UNIVERSITY OF OREGON | Research Compliance Services

RAP IRB
RAP PROCEDURES FOR CREATING EXTERNAL SITE (PSITE) WHEN UO IS REVIEWING IRB

Purpose: This guide includes information about how to set up an external site (also called participating sites or pSites) on an multi-site/collaborative IRB project. A pSite houses the documents specific to that external site and allows the UO IRB to be the IRB of record for another institution that is external to the UO. Only pSites that are engaged in the human subjects research should be added to the study.

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Tips and General Guidance

- For assistance with terminology, see the Human Subject Research Definitions.
- Although the parent study will contain details specific to the UO and/or about the study as a whole, the pSites contain details specific to the activities taking place at an external site that is engaged in the research. If you are unsure about whether a collaborator is engaged in the research, the collaborator should check with the IRB at their institution or you can contact RCS. If the other institution is not engaged, no pSite will be needed.
- Not all institutions will enter into a reliance agreement for exempt studies, studies that are not federally funded or are not otherwise under an sIRB mandate. Please work with RCS and collaborating institutions to determine if a reliance agreement is appropriate under an exempt study and/or an unfunded study.
- A pSite is generally created after a UO researcher already has IRB approval for a multi-site/collaborative study. See separate RAP guidance for how to "Create a Multi-site study where UO is the reviewing IRB". If you already have IRB approval for a study that was only set up as a single-site, a modification (MOD) will be needed to your existing study to make it multi-site/collaborative before you can create a pSite.

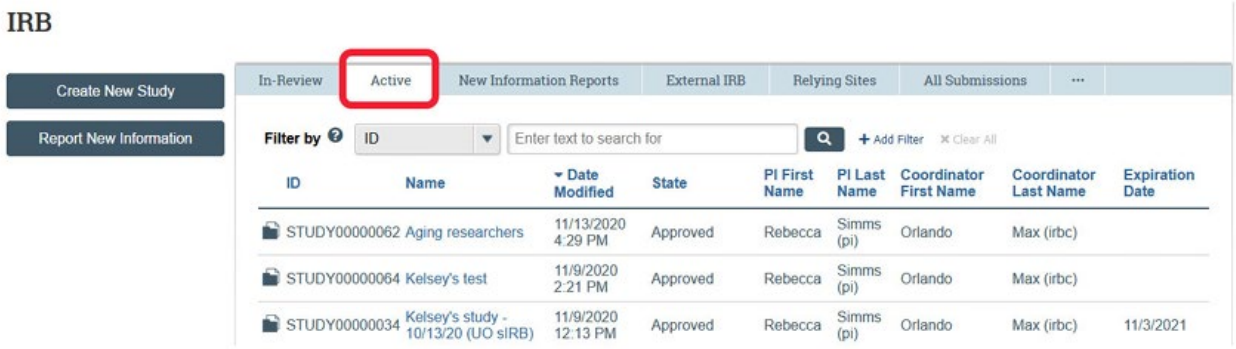
A. Determine if your study is a single-site or multi-site/collaborative study.

- A *single-site study* is project where only the University of Oregon and its investigators are engaged in the research. This includes research personnel working under an Individual Investigator Agreement (IIA). ***A single-site study can have multiple research locations, but only one institution with a federal wide assurance (FWA) is involved.***
- A *multi-site or collaborative study* is a project where multiple institutions with an FWA/IRB are engaged in the research. See our Collaboration in Research website for more information.
- Log in to your project in the RAP to determine if it is single-site or multi-site/collaborative (details about what to look for are included in the section below).
- If you have any questions on whether your study is single or multi-site, contact RCS at researchcompliance@uoregon.edu or (541) 346-2510.

Login and Find Existing Submission that will have a pSite

1. Go to irb.rap.uoregon.edu and login using your Duck ID. If you have log in issues, email RCS.
2. Once logged in, the system will take you to your dashboard. Click on IRB at the top navigation bar:

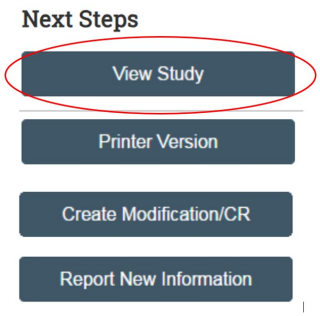
3. Click the **Active** tab to see all currently approved studies you are listed on as principal investigator or as a study team member.



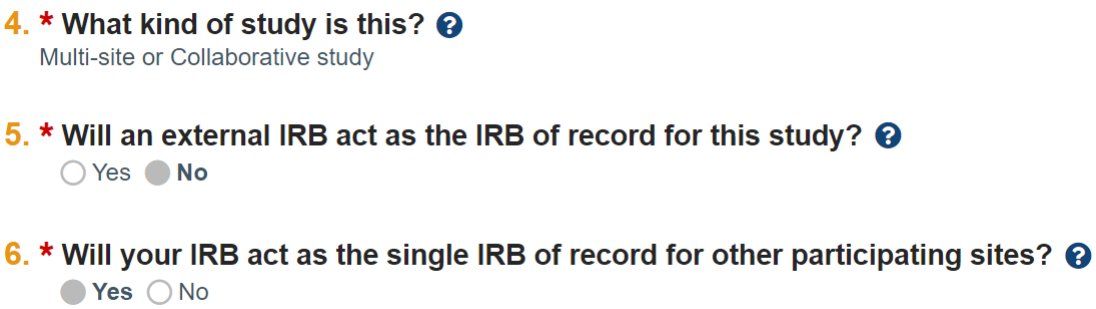
4. In the list of active studies, find the study you want to add a pSite on and click on the name of the study to view it. This study will be called the parent study throughout this document.

Confirm your study is set up as a Multi-Site or Collaborative Study

1. On the parent study, click View Study on the left side of the project.



2. Confirm the Basic Study Information section displays the following details:



   If your existing parent study doesn't have the above selections, you will need a modification to change those details (see Modify the parent study section below).

3. Look at your approved study documents throughout the application to confirm that your study already has an approved Reliance Request Form (UO Reviewing IRB). This document should be located in the Basic Study Information section (last question) but it may also be uploaded to other locations (e.g., Study-Related Documents or Local Site Documents). If a reliance request form is on file, review it to determine if it accurately describes your collaborator's role and details.

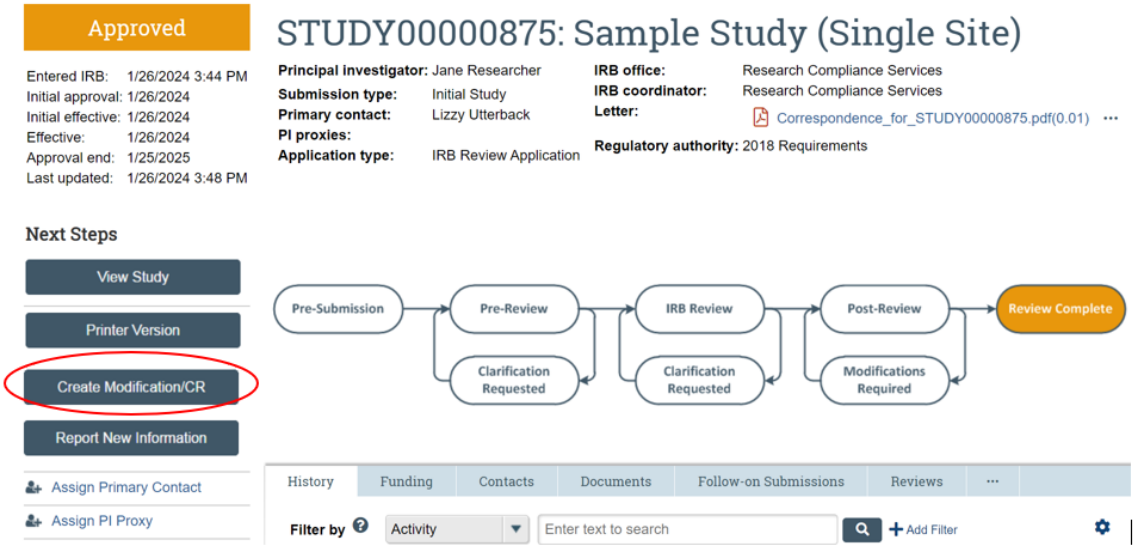
   Note: if your existing parent study doesn't have an approved Reliance Request Form (UO Reviewing IRB) or if your existing reliance request form does not describe the collaboration with the external site you want to add, you will need a modification to provide those details (see section below).

B Modify the parent study (if needed)

- If the parent study is already set up as a multi-site or collaborative study and the reliance request form on file describes all your planned collaborations, you can skip this section. Otherwise, follow the steps below.

Create Modification

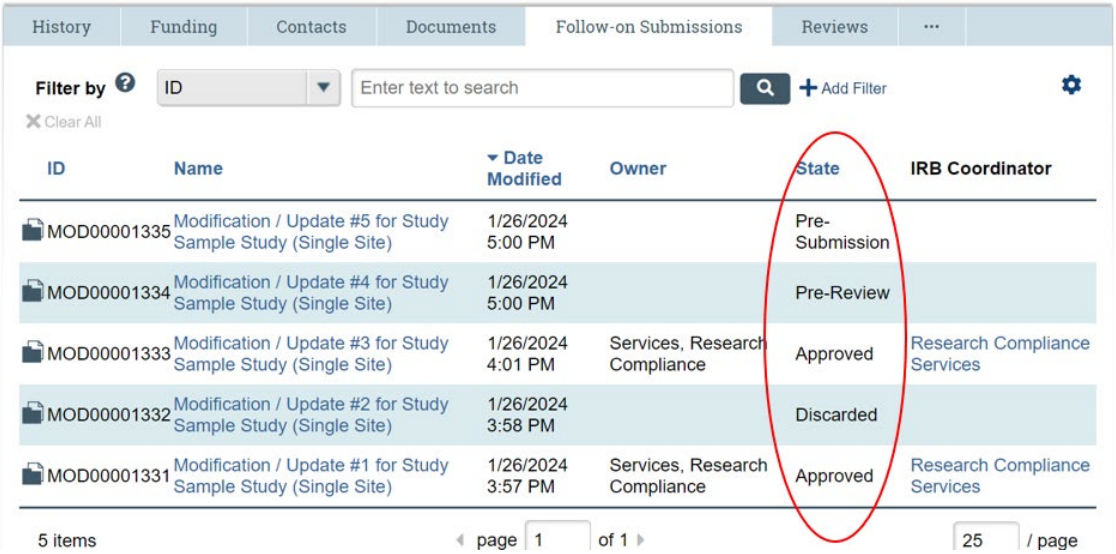
1. In the parent study, click "Create Modification/CR" on the left side of the page.



2. Select "Modification/Update" as the purpose of the submission and "Other parts of the study" as the modification scope. If you also want to change personnel, you can also select "Study team member information" in the scope but "Other parts of the study" must be selected. Then click Continue.

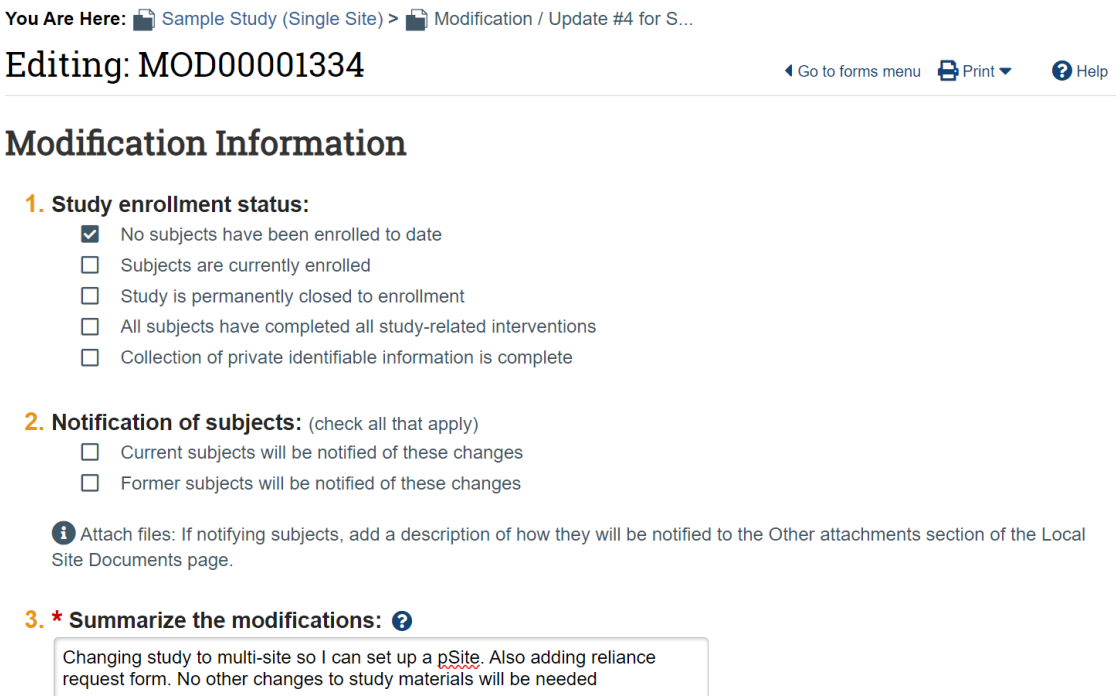
   Note: if you are unable to select "Other parts of the study" as the modification scope, it may mean that you already have a modification open with that scope identified. Only one modification of each type can be active at one time. To check if you already have a modification that is created, click on the follow-on submissions tab on the parent study.

   Modifications that are in Pre-Submission, Pre-Review, Clarification Requested, Modifications Requested, Non-committee Review, Committee Review or Post-Review states are still in progress and can prevent you from creating a new modification. If a modification is in a pre-submission state, you can click on the modification and edit it before you submit it. For modifications in other states, you can choose to discard or withdraw them or you can reach out to RCS to see if it is possible for you to make additional changes to them to include your new changes. Discarding a follow-on submission permanently removes it. Withdrawing a submission brings it back to the pre-submission state. We do not recommend that you discard or withdraw modifications that are not in a pre-submission state without checking with RCS first as that may result in lost progress for your existing modification.



3. Complete the Modification Information section, including current enrollment status, whether you intend to notify current or former subjects of your changes and include a summary of what is changing in the modification. When done, click continue.

   Note: Unless you are making other changes besides changing the study from single site to multi-site/collaborative, you likely won't need to notify current or former subjects of the changes.



Edit Basic Study Information Section

1. *What kind of study is this?* Select multi-site/collaborative study.
2. *Will an external IRB act as IRB of record for this study?* Choose "no" to indicate that the University of Oregon IRB will review this research.
3. *Will your IRB act as the single IRB of record for other participating sites?* Choose "yes" to indicate that the University of Oregon IRB will be the IRB of Record for this research and that one or more external institutions will rely on the University of Oregon IRB review.
4. *In the last question of the Basic Study Information section*, upload the Reliance Request Form (UO Reviewing IRB). For a current copy of this form, see our Applications, Forms and Guidance website. If you already have a previously approved version of a reliance request form and you need to update it, use the update button next to the existing form to upload the revised version of the form over the older version. Please do not delete and re-add the document as this destroys the document history and avoid uploading duplicates of the same document.

5. If you are making additional changes to your study beyond making the study multi-site/collaborative, complete a Modification Application and attach it to the last question of the Basic Study Information section. For the most recent copy of this form, please refer to the Forms and Applications section of our Applications, Forms and Guidance page. If the only change you are making is to change the study to one that is multi-site/collaborative, a Modification Application will generally not be required.
6. Review the other previously approved materials and update them if needed to reflect your collaboration. Examples of documents which often require revision:
    a. Most studies will either have an Initial Review Application form or an Exempt Application in the Basic Study Information section. These forms contain a section for Other Institutions, Performance Sites, and Non-UO Research Personnel (part V in Initial Review Application and part IX in the Exempt application form). If changes are needed, please update the form and use the update button to upload the revised version over the existing version in your mod.
    b. We also suggest that you review the previously approved research plan in the Basic Study Information section to determine if any edits may be needed in order to reflect your new collaboration. If changes are needed, please update the research plan and use the update button to upload the revised version over the existing version in your mod.
7. Select "Continue" at the lower right side of the screen to access the next page of the smartform. Selecting continue will save your work. You may also select "Save" to return at a later time by selecting the study and choosing "Edit Study".

Edit Other Sections (if applicable)

- Go through each section of the smartform and edit as needed. Examples of other sections and materials that are more likely to be impacted by a new collaboration are described below. However, we recommend that you briefly review each section and document to determine if edits are needed.

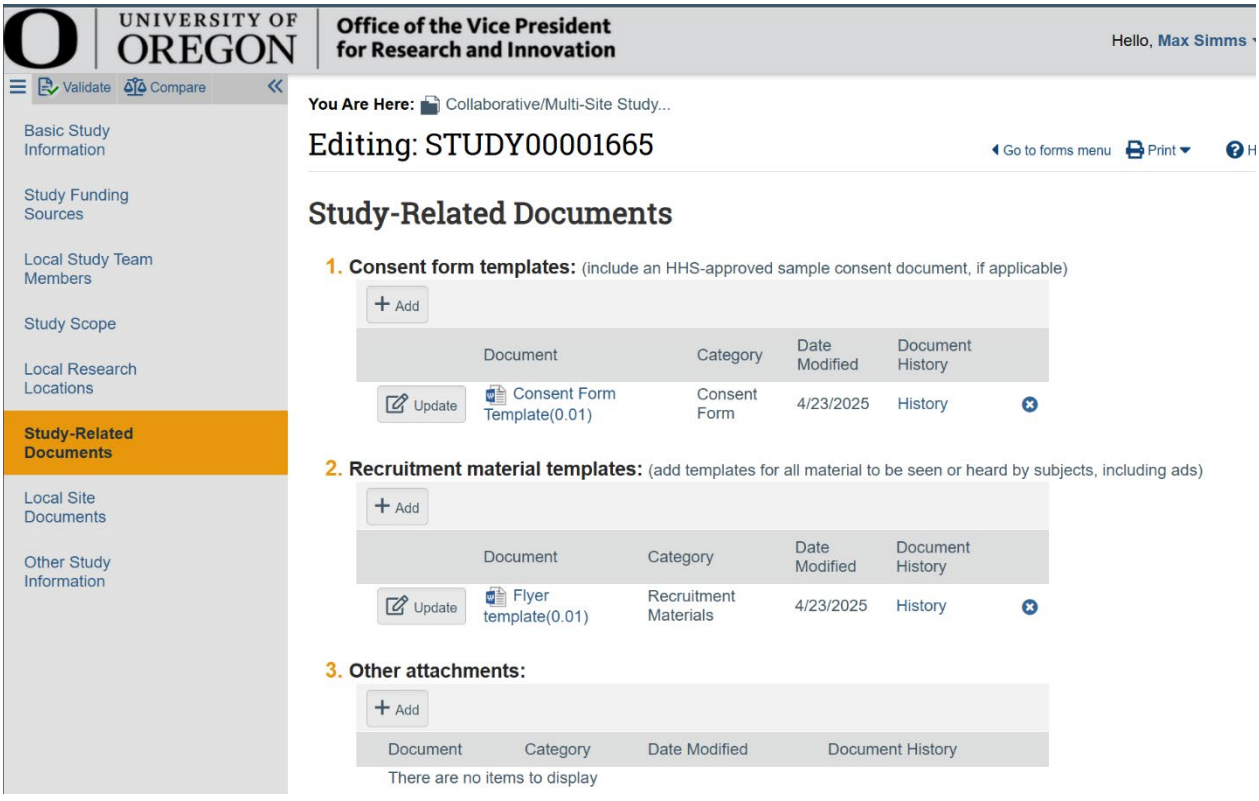
1. Local Research Locations

   a. *Will activities take place at non-University of Oregon campus locations?* Identify any research locations that are not part of the University of Oregon campus.

   b. *If yes, describe and address any permissions and/or review processes required in the text box.*

   c. Select "Continue" at the lower right side of the screen to access the next page of the smartform. Selecting continue will save your work. You may also select "Save" to return at a later time by selecting the study and choosing "Edit Study".

2. Study Related Documents
   - This is a new section that will appear in the smartform only for multi-site/collaborative studies. When you turn a single site study into a multi-site/collaborative study, all existing consent, recruitment, data collection and other attachments will remain in the existing Local Site Documents section.
   - This new Study Related Documents section can be revised to include study templates/materials that can be altered by the individual sites to include site specific information. If there are documents that will be used at *all sites* (i.e., UO and all pSites), they can be moved to the new Study Related Documents section.
   - Any documents that are *only* used by the UO should remain in the Local Site Documents. There will also be a place in the pSite to attach documents unique to each pSite and will not be used at the UO and/or other sites (more about this in the section below about the pSite). Contact RCS with any questions.



a. *Consent form templates.* Include consent documents that may be used by all collaborating sites and/or templates that can be altered by the individual sites to include site specific information.

   - If consent will not be documented in writing, attach a script of information to be provided orally to subjects.
   - The IRB must approve the use of translated consent materials. Because it is common that consent materials require revisions prior to approval, researchers may either: (a) provide translated consent materials in their initial IRB application; ***or*** (b) provide translated consent materials as a modification after the English version of the consent materials have been approved.

Table 1: Study Related Documents Question 1 Attachments, Consent form templates
➢ Informed Consent ➢ Passive Parental Consent (opt-out consent) ➢ Oral consent scripts ➢ Assent forms ➢ Translations and Translated Materials

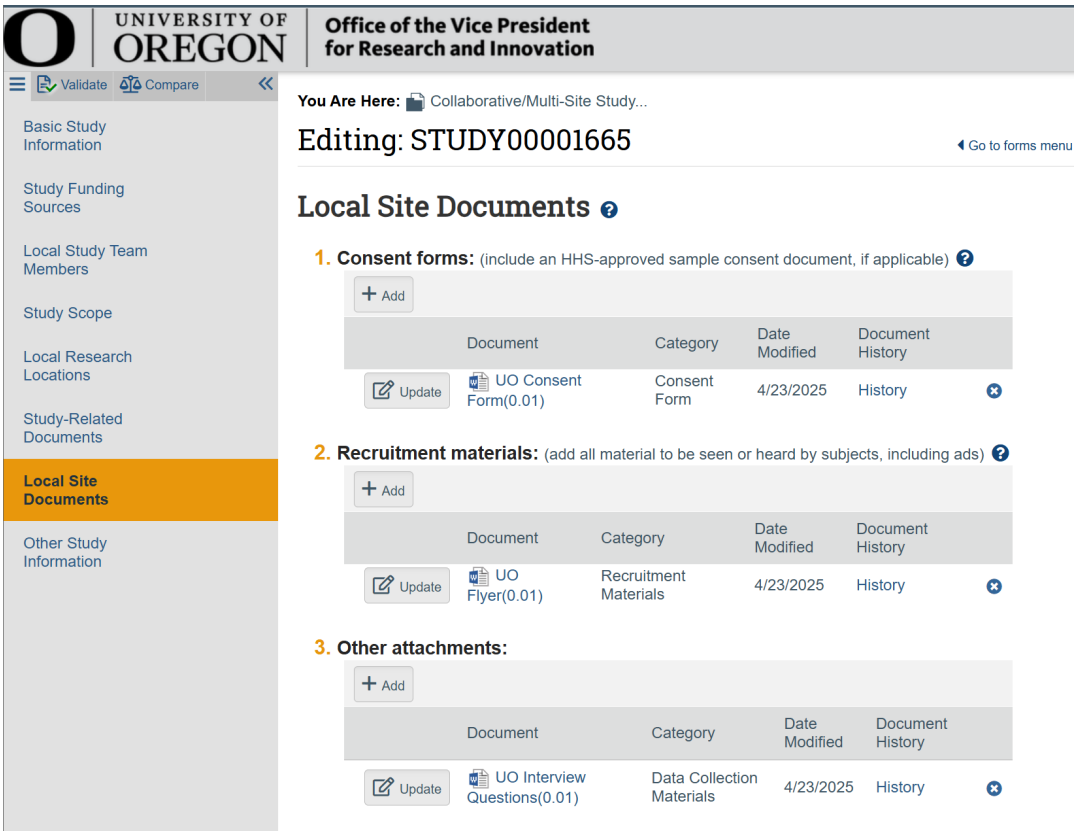
b. *Recruitment material templates.* Include recruitment materials that will be used by all collaborating sites or templates that can be altered by the individual sites to include site specific information. Recruitment materials consist of ***all communication seen or heard by potential participants***. For additional information on recruiting subjects see the Recruiting Research Participants page.

Table 2: Study Related Documents Question 2 Attachments, Recruitment material templates
➢ Recruitment flyers ➢ Print media, such as newspaper ads ➢ Verbal/email recruitment and screening scripts ➢ Social media/online advertising/MTurk HIT ➢ Video advertisement

c. *Other attachments.* Include any other study documents that will be used by the UO and all pSites. For example, surveys or intervention materials that will be used by the UO and all collaborating sites.

Table 3: Study Related Documents Question 3 Attachments, Other attachments
➢ Research instruments ➢ Debriefing materials ➢ Permissions and approvals (e.g., human subjects pool coordinator, school districts, owner of a bulletin board, listserv, etc.) ➢ Data use agreements ➢ Data safety monitoring plans ➢ Data safety monitoring boars/committee information ➢ Release form for translators and transcribers ➢ All other related documents not attached elsewhere

3. Local Site Documents
   - Materials specific for use by UO/UO investigators and not included under question 9 in the Basic Study Information section should be included here under the corresponding section.
   - This section will include study documents that are specific to UO that are not used at other sites. The most commonly edited documents are the consent forms and recruitment materials.



   a. *Consent Forms.* Only UO specific consent documents need to be submitted here. For example, UO specific consent documents may include a local contact person/local PI or reference site specific research activities.

Table 4: Local Site Documents Question 1 Attachments, Informed Consent
○ Informed Consent ○ Passive Parental Consent (opt-out consent) ○ Oral consent scripts ○ Assent forms ○ Translations and Translated Materials

b. *Recruitment materials.* Only UO specific recruitment materials need to be submitted here. For example, UO specific recruitment may include a local contact phone number or local research location.

Table 5: Local Site Documents Question 2 Attachments, Recruitment
○ Recruitment flyers ○ Print media, such as newspaper ads ○ Verbal/email recruitment and screening scripts ○ Social media/online advertising/MTurk HIT ○ Video advertisement

c. *Other attachments.* If applicable, attach any other UO materials not otherwise submitted. Only UO specific documents need to be submitted here. For example, if surveys or interviews have questions specific to the UO site and not other research locations.

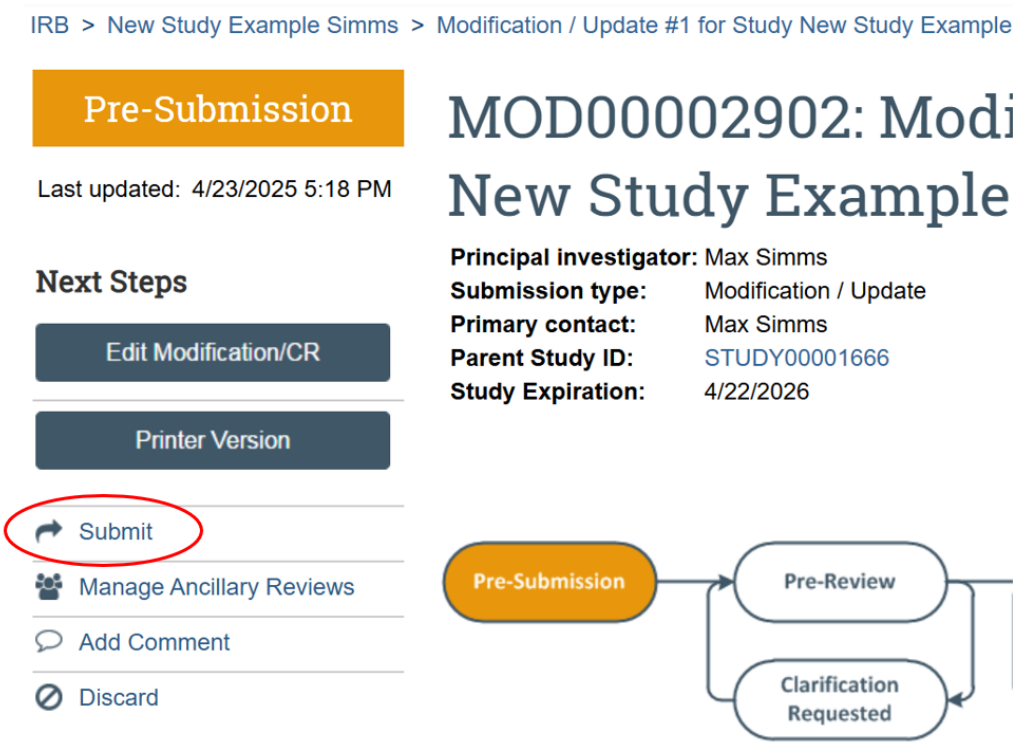
Table 6: Local Site Documents Question 3 Attachments, Other Site Documents
○ Research instruments ○ Debriefing materials ○ Permissions and approvals (e.g., human subjects pool coordinator, school districts, owner of a bulletin board, listserv, etc.) ○ Data use agreements ○ Data safety monitoring plans ○ Data safety monitoring boars/committee information ○ Release form for translators and transcribers ○ All other related documents not attached elsewhere

d. Select "Continue" at the lower right side of the screen to access the next smart form. Selecting continue will save your work. You may also select "Save" to return at a later time by selecting the study and choosing "Edit Study".

Submit the Modification for Review and Approval

1. After you are done revising the materials in the parent study modification, click Save and then Exit or Finish in the smartform. This will bring you back to the workspace for the modification.

2. Click the Submit button (left side of modification workspace). For additional guidance, see the "Modify Study (RAP Instructions)" and the Submit Study Instructions in the RAP Guidance website.



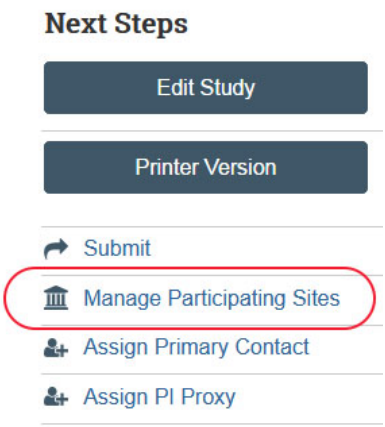
C. Manage or Add Participating Sites

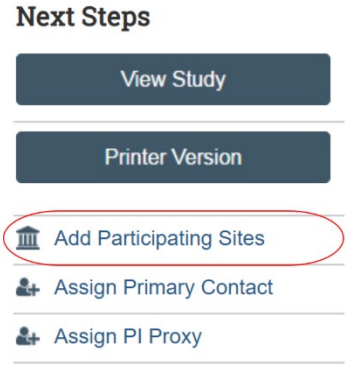
- Once your new multi-site/collaborative study is approved or the modification changing your existing single-site study to a multi-site/collaborative study is approved, a pSite will need to be created to house documents specific to that site. **RCS staff can do this step for you if needed.**
  - For new studies that are being set up as multi-site/collaborative from the very first submission, the Manage Participating Sites button will be available as soon as the study is created. Although this allows researchers or RCS to indicate which pSites they would like created in the future, the pSites will not actually be created or available for editing until the multi-site/collaborative studies are through the pre-review stage of the review.
  - For modifications to single-site studies to become multi-site/collaborative studies, the add participating site button will not be available until the modification is approved.

- If it is the first time a reliance agreement has been set up for the external IRB to rely on the UO IRB, an institutional profile form will also be required. If needed, this institutional profile form will need to be completed by the IRB staff *at the external IRB site* that will rely on the UO IRB review and approval. Institutions that do not show up in the list of Institutional Profiles when the pSite is being created will need an institutional profile form. You can also contact RCS to ask them to check on whether an organization already has an institutional profile. When in doubt, check with RCS first. If you receive an institutional profile form, email it to RCS and request that they set up the profile.

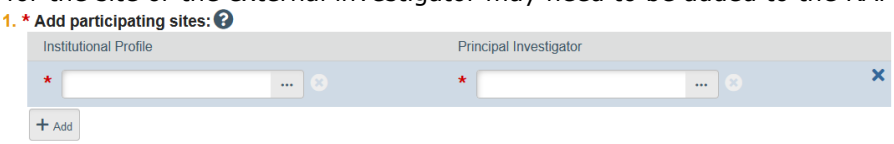
Add Participating Site(s)

1. From the buttons on the left-side of the study workspace, choose either "Manage Participating Sites" or Add Participating Sites" depending on which option is available to you.





2. Select "+Add" and then click on the icon with three dots to select the participating site (pSite) from the Institutional Profile list and the external investigator from the Principal Investigator list. If your pSite or external investigator do not appear in the list, email RCS. An Institutional Profile may need to be set up for the site or the external investigator may need to be added to the RAP and RCS can help.



3. Click "OK" to return to the study workspace. The pSite will be available for editing in the Sites tab of the parent study.

D. Obtain Documents for pSite

1. The external researchers will need to work with their IRB to understand the process for that site to rely on the UO IRB. Once the parent study is approved at the UO, the UO approved documents will need to be sent to the external IRB (e.g., approval letter for parent study IRB, approved protocol, approved reliance request form, approved consent forms) along with a request for their IRB to rely on the review and approval of the UO IRB. RCS will facilitate this process if needed. The external IRB staff will be asked to complete a "Relying Site Survey" (see current version on UO Forms and Guidance website).

2. A reliance agreement such as an IRB Authorization Agreement (IAA), SMART IRB Letter of Acknowledgement (LOA) or an alternative reliance arrangement (e.g., SMART IRB Online Reliance) will be needed to document each institution's expectations and requirements for the reliance. RCS and the UO IRB can be flexible regarding which mechanism is used. However, the IAA or LOA are the preferred options. RCS will facilitate communications between the UO and the external IRB office for this agreement.

3. UO researchers should obtain confirmation that the external researchers have completed human subjects research training (e.g., CITI or alternative) and have no conflicts of interest. If they do have conflicts of interest, a completed Conflict of Interest (COI) Form for Investigators Conducting Human

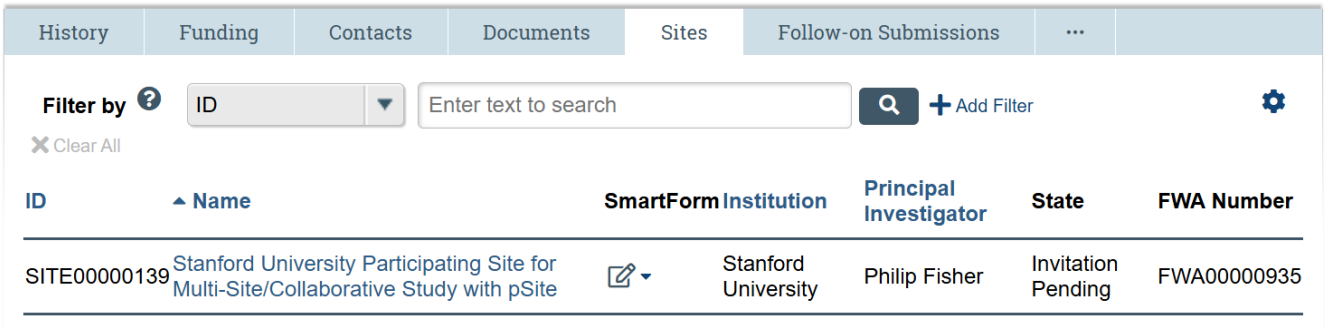
Subjects Research will be required along with details about how the other institution is managing the conflict.

4. If there is additional site-specific funding going to the pSite for this research in addition to the UO funding already on record for the parent study, obtain details about that additional funding (e.g., funding source) and these details will need to be added to the pSite (see section E below).

5. If there are site specific materials that will be used by researchers at the pSite that differ from the UO approved materials (e.g., specific recruitment and/or consent forms with info about pSite that differ from the UO approved versions), collect those site-specific materials so they can be included in the pSite (Local Site Documents section). If the external researchers will use the UO versions of documents with no edits, there may not be any site-specific materials to add to the Local Site Documents section of the pSite.

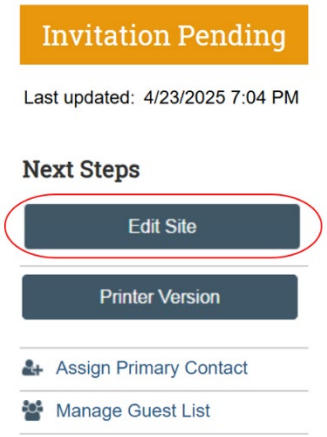
E. Edit Site

- After you have created the pSite and gathered the materials to attach for review, it is time to edit the site. If you successfully created a pSite (see section C above), a site will be visible in the Sites tab on the parent study.



1. Click on the name of the site in the Sites tab to go to the new pSite that was created.

2. Click Edit site on the left side of the page to edit the pSite documents and details



3. Go through each section of the pSite and respond to the questions and upload materials as applicable.
   a. *Basic Site Information*.
      - Indicate if the local principal investigator (i.e. lead researcher at pSite) has a conflict of interest.

- Provide a brief description of the activities that will take place at the pSite. Ensure this information is consistent with what is described in the reliance request form in the parent study.

b. Additional Local Funding Sources

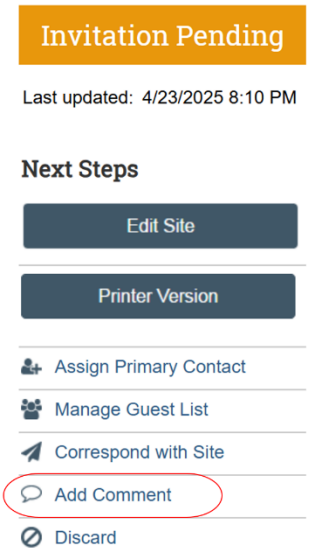
- If there is additional site-specific funding going to the pSite that is not already described on the parent study, include those details in the Additional Local Funding Sources section.
- When searching for information for an open-ended question, such as in the Additional Local Funding Sources section in the pSite, use the percentage sign (%) as a wildcard to maximize your search results. For example, "%institutes" will bring up sources with "institutes" anywhere in the name.

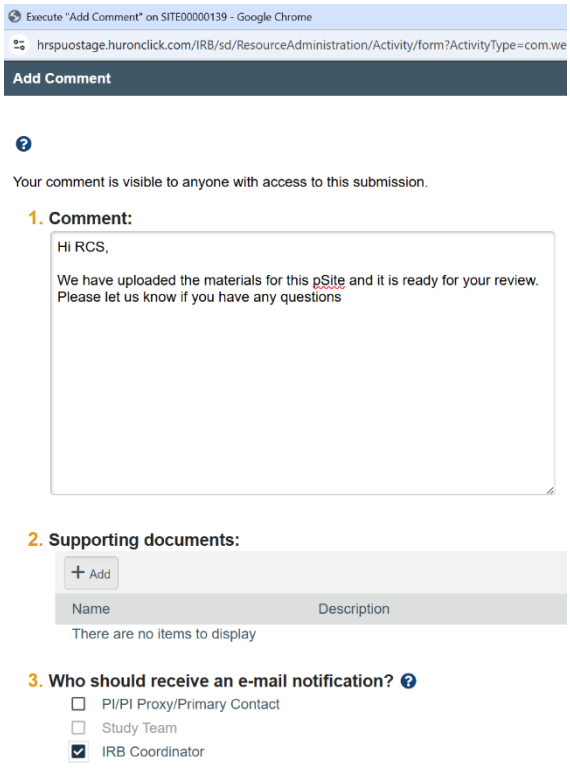
c. Local Site Documents

- If there are any site-specific recruitment or consent forms, attach them to this section
- Attach the completed Relying Site Survey (other attachments)
- If you have COI forms for external personnel that were not already provided in the parent study, add them here (other attachments).
- Attach the signed reliance agreement (e.g., IAA, SMART IRB LOA).

F. Let RCS know when the pSite is complete and ready for review

- There is no submit button on a pSite when it is in the Invitation Pending state. Once you have completed all sections of the pSite and have clicked "Finish", you will be brought back to the pSite workspace page where you can see the history and status of the pSite. If you created the pSite rather than RCS staff, use the Add Comment button on the left side of the page to notify RCS that the pSite is ready to review. Select "IRB Coordinator" on the comment box to ensure they receive an email notification of your comment.





G. Obtain RCS/UO approval for pSite

- An approval letter will be sent through the pSite when the pSite is approved.
- Assign yourself as the primary contact on the pSite to receive notification of approval.

H. Appendix: Document Placement for parent study vs. pSite:

Parent Study Record

Section 1. Basic Study Information

- Upload over-arching study documents (e.g., Research Plan, application forms, etc.)
- Upload Reliance Request Form (UO reviewing IRB)
- COI forms for conflicted researchers

Section 2. Study Related Documents

- Upload consent, recruitment, and data collection materials that apply to all sites including the UO, or that are template versions of those materials that might have minor changes made when applied to specific sites.

Section 3. Local Site Documents

- Upload consent, recruitment, and data collection materials that are specific to the UO site.

pSite Record

Section 3. Local Site Documents

- Reliance Agreement e.g., IAA (Other Attachments)
- Upload consent, recruitment, and data collection materials that are specific to the pSite.
- Relying Site Survey for site (Other Attachments)
- COI forms for conflicted researchers (if not already in the parent study – Other Attachments)