Community-Based Participatory Research (CBPR) Request for Proposal (RFP) Program

Full Proposal

Instructions to Applicants Invited to Submit Full Proposals

Community-Based Participatory Research (CBPR) program

Thank you for your interest in the Community-Based Participatory Research (CBPR) program through Gilead Sciences Inc. For easy reference, this document provides step-by-step instructions to submit a Full Proposal if your LOI has been selected for further review.

1. Login to your G.Optics account.
2. Navigate to your LOI and click on the “Convert to Full Proposal” button in the top right.
3. Refer to this document for guidance filling out the proposal fields for this CBPR program.
4. Contact CREATE@gilead.com if you need further assistance

Converting LOI 1: Receiving an email invitation to submit

1. An invitation will be sent to the email address registered in G.Optics

From: noreply@gilead.com
Date: August 2, 2023 at 11:23:29 AM PDT
To: [redacted]
Subject: G.OPTICS: Invitation to Submit Full Proposal to Test RFP Program for "Convert to a full proposal" RFP Program - L-2023-0410

Dear [redacted],

Thank you for submitting a letter of intent (LOI) for your proposal titled Study Title Transfers to Full Proposal to the Gilead Medical Affairs Test RFP Program for "Convert to a full proposal" RFP Program. We received many highly competitive submissions from across the world and we had to select a small number of proposals for further consideration. Your LOI scored well during a formal, cross-functional committee review. We are pleased to invite you to submit a full proposal with detailed budget for further review. The full proposal is due [redacted]

2. Note the due date for submitting a full proposal. The system will not allow submission after this date.

3. Click on the link to navigate directly to your LOI. Alternatively, you can login to your G.Optics account at: https://gileadmedaffairs.appiancloud.com/suite/portal/login.jsp

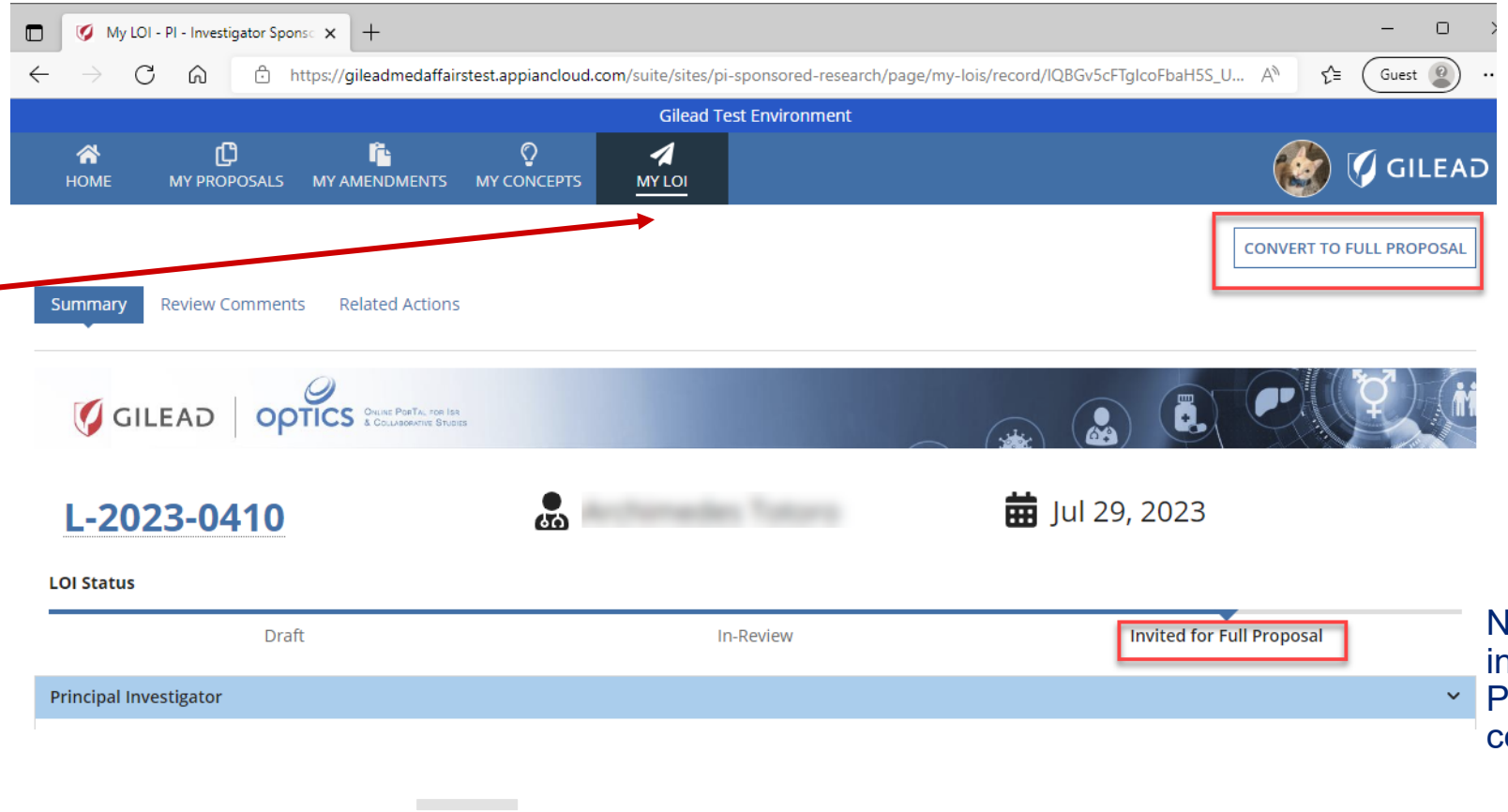
To complete the proposal, please return to G.OPTICS L-2023-0410 and select the "Convert LOI to Full Proposal" button. Details from the LOI will be populated automatically, and additional fields including the budget template will be available for you to complete.

In light of the FDA's Patient-Focused Drug Development initiative to gather patients' and family caregivers' perspectives on living with a disease, the symptoms that matter most to them, and their experiences with available therapies, we are interested in supporting proposals that incorporate patient perspectives, patient reported outcomes and other methodologies that meet patient needs and goals and enhance patient outcomes. We encourage proposals that utilize study protocols that reflect patient input and capture data that is meaningful to patients. In addition, if your research center has a Community Advisory Board, which reviews, comments or is involved in your research, please add this information to the application.

Please ensure that your full proposal is submitted by [redacted] as proposals received after that time will not be reviewed.

Converting LOI 2: Converting your LOI to a full proposal

Access your LOI in the MY LOI section

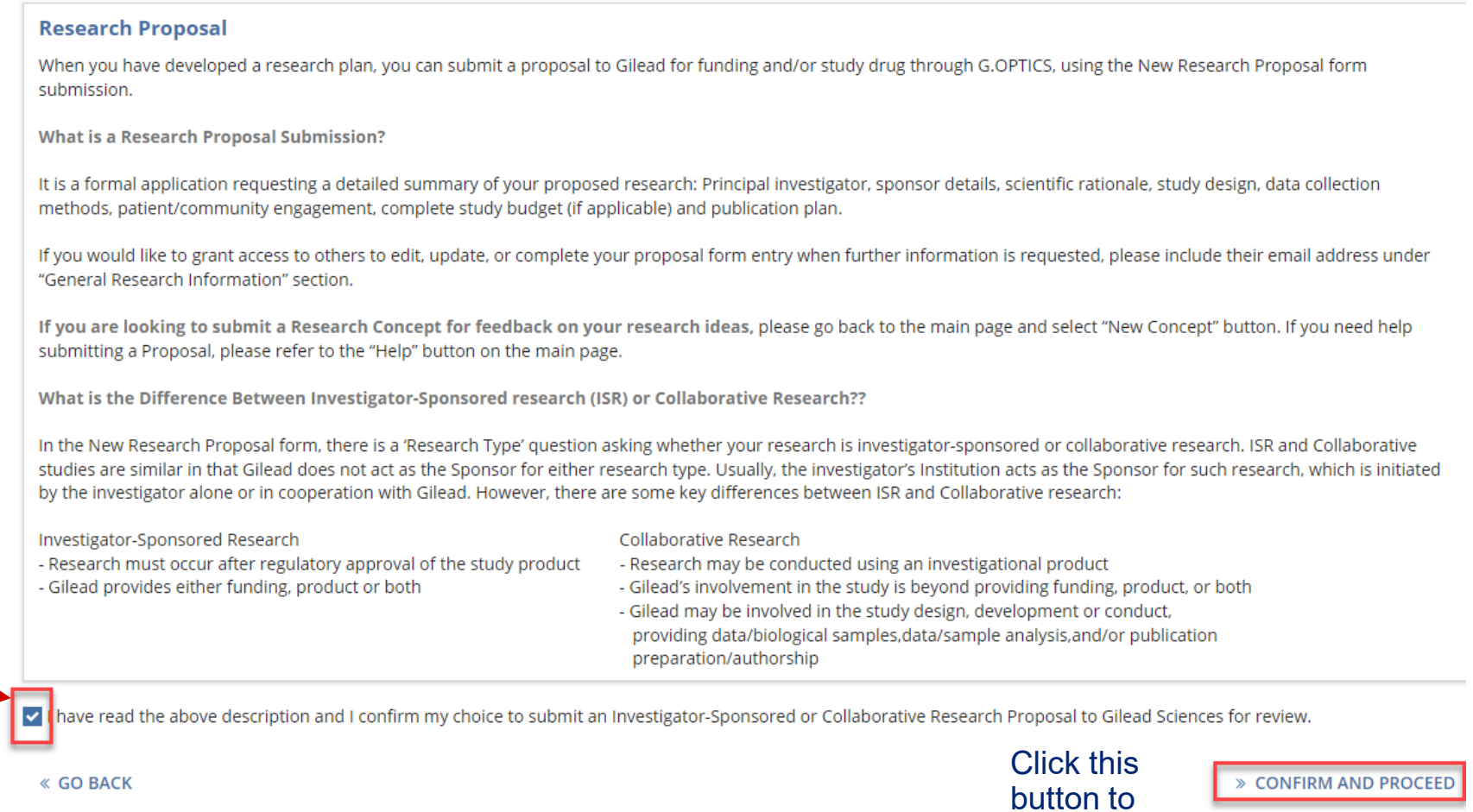


Click this button to convert your LOI

Note: Only LOIs invited for Full Proposals can be converted

Converting LOI 3: Acknowledgement step

Review info on screen and check this box

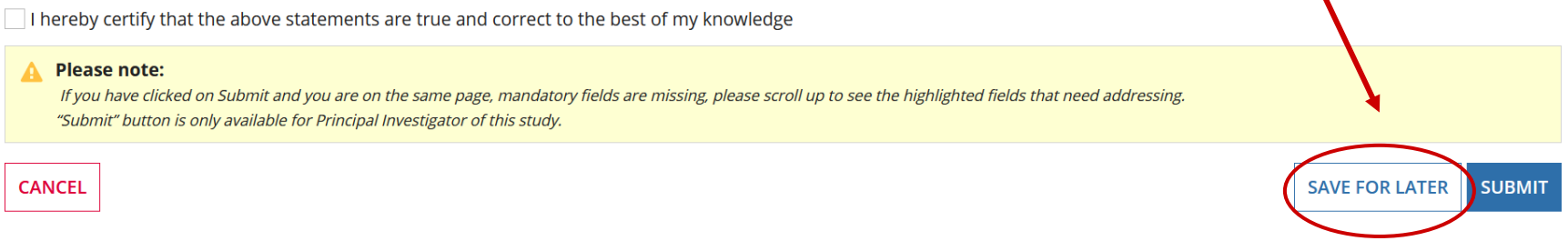


Click this button to convert your LOI

Proposal Submission 1: Tips

- We recommend starting a proposal draft and reviewing the submission data fields as a first step.
- It may be easier to draft text for longer fields in a word processing program, noting the character count, and pasting the final version into the submission website fields.
- Please note the deadline for submission of your Full Proposal in your email invitation. The submission window closes automatically by the date shown and cannot accept late submissions.

Note: you can scroll down to the bottom of the submission page and click here to save your work at any time



Proposal Submission 2: Filling in the Submission Fields
Study Title, Therapeutic Area, Product, Research Type, Scope of Research

General Research Information

Study Title *

Your study Study title will be automatically transferred from your LOI, but you can edit if you wish

10/255 (max 255 Characters)

Therapeutic Area *

HIV Treatment Select therapeutic area of the CBPR RFP that you are applying to

Please select all applicable Therapeutic Areas if there are more than one.

Product(s) being studied

Drug Agnostic Because no drugs are involved in CBPR proposals, select "Drug Agnostic"

Research Type *

Investigator Sponsored Select Investigator Sponsored

Difference between investigator-sponsored and collaborative research are described on the 'Research Proposal' landing page (viewed before this page) and the Gilead ISR FAQ document in the 'Help' section (found on the main site). Consider saving your work if navigating away from this page ('SAVE FOR LATER' button at the end of this form).

Scope of Research

Other

Select Community Research. If none of the choices apply to your proposal, please select "Other"

Proposal Submission 3: Filling in the Submission Fields
Study Lead and additional contacts

Tip: We strongly recommend that the research lead is the requestor/applicant and that any team members are added as assistants

Have you contacted anyone at Gilead regarding this Proposal?

○ Yes ◉ No Answer yes or no. If you answer yes, you will be asked to provide the name of the contact

Will anyone else in your organization be assisting you on this proposal?

◉ Yes ○ No If you would like someone to help you with this proposal, answer Yes.

Please provide their email id(s)

Email

Provide their email address here by clicking on “Add Email Ids”
They will be contacted with further instructions via email on how to create a G.Optics account and access this proposal.

⊕ Add Email Ids

Proposal Submission 4: Filling in the Submission Fields
Principal Investigator Details

Most of these fields will autofill from the LOI. Please refer to notes on this slide for further guidance if needed

Principal Investigator

Prefix Mr.

First Name * First Name
10/255 (max 255 Characters)

Last Name * Last Name
9/255 (max 255 Characters)

Suffix
0/10 (max 10 Characters)

Degree(s) n/a
3/255 (max 255 Characters)

Enter your highest academic degree here. If none, put N/A

Institution Name Your Community Organization
27/255 (max 255 Characters)

Institution Type Charitable/Non-profit Organization

Choose your organization type. If none apply, select Other

Specialty Other

Choose the area of your studies. If none apply, select Other

Address (Line 1) Address of community organization will autofill
47/255 (max 255 Characters)

Address (Line 2)
0/255 (max 255 Characters)

City City
4/255 (max 255 Characters)

Country *

State/Province

Postal Code
5/50 (max 50 Characters)

Email Address * email address of principal investigator/research lead/applicant should go here
This should be the email address of the Principal Investigator who would be the primary owner of the proposal.

Phone Number

Proposal Submission 5: Filling in the Submission Fields
Sponsor and Site Information

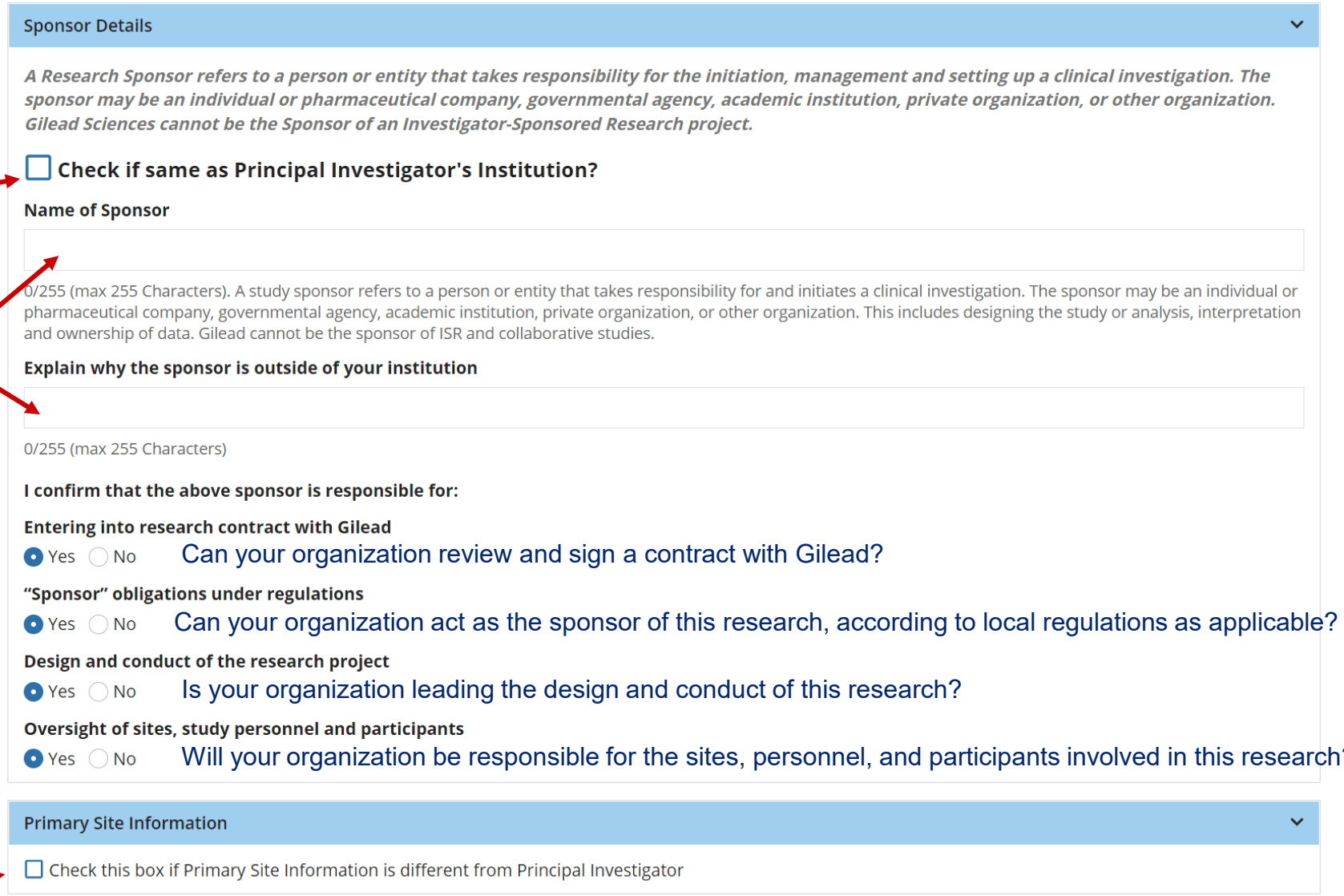
1. Please review the sponsor definition

2a. Check this box if your community organization will be the sponsor of the research project

2b. If your community organization will NOT be the sponsor, please give the sponsor name here and provide explanation in the box below

3. Please answer these questions about the sponsor. If No is chosen, a text box will appear to allow you to provide additional detail.

4. If the research will be conducted at a location that is different from that of the organization, please check this box and provide additional detail



Proposal Submission 6: Filling in the Submission Fields
Research Details

Scientific Basis/Rationale

Tell us about the overall main concern that your proposed study will address. Tell us briefly what is already known and short descriptions of the key elements of your proposal. Then tell us the main thing that is unknown or the unmet need that you would like to investigate. Provide references if you have them

0/6000 (max 6000 Characters)

Hypothesis

Provide a specific research question this study will answer or hypothesis that this study will test.

0/4000 (max 4000 Characters)

Primary Objective

Describe in a sentence or two your main plan to investigate (for example, the goal of your proposed program or intervention)

0/4000 (max 4000 Characters)

Secondary Objectives

Describe in a sentence or two any additional goals of your proposed program or intervention

0/4000 (max 4000 Characters)

Trial/Study Design

--- Select all that apply---

Select Community Research.
If no options apply, choose Other

Study Design and Research Methods

Tell us the details of how you plan to study this research question. Give details of your proposed program or intervention, what data you will collect, how it will be collected, and how it will be analyzed

0/4000 (max 4000 Characters)

Number of Sites

Answer “1” for your primary organization site. Answer “2” or more if there will be additional locations gathering data for your study.

List all countries where study activities will occur

Start typing the Country....

Proposal Submission 7: Filling in the Submission Fields
Research Details

Priority Populations

Select options that would describe study participants that apply and if no options apply, choose Not Applicable

Treatment Regimen

As CBPR is drug agnostic, please enter “Not Applicable”

0/4000 (max 4000 Characters)

Inclusion Criteria

List the characteristics that you will require of your study participants

0/2500 (max 2500 Characters)

Exclusion Criteria

List the characteristics that will make prospective participants ineligible for your study

0/4000 (max 4000 Characters)

Primary Endpoint

Describe exactly what you will be measuring for your main study objective (Examples could be, but are not limited to: Average change in quality-of-life questionnaire scores, difference in percentage of participants fully adhering to HIV treatment)

0/4000 (max 4000 Characters)

Secondary Endpoint

Describe exactly what you will be measuring for each of your additional study objectives

0/4000 (max 4000 Characters)

Sample Size Justification/Statistical Analysis

Provide details of what statistical analysis you have planned and how many study participants you estimate you will need, in order to collect enough data for it to be statistically meaningful.

0/4000 (max 4000 Characters)

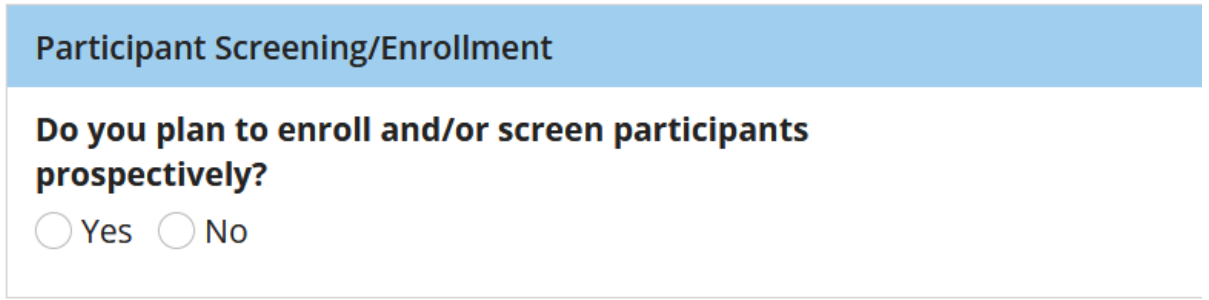
Additional Comments

Please use this field to add any additional information you feel is relevant to your application

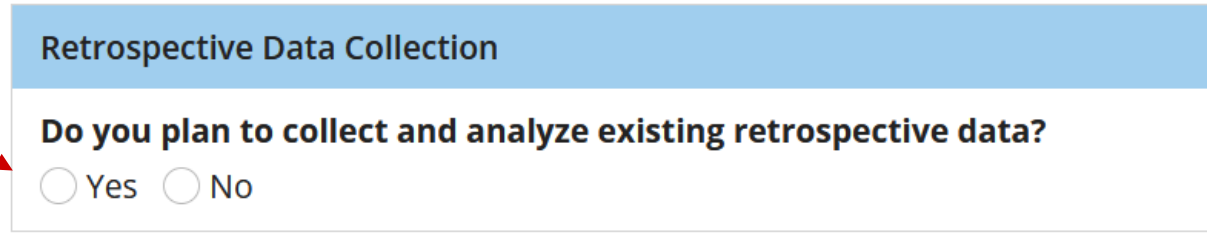
0/4000 (max 4000 Characters)

Proposal Submission 8: Filling in the Submission Fields
Data Collection and Community Engagement

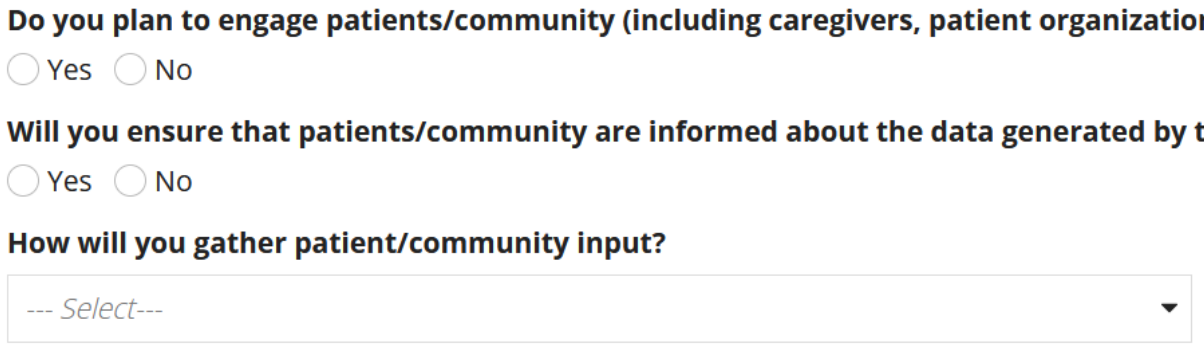
Select “yes” if you plan to follow participants forward in time, from study beginning to study end.



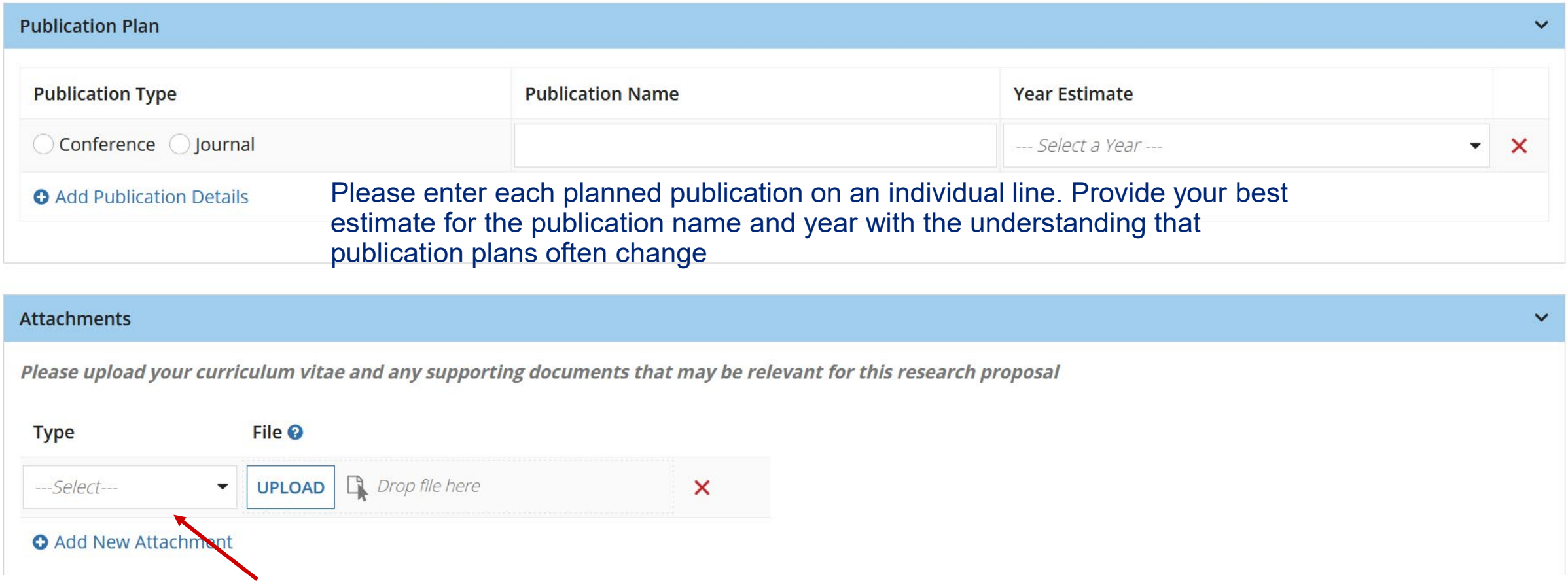
Select “yes” if you plan to analyze data that has already been collected (for example, from medical records)



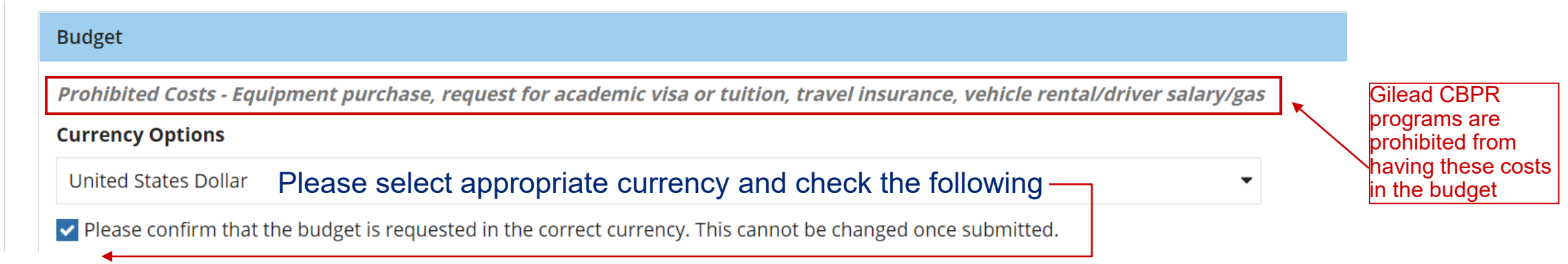
Click Yes or No for the first two questions, and select all that apply for the third question



Proposal Submission 9: Filling in the Submission Fields
Publication Plan and Attachments

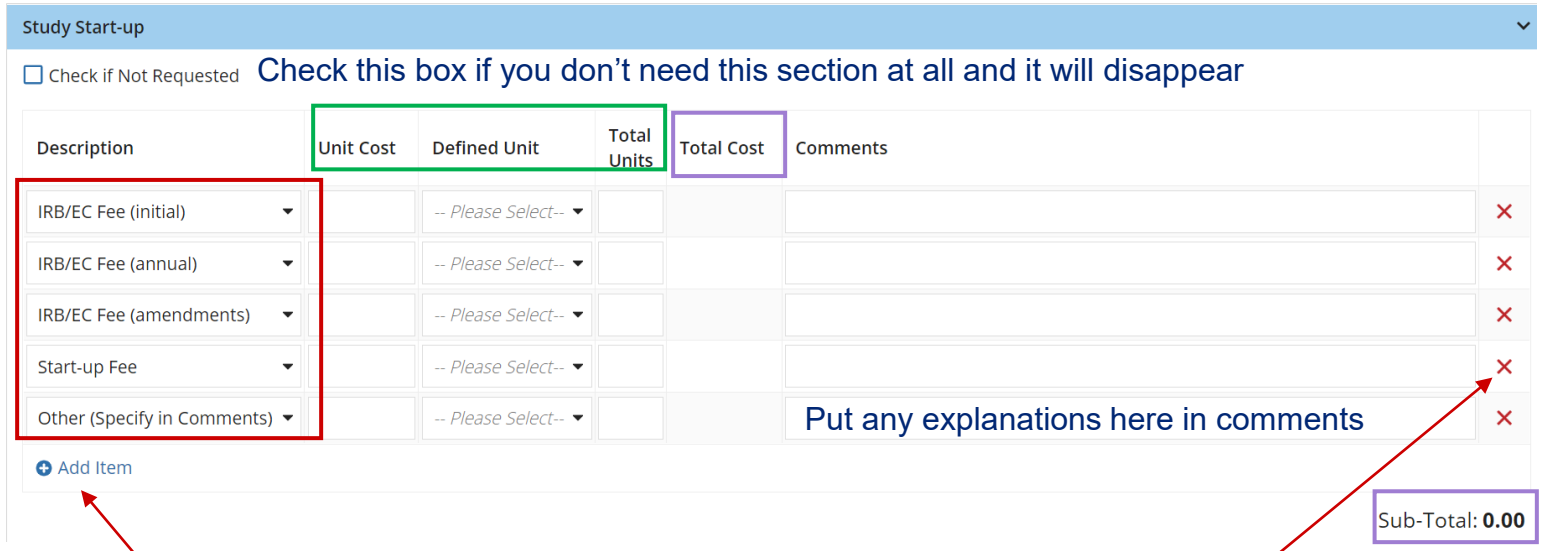


Proposal Submission 10: Budget slide 1
Study Support and Currency



Proposal Submission 11: Budget slide 2
General tips and Study Start-up Section

- The budget is divided into different sections to help you fill out a complete budget for your project.
- The first section is for Study Start-up, which are costs needed to start the project.
- For every line item, you will have to fill out Unit Cost, Defined Unit, and Total Units. Total Cost and Sub-Total will be automatically calculated. Here's an example, for a project manager for $200 who is paid $20/hour for 10 hours:
  - Unit Cost= $20
  - Defined Unit= per hour
  - Total Units =10
- Common line items for projects are provided for your use

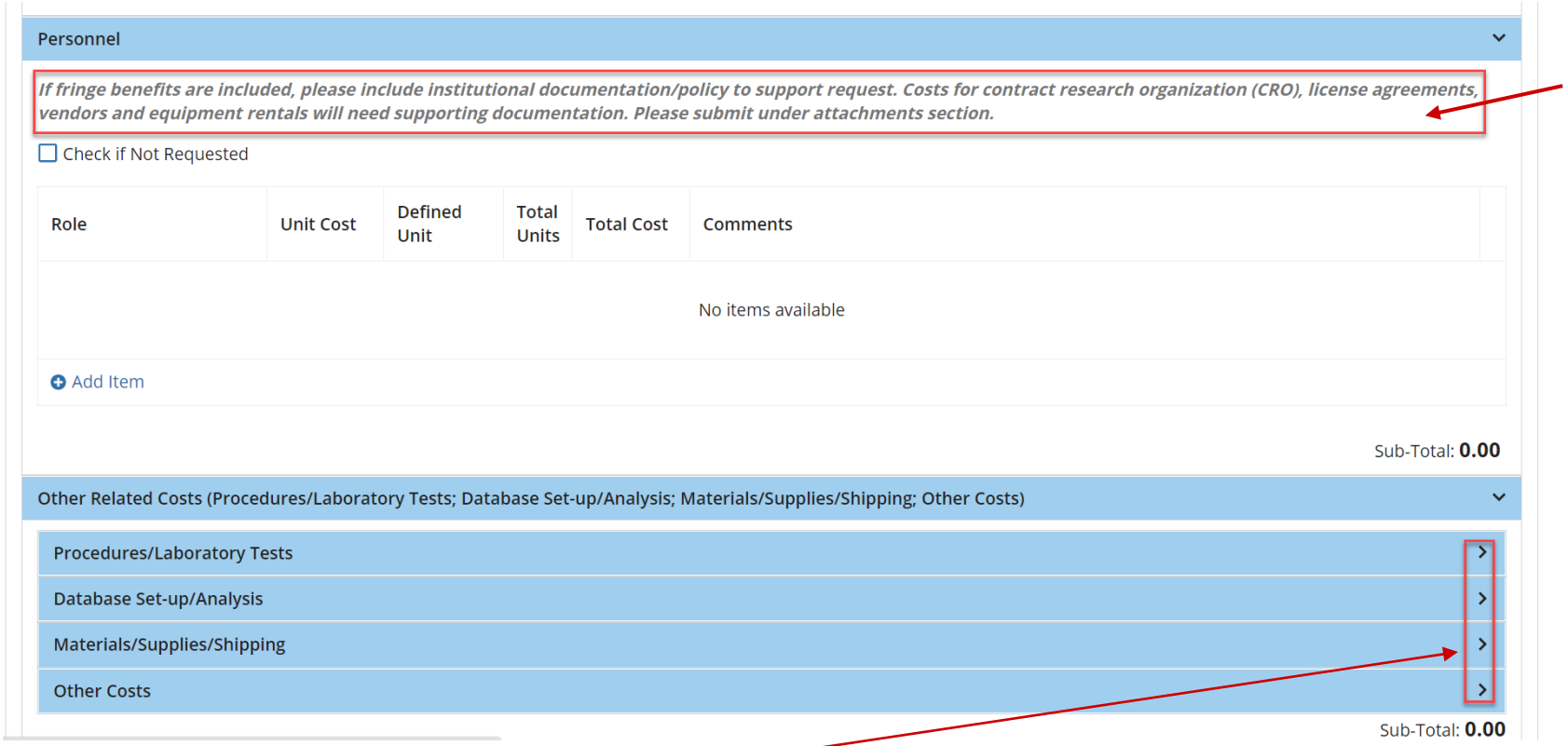


Click "Add Item" to add a new line

Click x if you need to delete a line. Remember-for every line, you have to fill out unit cost, etc. So if you don't need a line, it is easier to delete it instead of entering zero's

FAQ: What is IRB/EC? Some projects will require review by an Institutional Review Board or Ethics Committee. Typically, these reviews have a fee for the first review, an annual review if the project continues for more than a year, and a fee if the proposal changes significantly (amendment)

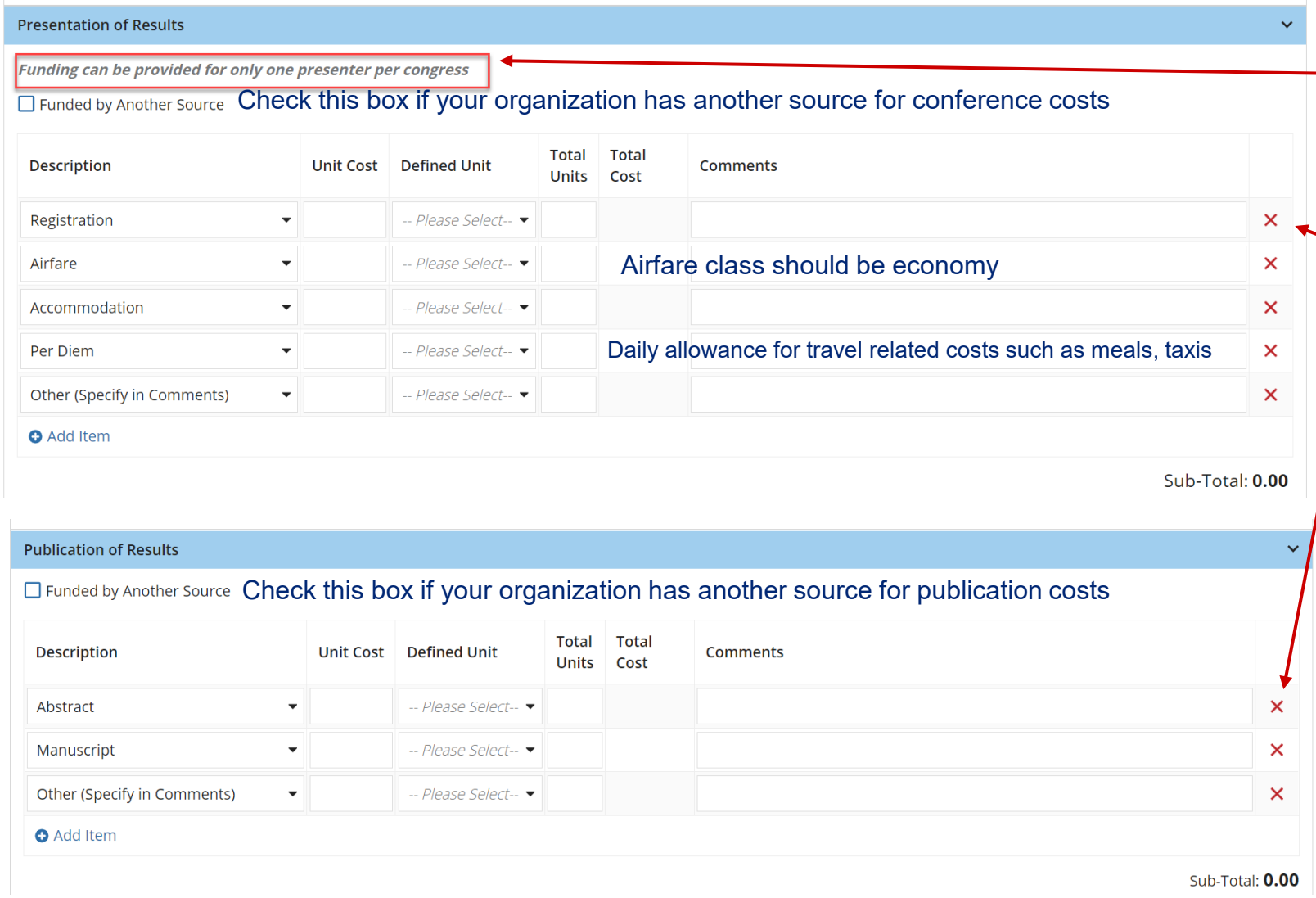
Proposal Submission 12: Budget slide 3
Personnel and Other Related Costs Sections



You can open and close sections by clicking on this icon

- Please note help text at the top. In general, lump sum amounts such as costs for vendors, equipment rentals, etc will require a quote that you can upload in the Attachment section.
- The Personnel Section is for costs of people involved in this project. Please describe Role (e.g. Investigator, Project Manager, Student) as well as any additional detail such as qualifications in the Comments section
- We recommend Unit Cost= hourly rate; Defined Unit= per hour; and Total Units= total # of hours person will be working on project

Proposal Submission 13: Budget slide 4 Presentation and Publication Sections



Please note help text at the top. This program can only fund 1 person to travel to a particular conference.

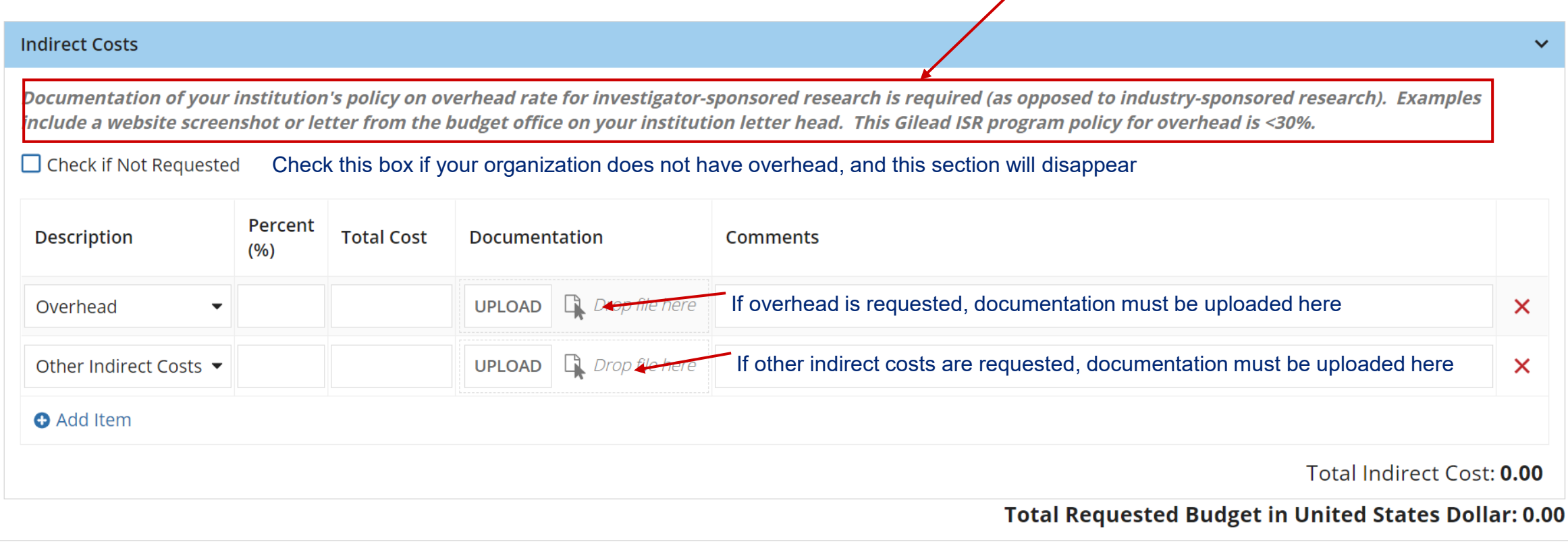
Reminder: If you don't need these sections, just delete these line items

The Publication of Results section is for costs charged by conferences and journals for publishing.

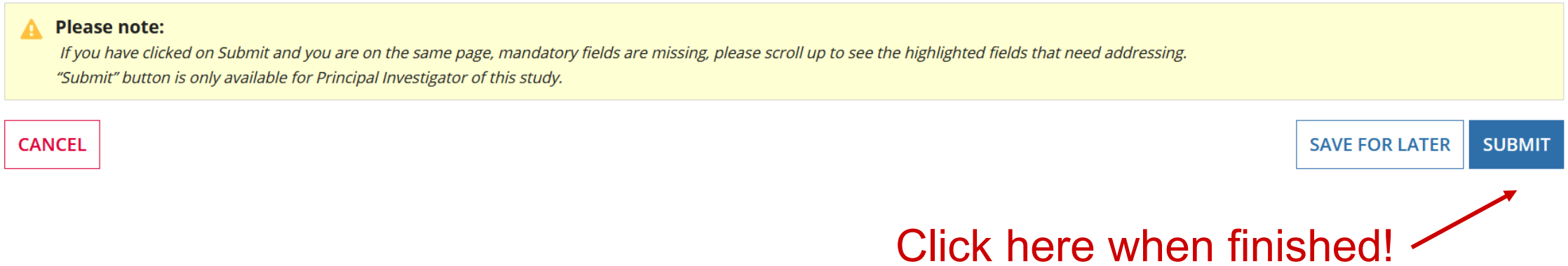
An example of an "Other" line item would be a vendor that provides writing support. Please don't forget to also upload a quote

Proposal Submission 14: Budget slide 5 Indirect Costs Section

- Please note help text at the top. Overhead and other indirect costs combined cannot be greater than 30%

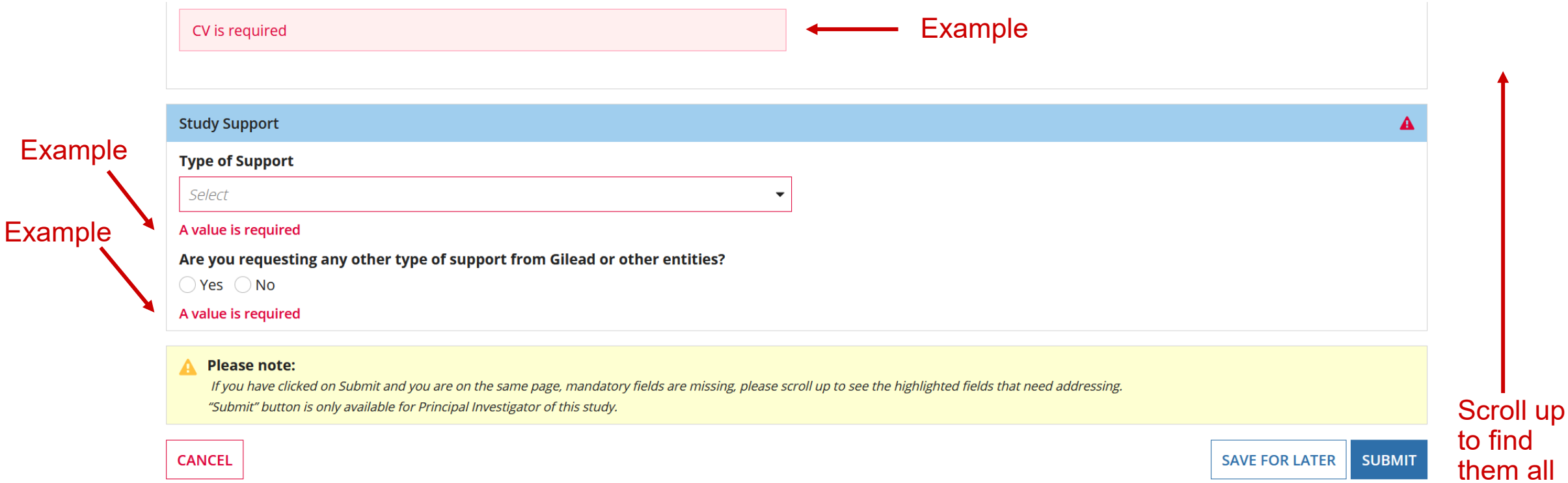


Proposal Submission 15: Submitting Full Proposal

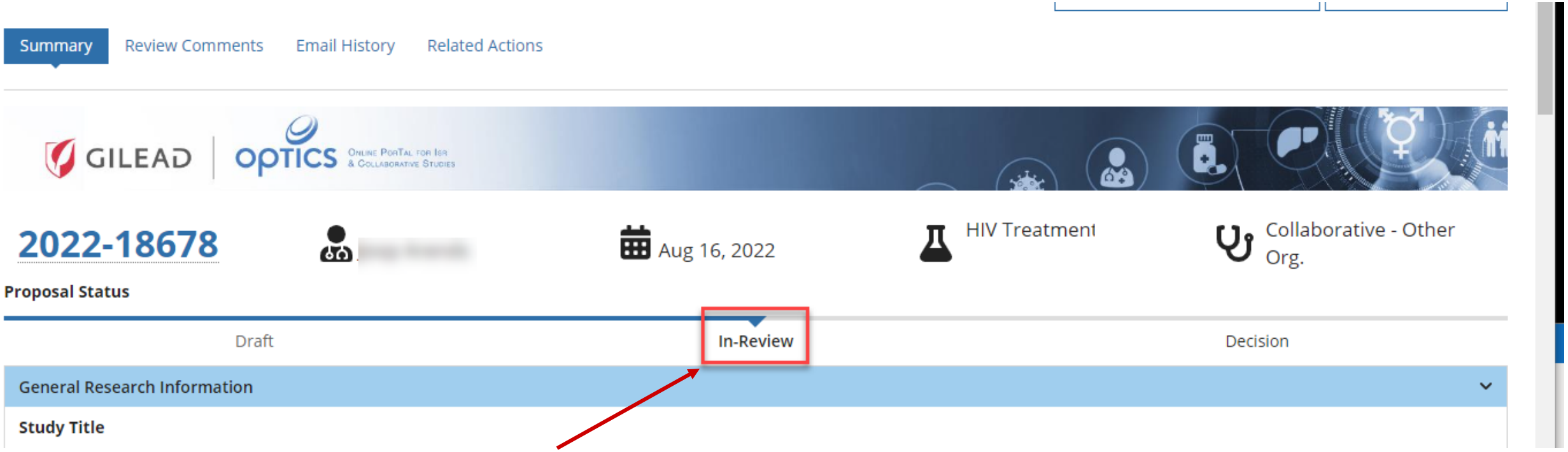


Proposal Submission 16: Troubleshooting an incomplete submission

If you are returned to this page after you confirm submission, scroll up, find all the red-highlighted fields that need your attention, and fill in the required information. Then click SUBMIT again.



Proposal Submission 17: Thank you!



- After submission, status bar should change to In-Review
- Please direct questions to CREATE@gilead.com