Document Title: Relying Site Directions for PSite Application

A. Introduction

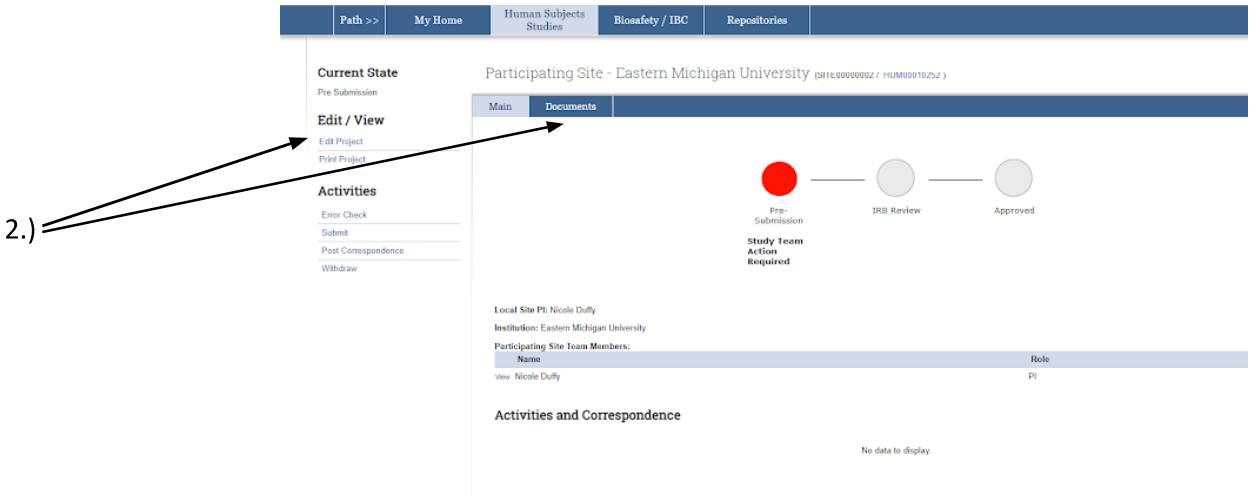
The purpose of this document is to help study teams that are relying upon an University of Michigan (U-M) IRB for the purpose of regulatory oversight on a multi-site research study. U-M IRBs use a PSite application to collect information from the external sites. This guidance document has been prepared jointly by the IRB-HSBS and IRBMED to summarize harmonized procedures established between the two departments.

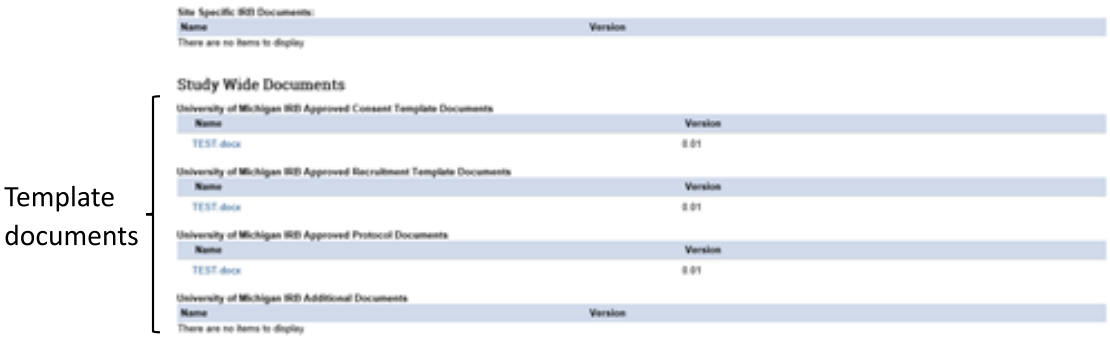
Note: Any and all study numbers seen in screenshots below are made up applications for the purpose of this document.

B. Process

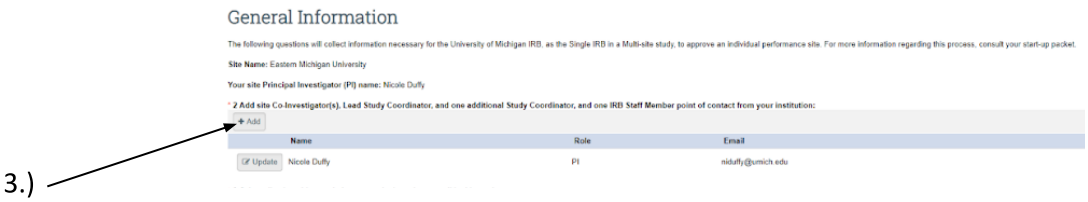
1. After logging in the relying site PI will land on a page that looks like the picture below. On this screen the individual will see any participating site applications that they have been added to. So if they are collaborating on more than one project with the University of Michigan as the single IRB, there will have more than one listing.

2. The relying site PI will then click on the participating site application that is to be revised. This will open up the participating site workspace where they will be able to select “Edit Project” on the left side of the screen or download the template documents from the “documents” tab.



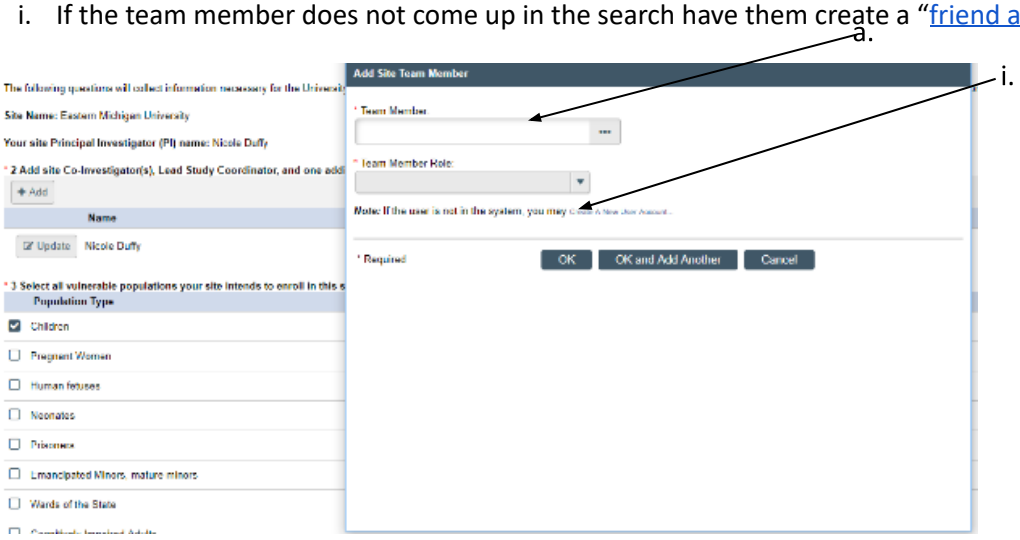


3. Once "edit project" is selected there will be two pages of questions to be filled out. On the top of the first page, they will have the opportunity to add more study team members. U-M asks that at least one Co-Investigator, one or two study coordinators and an IRB personnel member be added to the application. To do this, click "+Add"



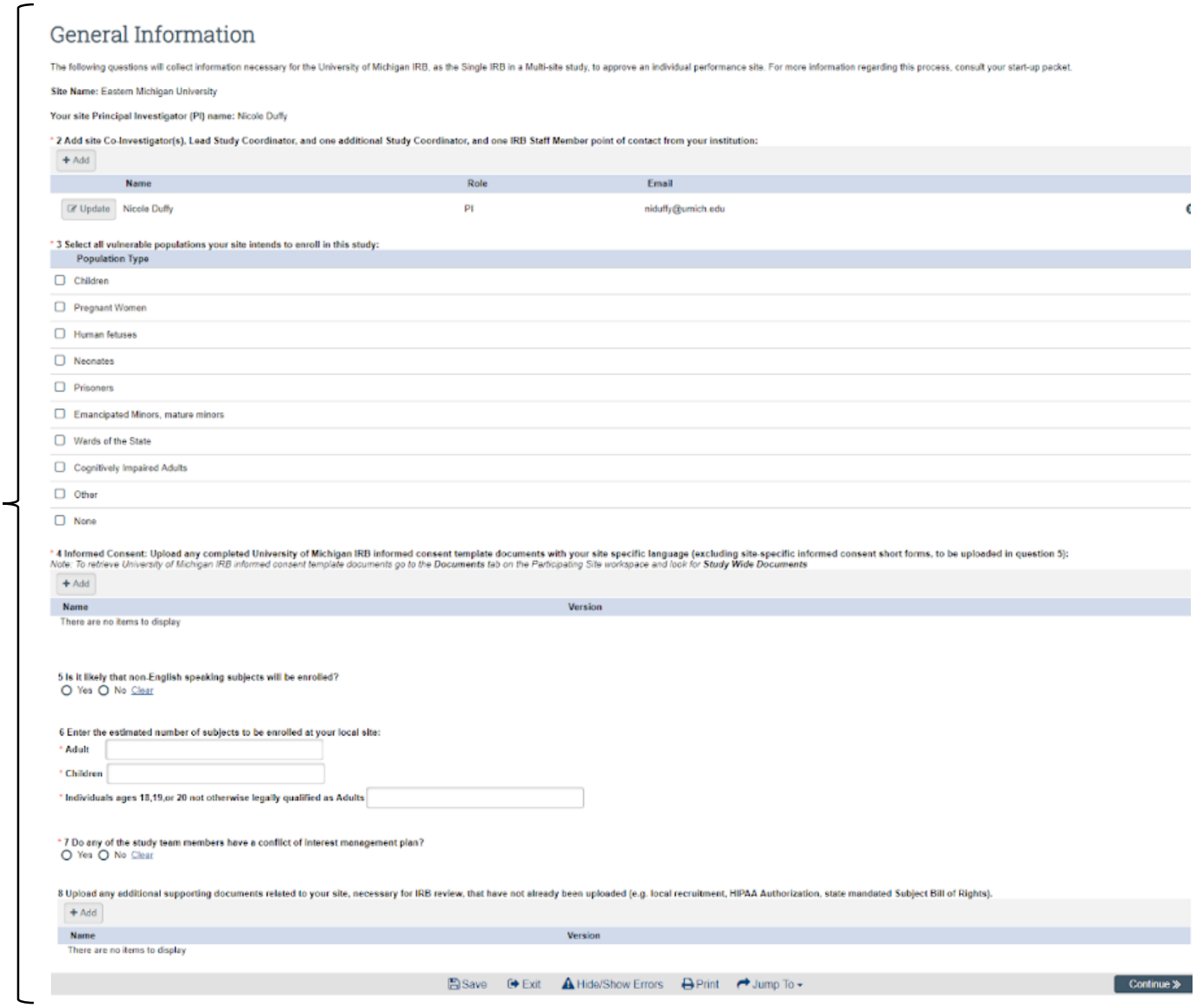
   a. Another popup will open where a search can be performed for each team member and the team member role can be assigned.

      i. If the team member does not come up in the search have them create a "friend account".



4. Once study team members are added, click “save”. At this time, all the study team members will be able to access the application and someone else could continue the application, if needed. Page 1 asks about local information specific to the study enrollment, this will need to be filled out before being able to click “continue”.

4.)



General Information

The following questions will collect information necessary for the University of Michigan IRB, as the Single IRB in a Multi-site study, to approve an individual performance site. For more information regarding this process, consult your start-up packet.

Site Name: Eastern Michigan University

Your site Principal Investigator (PI) name: Nicole Duffy

* 2 Add site Co-Investigator(s), Lead Study Coordinator, and one additional Study Coordinator, and one IRB Staff Member point of contact from your institution:

+ Add

	Name	Role	Email
Update	Nicole Duffy	PI	niduffy@umich.edu

* 3 Select all vulnerable populations your site intends to enroll in this study:

Population Type
☐ Children
☐ Pregnant Women
☐ Human fetuses
☐ Neonates
☐ Prisoners
☐ Emancipated Minors, mature minors
☐ Wards of the State
☐ Cognitively Impaired Adults
☐ Other
☐ None

* 4 Informed Consent: Upload any completed University of Michigan IRB informed consent template documents with your site specific language (excluding site-specific informed consent short forms, to be uploaded in question 5):
Note: To retrieve University of Michigan IRB informed consent template documents go to the ***Documents*** *tab on the Participating Site workspace and look for* ***Study Wide Documents***

+ Add

Name	Version
There are no items to display	

5 Is it likely that non-English speaking subjects will be enrolled?
○ Yes ○ No Clear

6 Enter the estimated number of subjects to be enrolled at your local site:
* Adult
* Children
* Individuals ages 18,19,or 20 not otherwise legally qualified as Adults

* 7 Do any of the study team members have a conflict of interest menegement plan?
○ Yes ○ No Clear

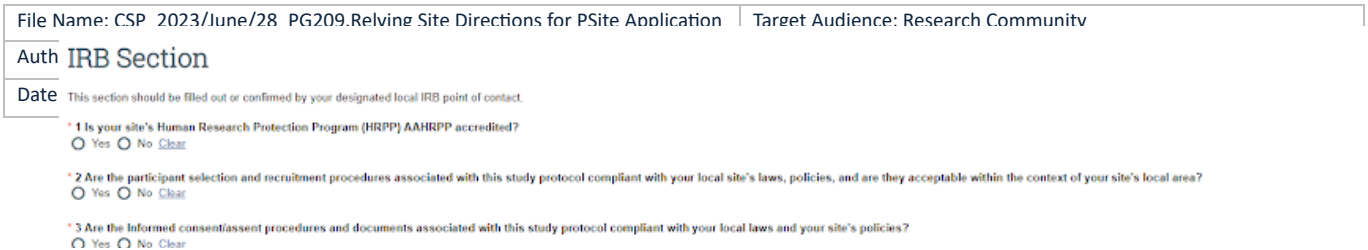
8 Upload any additional supporting documents related to your site, necessary for IRB review, that have not already been uploaded (e.g. local recruitment, HIPAA Authorization, state mandated Subject Bill of Rights).

+ Add

Name	Version
There are no items to display	

Save Exit Hide/Show Errors Print Jump To Continue

5. After clicking “continue”, the second page will open up. This page is specific to local IRB information. It is preferred that an IRB staff member fills this out or at least confirms the information. Once this section is filled out, click “Continue”.



File Name: CSP_2023/June/28_PG209.Relying Site Directions for PSite Application | Target Audience: Research Community

Auth

Date

IRB Section

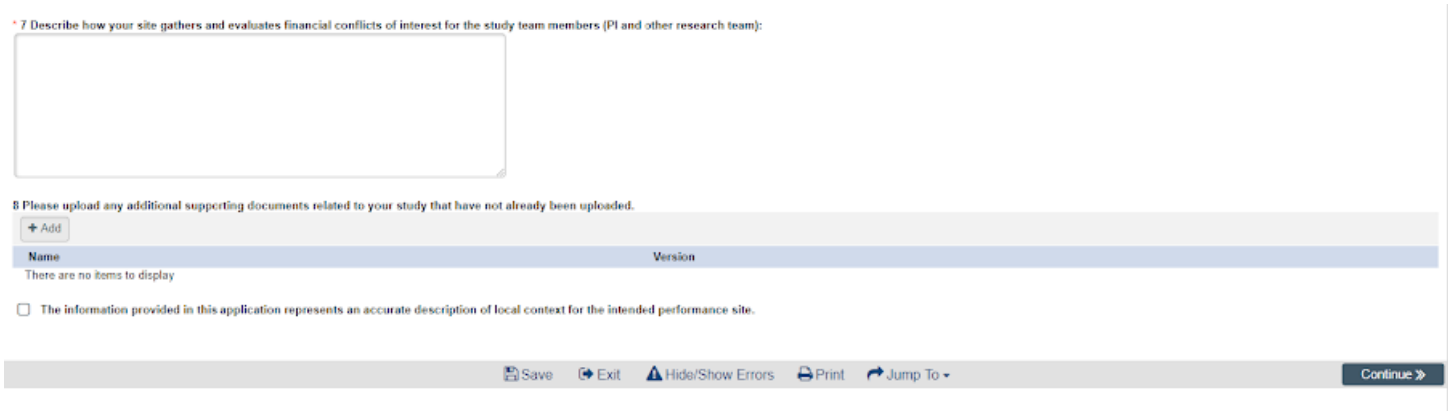
This section should be filled out or confirmed by your designated local IRB point of contact.

* 1 Is your site's Human Research Protection Program (HRPP) AAHRPP accredited?
○ Yes ○ No Clear

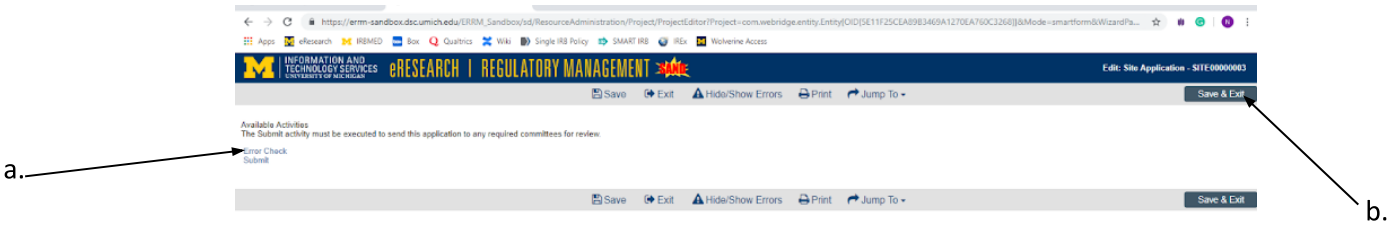
* 2 Are the participant selection and recruitment procedures associated with this study protocol compliant with your local site's laws, policies, and are they acceptable within the context of your site's local area?
○ Yes ○ No Clear

* 3 Are the informed consent/assent procedures and documents associated with this study protocol compliant with your local laws and your site's policies?
○ Yes ○ No Clear

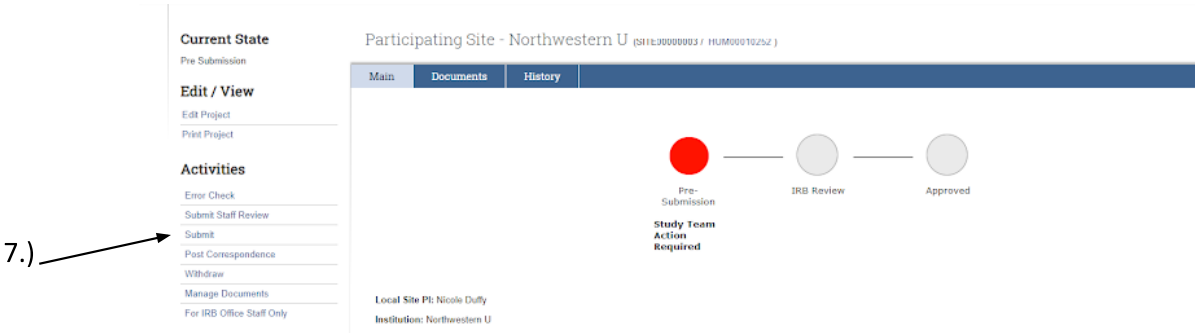
5.)



6. After the application is filled out:
    a. Perform an error check
    b. If there are no errors, then click “Save & Exit”

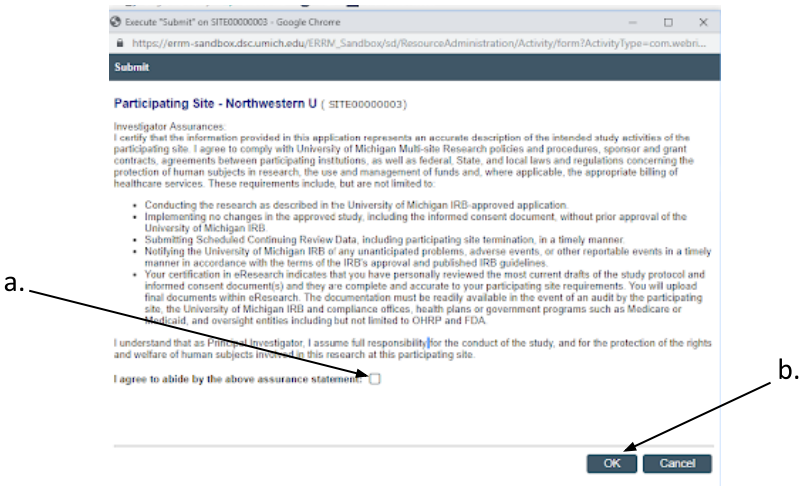


7. At this time, the relying site PI can "submit" the application.

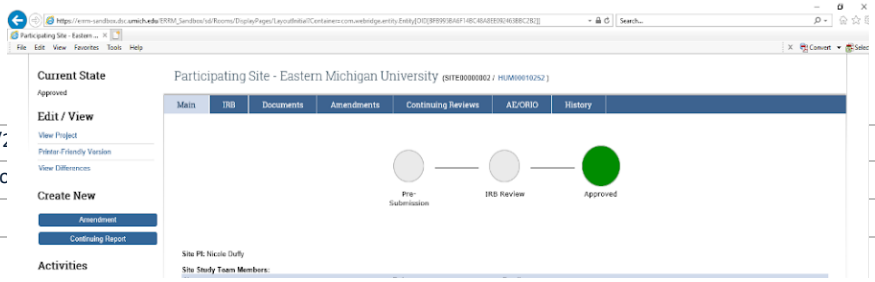


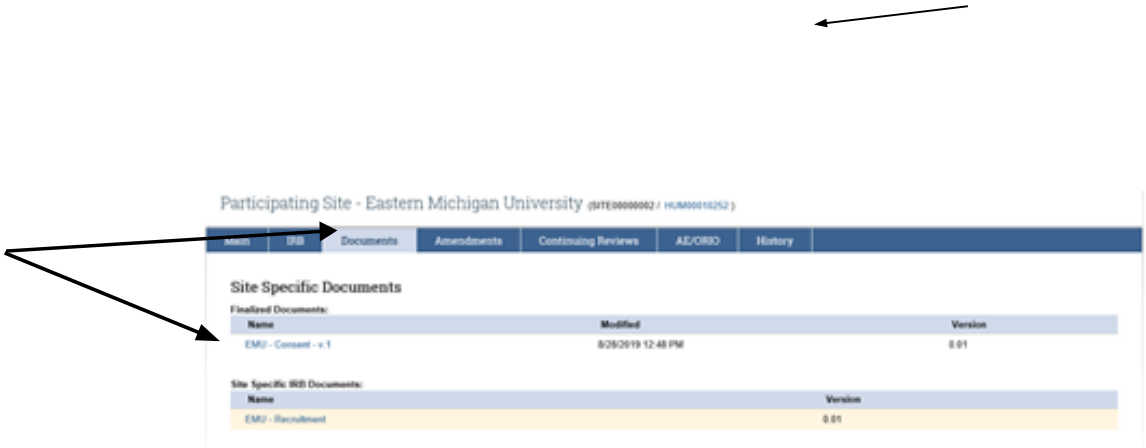
8. After clicking "submit" a new window will open. This window is the Investigator Assurances; the investigator is expected to read and agree with these assurances.

a. Once they have read the assurances they can agree via checking the box to indicate they agree.
b. Once the box is checked, they click "OK" to submit the application.



9. This submission will then go to the IRB for review and approval. Once the submission is approved the workspace will indicate so and the relying site study team will also be able to access their IRB approved site specific documents on the documents tab.





RESOURCES:

- For more eResearch information and how-to help, including how-to initiate amendments, reportable events and continuing reviews, reference: https://its.umich.edu/academics-research/research/eresearch/regulatory-management/reference-materials/participating-site-application
- For more information on multi-site research and supporting documents, reference: https://umich.box.com/v/MultisiteResearchDocuments