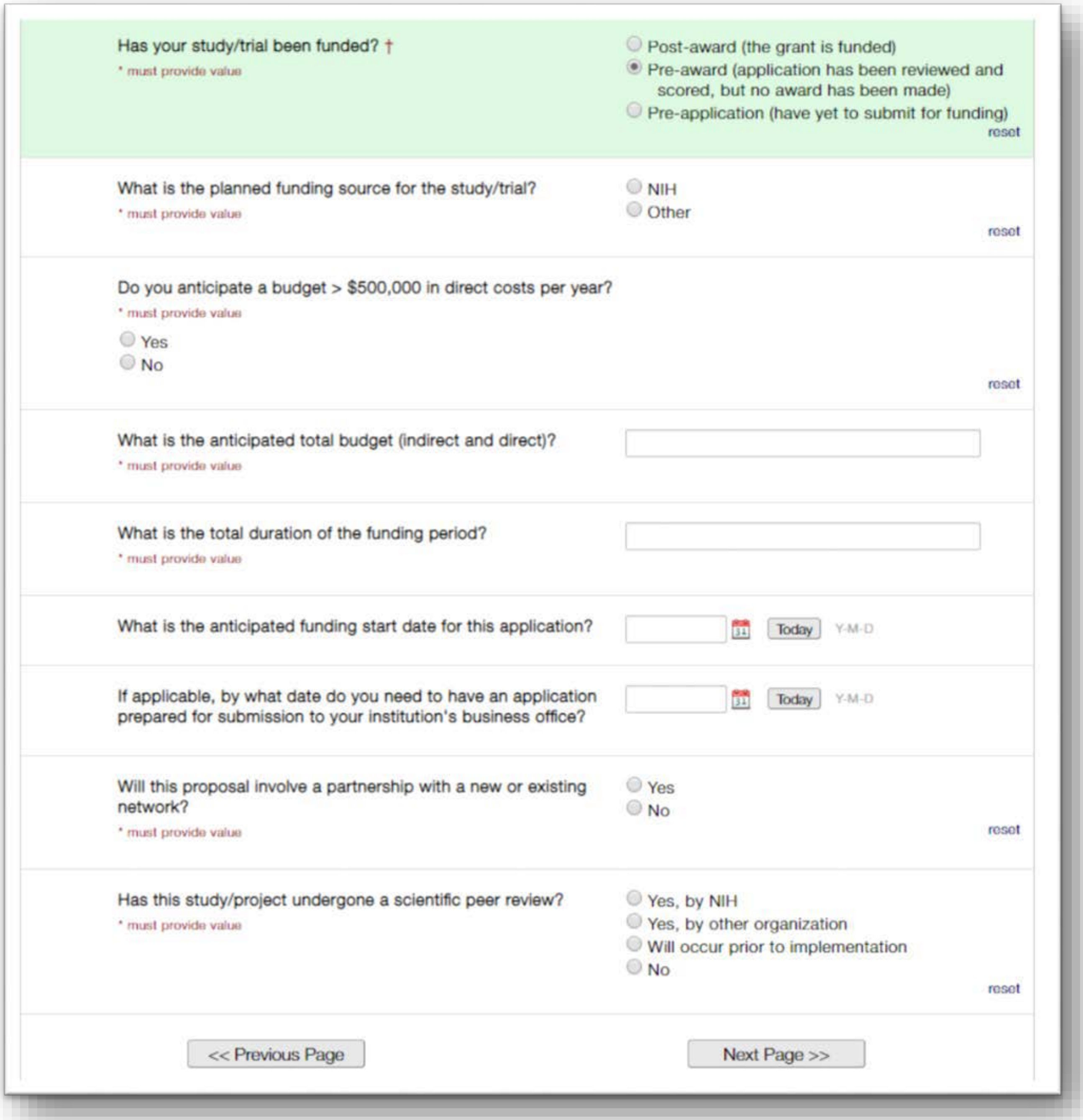
Has this study/project undergone a scientific peer review?
* must provide value

○ Yes, by NIH
○ Yes, by other organization
○ Will occur prior to implementation
○ No

Page 6 (continued)

If you respond “Pre-award (the application has been reviewed and scored, but no award has been made)”, your response page will look like this:

Please note: depending on responses to some questions, you may be required to fill in additional information.



Has your study/trial been funded? †
* must provide value

○ Post-award (the grant is funded)
● Pre-award (application has been reviewed and scored, but no award has been made)
○ Pre-application (have yet to submit for funding)

What is the planned funding source for the study/trial?
* must provide value

○ NIH
○ Other

Do you anticipate a budget > $500,000 in direct costs per year?
* must provide value

○ Yes
○ No

What is the anticipated total budget (indirect and direct)?
* must provide value

What is the total duration of the funding period?
* must provide value

What is the anticipated funding start date for this application?

If applicable, by what date do you need to have an application prepared for submission to your institution's business office?

Will this proposal involve a partnership with a new or existing network?
* must provide value

○ Yes
○ No

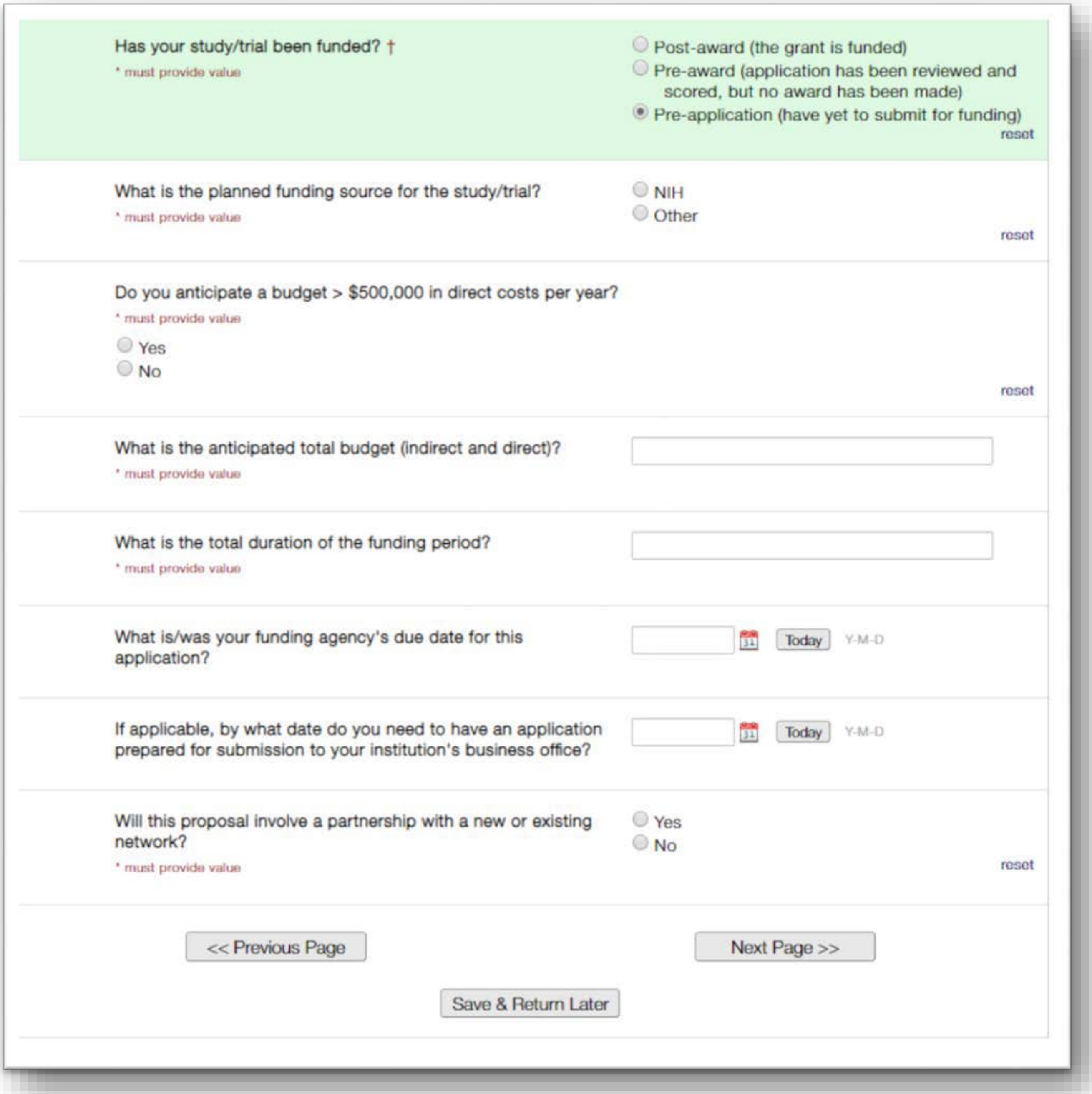
Has this study/project undergone a scientific peer review?
* must provide value

○ Yes, by NIH
○ Yes, by other organization
○ Will occur prior to implementation
○ No

Page 6 (continued)

If you respond “Pre-application (have yet to submit for funding)”, your response page will look like this:

Please note: depending on responses to some questions, you may be required to fill in additional information.



Has your study/trial been funded? †
* must provide value

○ Post-award (the grant is funded)
○ Pre-award (application has been reviewed and scored, but no award has been made)
● Pre-application (have yet to submit for funding)

What is the planned funding source for the study/trial?
* must provide value

○ NIH
○ Other

Do you anticipate a budget > $500,000 in direct costs per year?
* must provide value

○ Yes
○ No

What is the anticipated total budget (indirect and direct)?
* must provide value

What is the total duration of the funding period?
* must provide value

What is/was your funding agency's due date for this application?

If applicable, by what date do you need to have an application prepared for submission to your institution's business office?

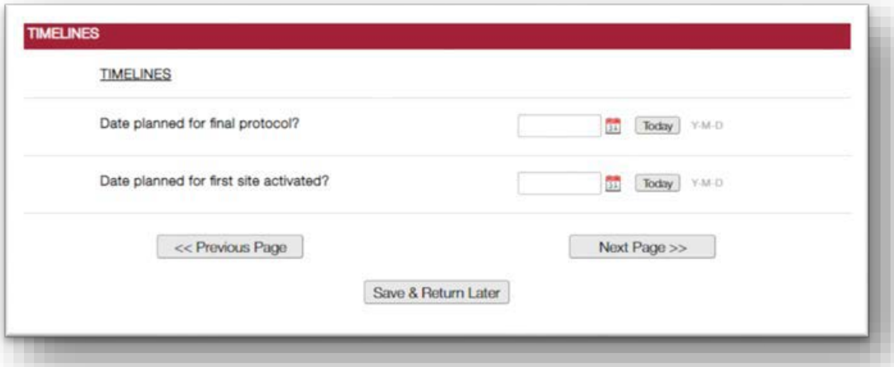
Will this proposal involve a partnership with a new or existing network?
* must provide value

○ Yes
○ No

Page 7

- On page 7 of the proposal intake form, you will be asked to provide information related to the study's timeline.
- Depending on your answers to funding status questions, the questions you will be required to answer may differ. Here are the three different timeline question scenarios you may see:

1. If you are "Post-award"



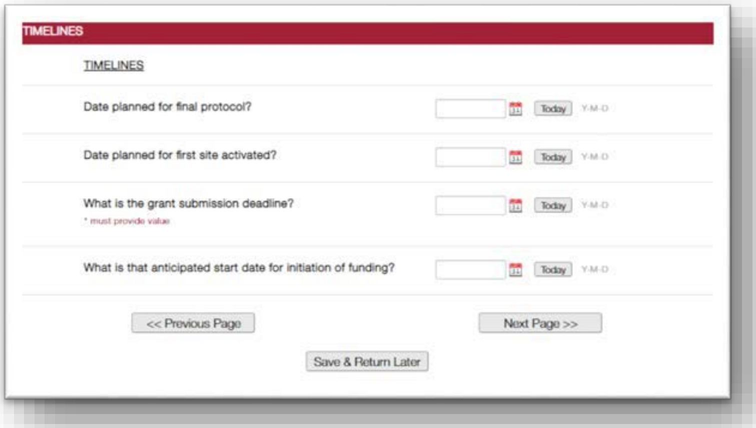
TIMELINES

TIMELINES

Date planned for final protocol?

Date planned for first site activated?

2. If you are "Pre-award"



TIMELINES

TIMELINES

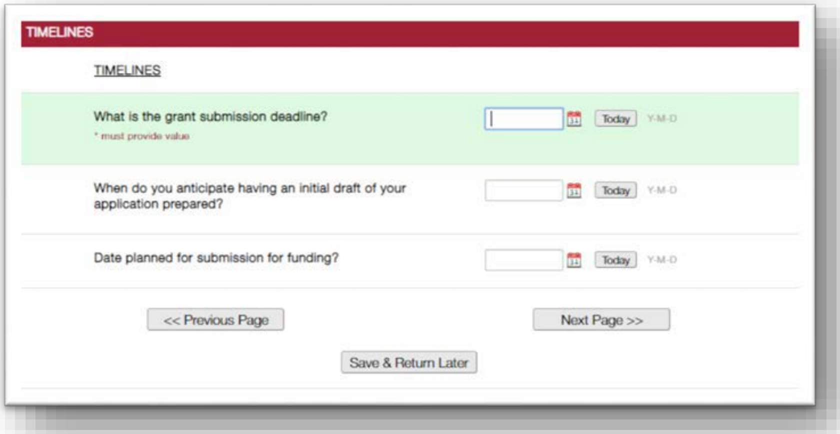
Date planned for final protocol?

Date planned for first site activated?

What is the grant submission deadline?
* must provide value

What is that anticipated start date for initiation of funding?

3. If you are "Pre-application"



TIMELINES

TIMELINES

What is the grant submission deadline?
* must provide value

When do you anticipate having an initial draft of your application prepared?

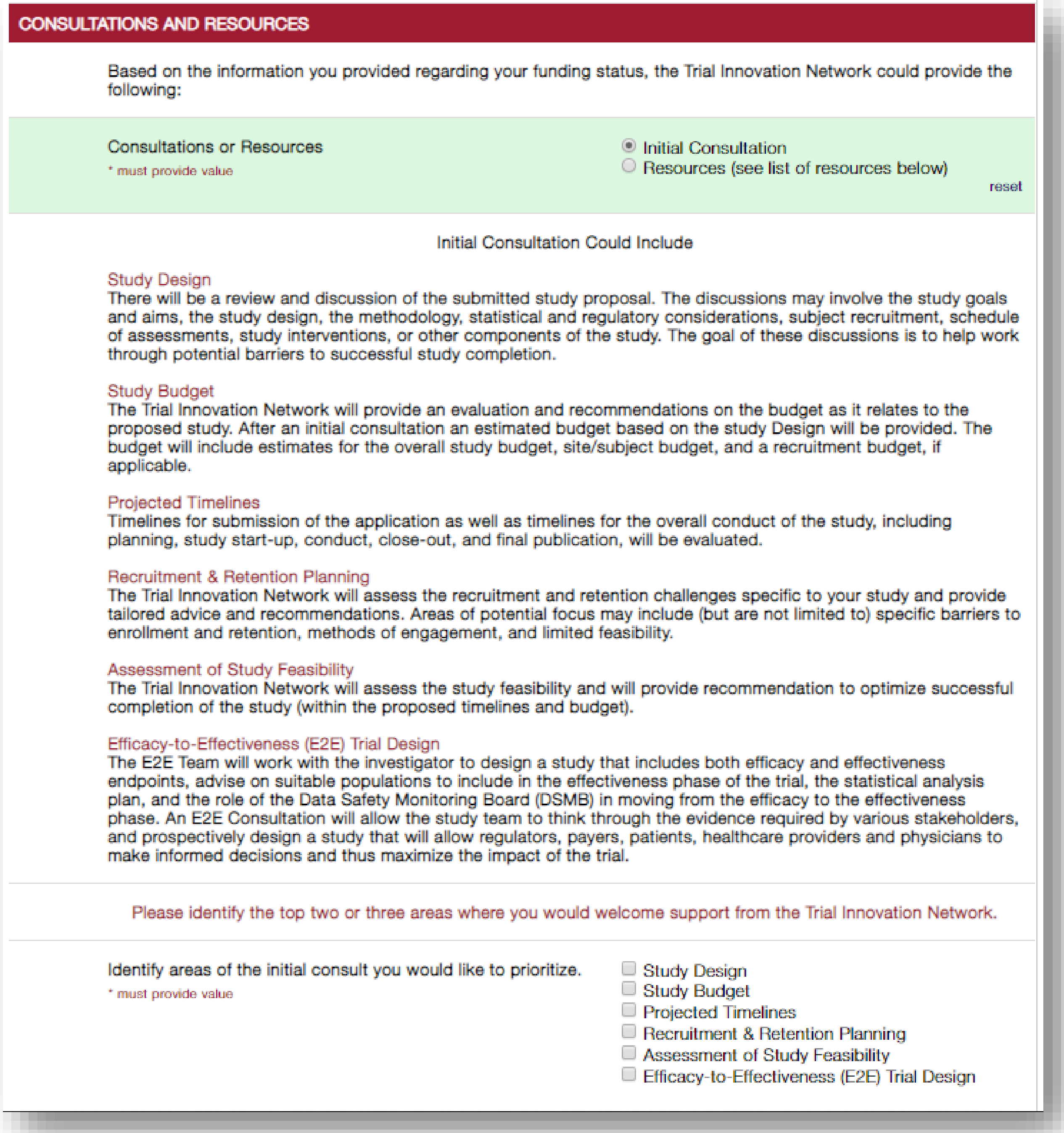
Date planned for submission for funding?

Page 8

- On page 8 of the proposal intake form, you will be asked to identify what type of resource(s) or consultation the study PI would like to receive from the Trial Innovation Network.

Here are options and what will be shown after the first selection:

Initial Consultation



CONSULTATIONS AND RESOURCES

Based on the information you provided regarding your funding status, the Trial Innovation Network could provide the following:

Consultations or Resources
* must provide value

● Initial Consultation
○ Resources (see list of resources below)

Initial Consultation Could Include

Study Design
There will be a review and discussion of the submitted study proposal. The discussions may involve the study goals and aims, the study design, the methodology, statistical and regulatory considerations, subject recruitment, schedule of assessments, study interventions, or other components of the study. The goal of these discussions is to help work through potential barriers to successful study completion.

Study Budget
The Trial Innovation Network will provide an evaluation and recommendations on the budget as it relates to the proposed study. After an initial consultation an estimated budget based on the study Design will be provided. The budget will include estimates for the overall study budget, site/subject budget, and a recruitment budget, if applicable.

Projected Timelines
Timelines for submission of the application as well as timelines for the overall conduct of the study, including planning, study start-up, conduct, close-out, and final publication, will be evaluated.

Recruitment & Retention Planning
The Trial Innovation Network will assess the recruitment and retention challenges specific to your study and provide tailored advice and recommendations. Areas of potential focus may include (but are not limited to) specific barriers to enrollment and retention, methods of engagement, and limited feasibility.

Assessment of Study Feasibility
The Trial Innovation Network will assess the study feasibility and will provide recommendation to optimize successful completion of the study (within the proposed timelines and budget).

Efficacy-to-Effectiveness (E2E) Trial Design
The E2E Team will work with the investigator to design a study that includes both efficacy and effectiveness endpoints, advise on suitable populations to include in the effectiveness phase of the trial, the statistical analysis plan, and the role of the Data Safety Monitoring Board (DSMB) in moving from the efficacy to the effectiveness phase. An E2E Consultation will allow the study team to think through the evidence required by various stakeholders, and prospectively design a study that will allow regulators, payers, patients, healthcare providers and physicians to make informed decisions and thus maximize the impact of the trial.

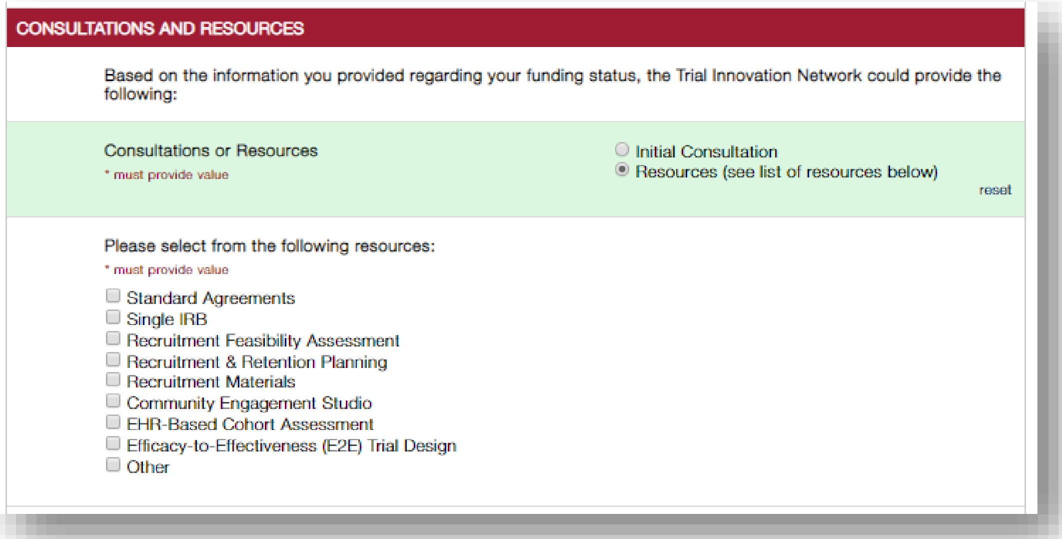
Please identify the top two or three areas where you would welcome support from the Trial Innovation Network.

Identify areas of the initial consult you would like to prioritize.
* must provide value

☐ Study Design
☐ Study Budget
☐ Projected Timelines
☐ Recruitment & Retention Planning
☐ Assessment of Study Feasibility
☐ Efficacy-to-Effectiveness (E2E) Trial Design

Resources

Please note: depending on what you select, you may be required to fill in additional information.



CONSULTATIONS AND RESOURCES

Based on the information you provided regarding your funding status, the Trial Innovation Network could provide the following:

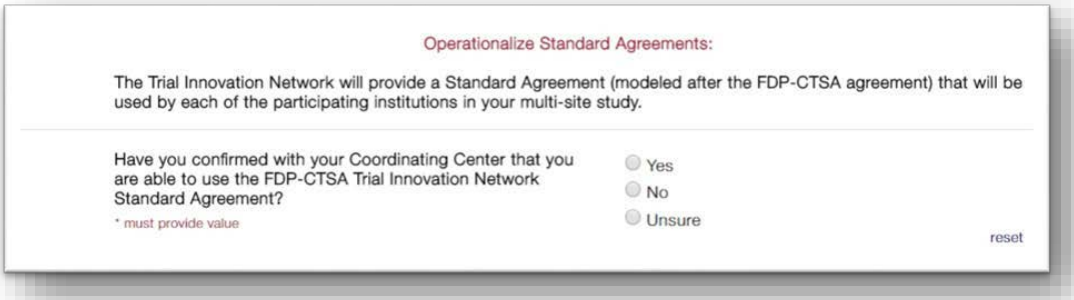
Consultations or Resources
* must provide value

○ Initial Consultation
● Resources (see list of resources below)
reset

Please select from the following resources:
* must provide value

☐ Standard Agreements
☐ Single IRB
☐ Recruitment Feasibility Assessment
☐ Recruitment & Retention Planning
☐ Recruitment Materials
☐ Community Engagement Studio
☐ EHR-Based Cohort Assessment
☐ Efficacy-to-Effectiveness (E2E) Trial Design
☐ Other

If you select “Operationalize Standard Agreements”, you will see:



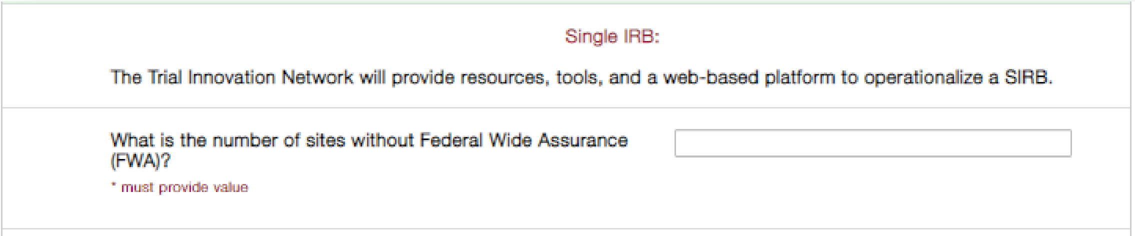
Operationalize Standard Agreements:

The Trial Innovation Network will provide a Standard Agreement (modeled after the FDP-CTSA agreement) that will be used by each of the participating institutions in your multi-site study.

Have you confirmed with your Coordinating Center that you are able to use the FDP-CTSA Trial Innovation Network Standard Agreement?
* must provide value

○ Yes
○ No
○ Unsure
reset

If you select “Operationalize Single IRB”, you will see:



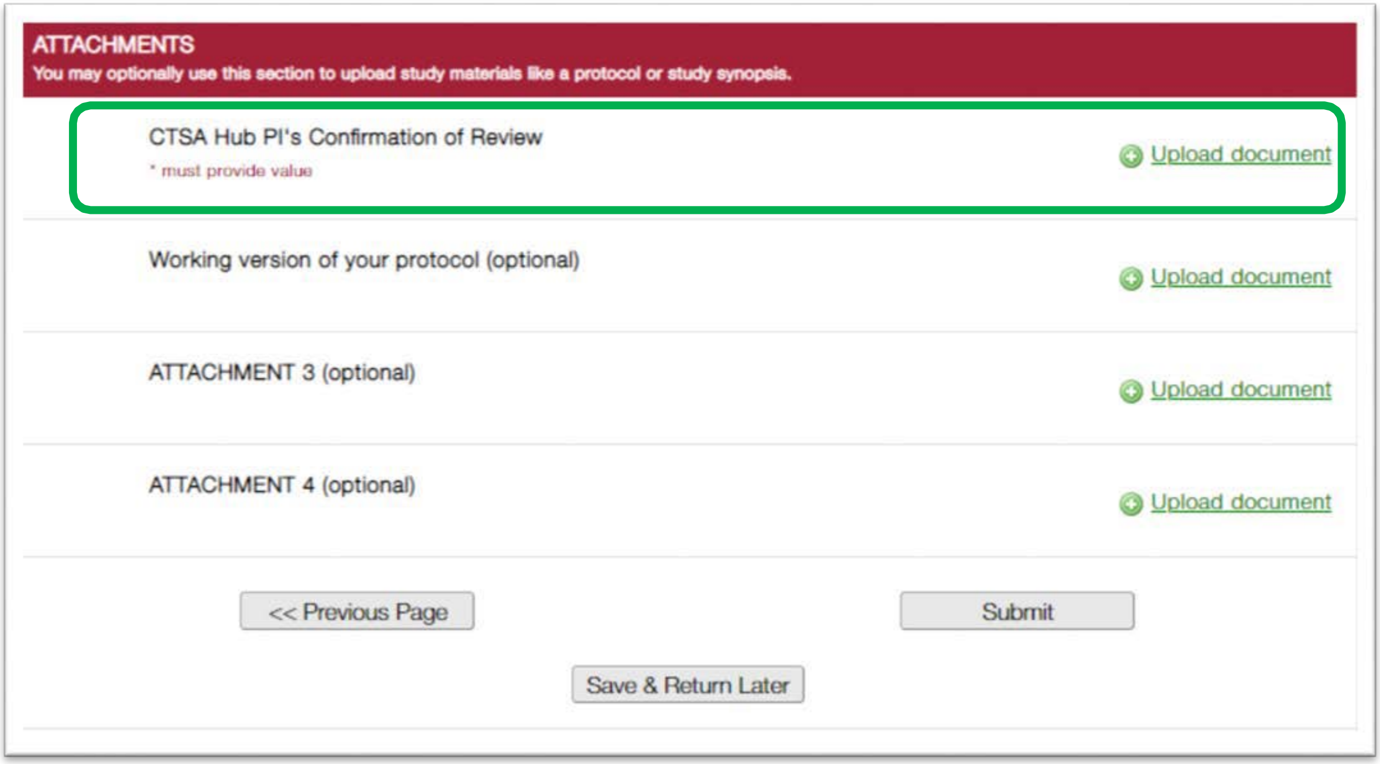
Single IRB:

The Trial Innovation Network will provide resources, tools, and a web-based platform to operationalize a SIRB.

What is the number of sites without Federal Wide Assurance (FWA)?
* must provide value

Page 9

- On page 9 of the proposal intake form, you will have the opportunity to upload all relevant or required documents. Please note that some form of documentation from the CTSA PI confirming support for this study is required.
- After attaching all relevant or required documents, click “Submit” to complete the application, or click “Save & Return Later” if additional changes are needed before submitting.



ATTACHMENTS

You may optionally use this section to upload study materials like a protocol or study synopsis.

CTSA Hub PI's Confirmation of Review

* must provide value

Working version of your protocol (optional)

ATTACHMENT 3 (optional)

ATTACHMENT 4 (optional)