THE OHIO STATE UNIVERSITY

Collaborative and Off-Site Research
Tools for Investigators

The Office of Responsible Research Practices has created several tools to assist Ohio State investigators in completing application materials when Ohio State research is conducted at non-Ohio State locations and/or involves external collaborators. They are designed to be used sequentially.

Step 1: Use the **Engagement Determination Decision Tree** to determine if external collaborators are engaged in Ohio State research.
- An online, interactive version of the decision tree tool is available at http://go.osu.edu/HSengagement.

Step 2: Use the **Collaborative Research Scenarios Decision Tree** to determine which of the **eight collaborative research scenarios** applies to your research.

Step 3: Use the **Buck-IRB Cheat Sheet** for collaborative research to see a list of Buck-IRB pages that must reflect the collaboration/off-site research, as well as which documents must be revised and/or provided for IRB review.

Step 4: Refer to the **Buck-IRB Collaborative Research Screenshots** for details about how to complete the Buck-IRB application form to reflect the collaborative/off-site research scenarios involved in your study.

Remember:

- These tools should be used when external personnel may or will be engaged in Ohio State research, not when Ohio State personnel may or will be engaged in external research (i.e., ceded studies).

- Multiple collaborative research scenarios may be applicable to a single study. If multiple external personnel will be involved, use the decision trees and tools *for each individual/ institution separately*.

- Questions? Contact us at IRBAgreements@osu.edu for further guidance.

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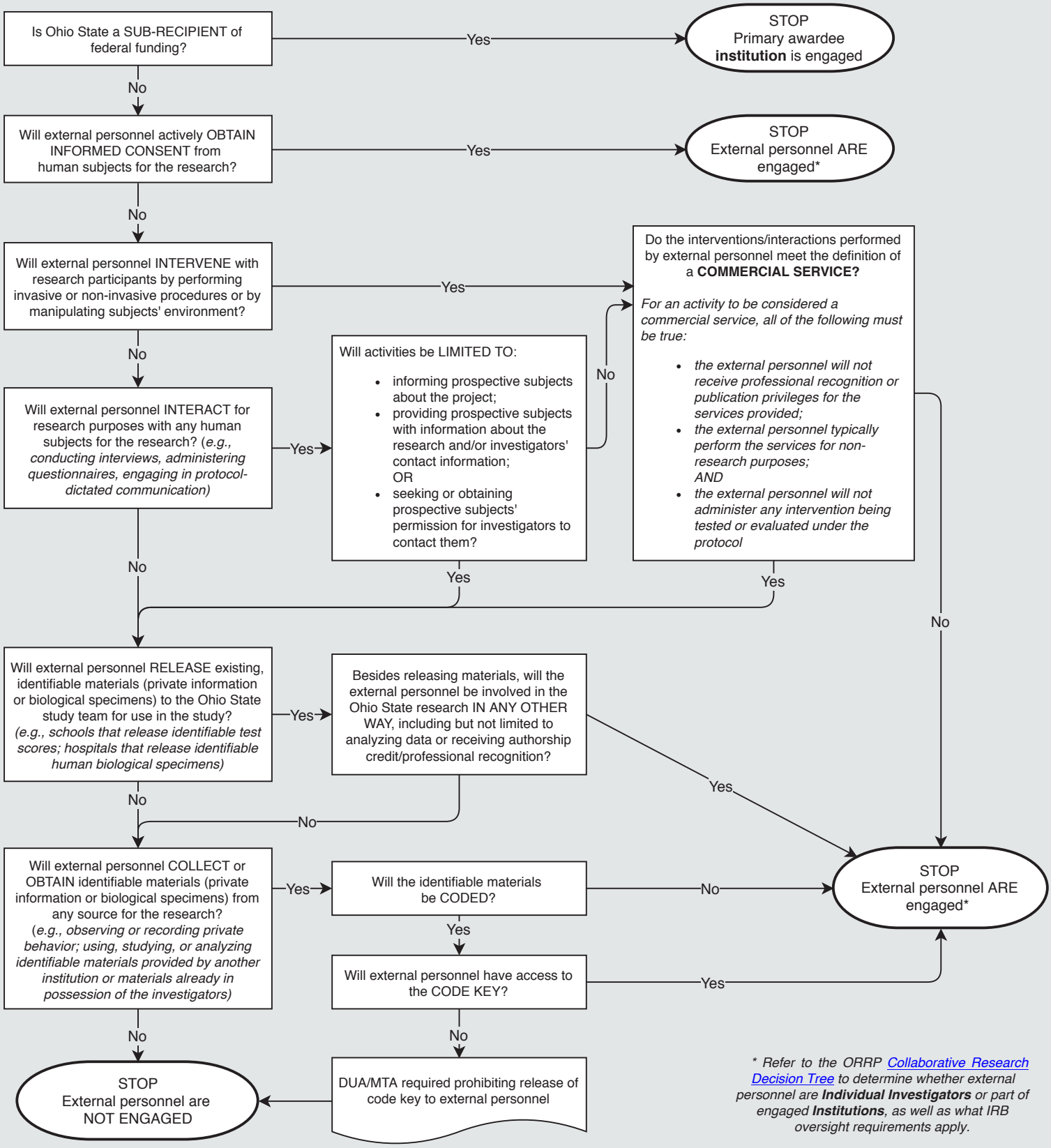
DECISION TREE:
ARE EXTERNAL PERSONNEL ENGAGED IN OHIO STATE RESEARCH?



** Refer to the ORRP Collaborative Research Decision Tree to determine whether external personnel are **Individual Investigators** or part of engaged **Institutions**, as well as what IRB oversight requirements apply.*

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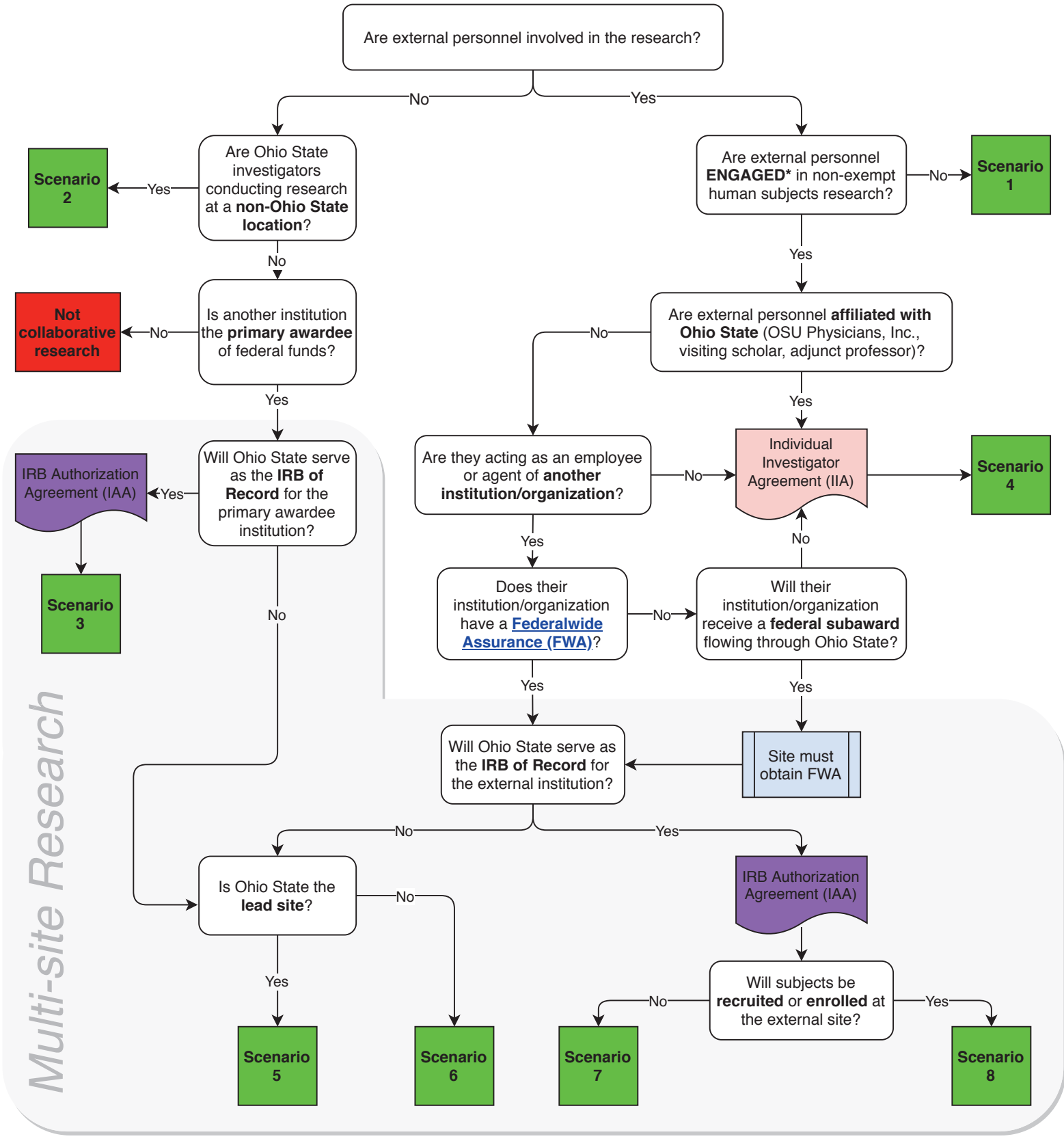
DECISION TREE:
COLLABORATIVE RESEARCH SCENARIOS



** If you cannot ascertain if external personnel are engaged in the research, refer the Engagement Determination tool before using this decision tree.*

Buck-IRB Cheat Sheet: Collaborative Research

Flowchart Scenario #	Description	Collaborative Research Agreement Type	Buck-IRB Application Pages	Documents Required
Scenario 1	External individuals/institutions receive de-identified or coded (without code key) data and/or biospecimens; site is not engaged	No reliance agreement required	• Not applicable – does not need to be noted in application	• Not applicable
Scenario 2	Ohio State personnel conduct off-site research; site is not engaged	No reliance agreement required	• Location of Research	• Letter of Support

Scenario 3	External institution is primary awardee of federal funds but no human subject research activities occurring at external institution; Ohio State is IRB of record	IRB Authorization Agreement (IAA)
		ORRP will coordinate agreement process
			• Multi-Site Study
			• Location of Research
			• External Collaborators
			  ○ List PI named on grant application
			• Funding
			• Number of Participants
			  ○ Multi-site accrual number should match Ohio State number of participants
			• Confidentiality of Data
				• Grant application
				• Ohio State ICF & HIPAA*
				• Executed IAA**

Scenario 4	Ohio State provides IRB oversight for engaged individual	Individual Investigator Agreement (IIA)
		ORRP will coordinate agreement process
			• Location of Research
			  ○ If research is occurring at a location that is not engaged/does not have a Federalwide Assurance
			• External Collaborators
			  ○ Add collaborator with Ohio State name.# lookup tool
			  ▪ Human research protections training (CITI)
			  ▪ Responsible Conduct of Research training (CITI)
			  ▪ eCOI disclosure
				• CV/résumé
				• Letter of Support, if applicable
				• Executed IIA**

* If applicable, document must reflect collaboration

** ORRP Reliance Team facilitates

Buck-IRB Cheat Sheet: Collaborative Research

Flowchart Scenario #	Description	Collaborative Research Agreement Type	Buck-IRB Application Pages	Documents Required
Scenario 5	External institution performs IRB review for local research activities; Ohio State is the lead site for multi-site research	No reliance agreement required	• Multi-Site Study • Location of Research • Research Methods and Activities • Number of Participants • Confidentiality of Data	• External IRB approval • Ohio State ICF & HIPAA*
Scenario 6	External institution performs IRB review for local research activities; Ohio State is NOT the lead site	No reliance agreement required	• Multi-Site Study • Number of Participants • Confidentiality of Data	• External IRB approval from lead site only • Ohio State ICF & HIPAA*
Scenario 7	Ohio State is IRB of record for the external institution; no direct participant interaction/intervention at external site (e.g., external site receives identifiable data and/or specimens for analysis)	IRB Authorization Agreement (IAA) *ORRP will coordinate agreement process*	• Multi-Site Study • Location of Research • External Collaborators • Research Methods and Activities • Number of Participants • Confidentiality of Data	• Ohio State ICF & HIPAA* • Executed IAA**

Scenario 8	Ohio State is IRB of record for the external institution; direct participant enrollment/interaction/ intervention at external site	IRB Authorization Agreement (IAA)
		ORRP will coordinate agreement process
			• Multi-Site Study
			• Location of Research
			• External Collaborators
			• Research Methods and Activities
			• Number of Participants
			• Participant Population
			• Participant Identification
			• Informed Consent Process
			• Confidentiality of Data
			• HIPAA Research Authorization (if applicable)
			• Monitoring (if greater than minimal risk)
				• Ohio State ICF/HIPAA*
				• Site-specific documents
				  ○ ICF/HIPAA
				  ○ Recruitment material/scripts
				  ○ Clinical consents or consent tools*
				  ○ Questionnaires or surveys*
				• Local context form
				• Institutional profile form
				• Executed IAA**

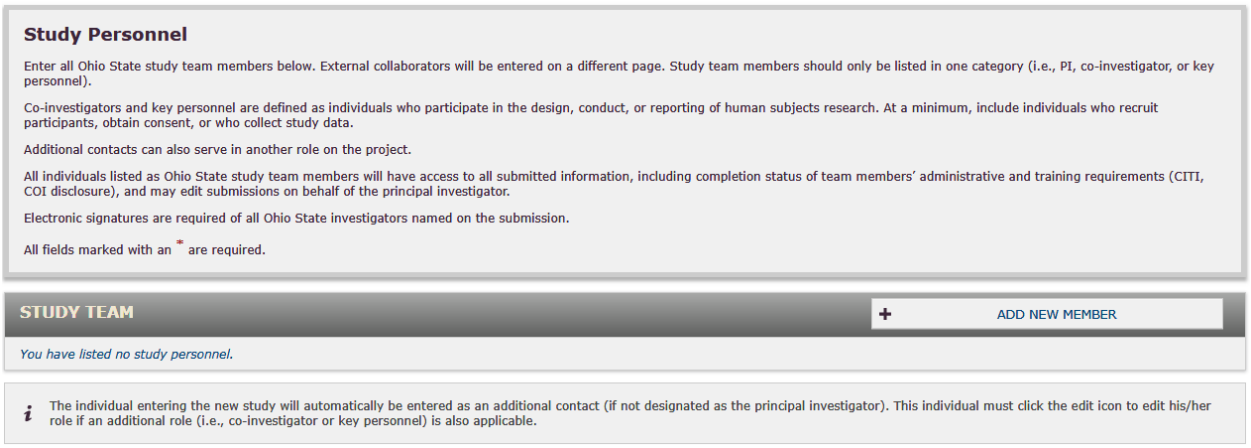
* If applicable

** ORRP Reliance Team facilitates

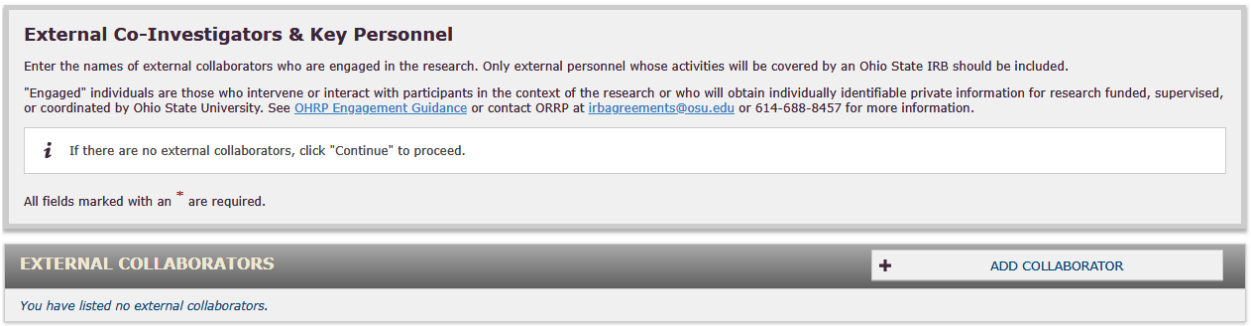
Buck-IRB Screenshots for Collaborative Research Scenarios

Scenario 1: Ohio State is conducting research involving a non-engaged individual:

Study Personnel page: Make sure non-Ohio State personnel are not listed on this page.

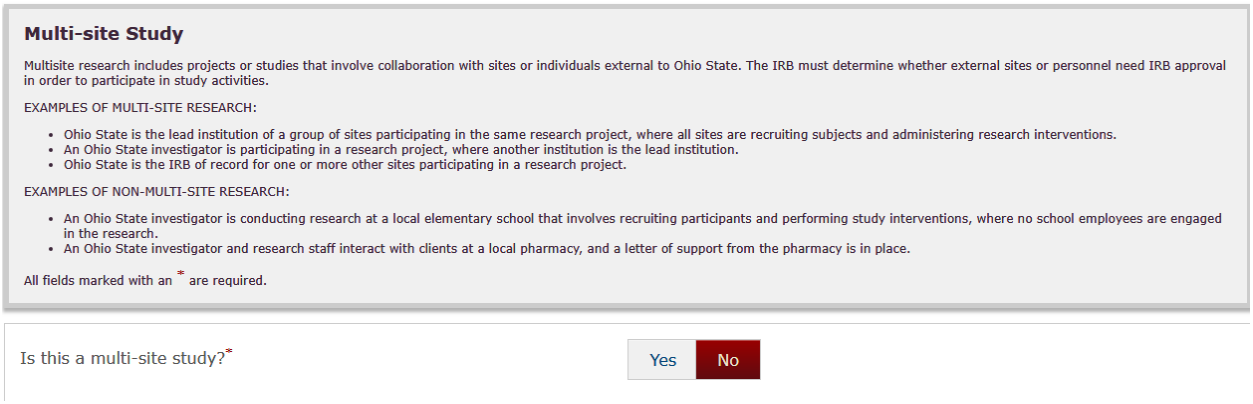


External Collaborators page: Make sure non-Ohio State personnel are not listed on this page.

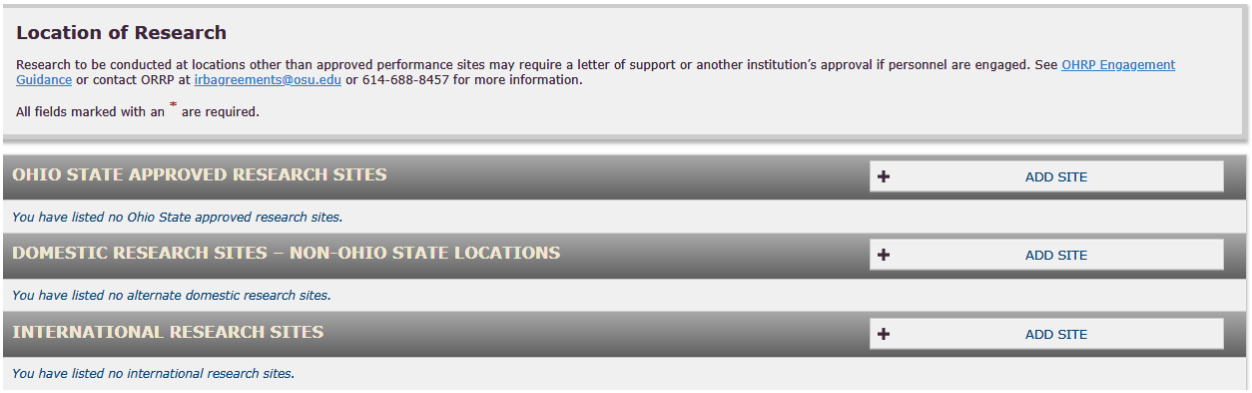


Scenario 2: Ohio State is conducting research involving a non-engaged site:

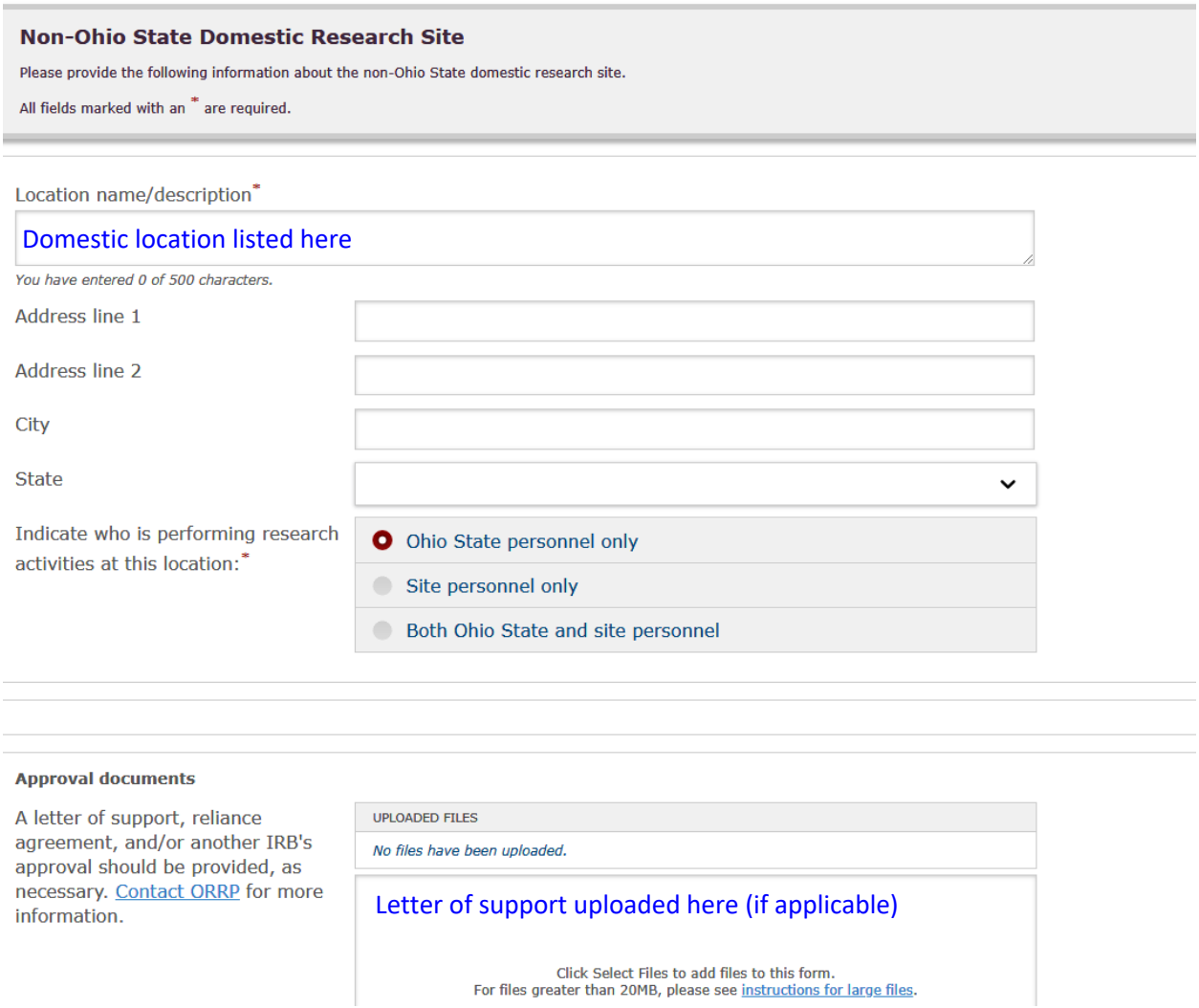
Multi-Site Study page: The first question on this page should be marked No



Location of Research page:



- **Domestic:**



Non-Ohio State Domestic Research Site

Please provide the following information about the non-Ohio State domestic research site.

All fields marked with an * are required.

Location name/description*

Domestic location listed here

You have entered 0 of 500 characters.

Address line 1

Address line 2

City

State

Indicate who is performing research activities at this location:*

- Ohio State personnel only
- Site personnel only
- Both Ohio State and site personnel

Approval documents

A letter of support, reliance agreement, and/or another IRB's approval should be provided, as necessary. Contact ORRP for more information.

UPLOADED FILES

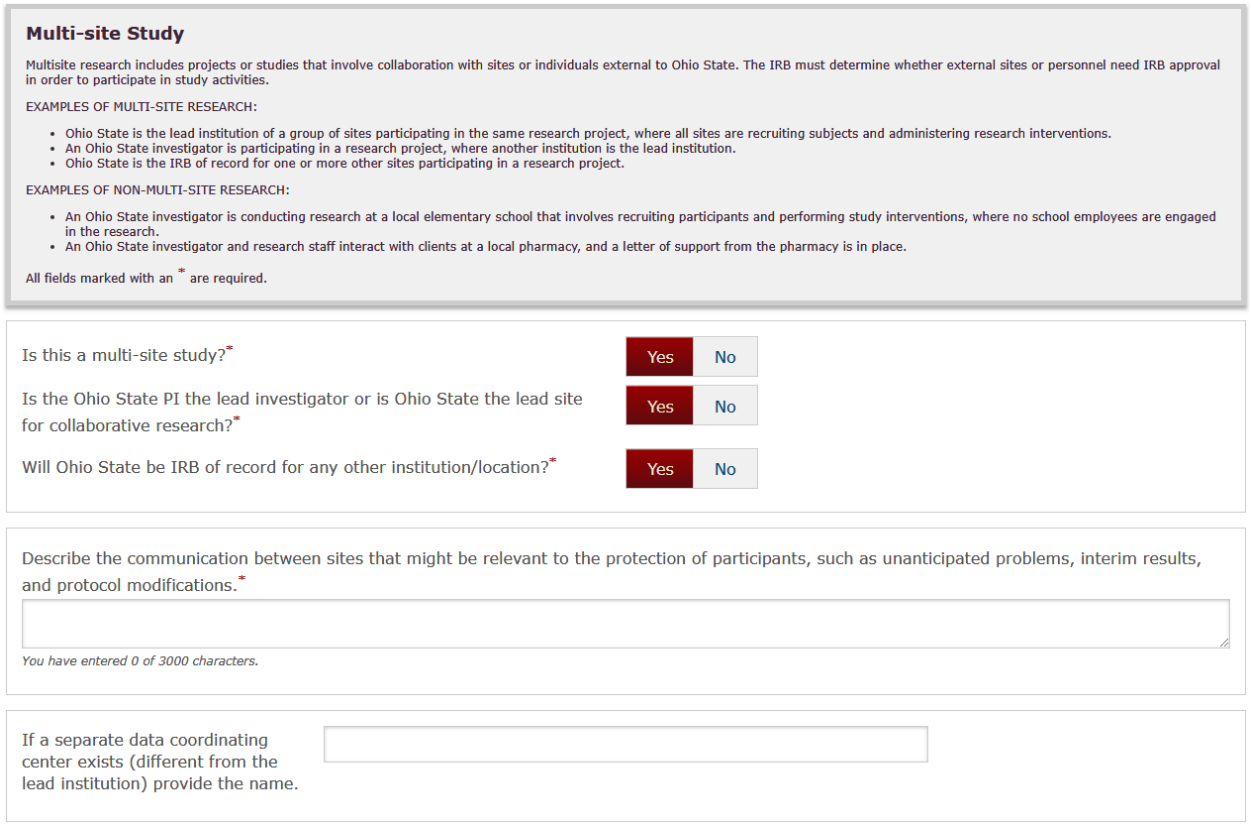
No files have been uploaded.

Letter of support uploaded here (if applicable)

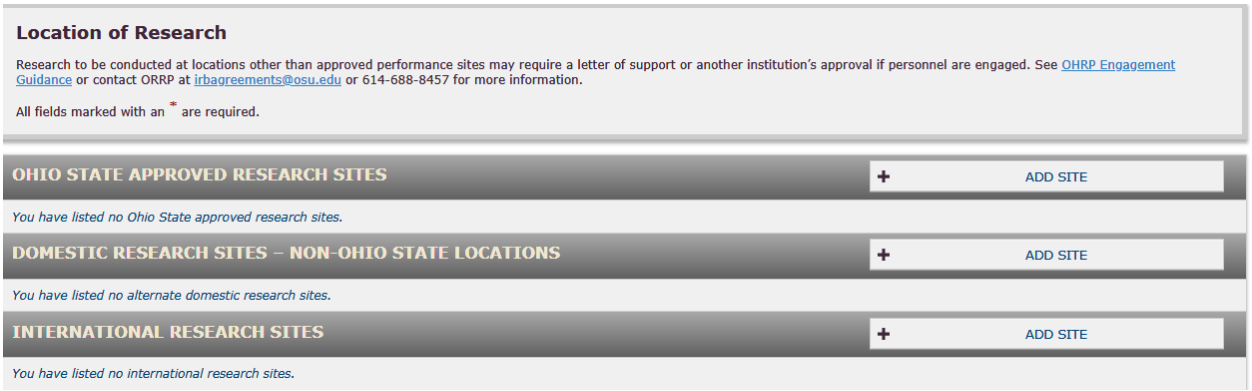
Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

Scenario 3: External institution is primary awardee, no human subjects activities at the external institution:

Multi-Site Study page: The questions on this page should appear as below



Location of Research page:



- **Domestic:**

Non-Ohio State Domestic Research Site

Please provide the following information about the non-Ohio State domestic research site.

All fields marked with an * are required.

Location name/description*

List institution of external collaborator here

You have entered 0 of 500 characters.

Address line 1

Address line 2

City

State

Indicate who is performing research activities at this location:*

- ○ Ohio State personnel only
- ◉ Site personnel only
- ○ Both Ohio State and site personnel

Potential activities for this location (check all that apply)*

- ☐ Protocol development/study design
- ☐ Participant recruitment
- ☐ Obtaining consent/parental permission/assent
- ☐ Research interventions and subject interactions (administer questionnaires/interviews/surveys)
- ☐ Specimen collection
- ☐ Data collection/entry/coding
- ☐ Access participant protected health information (PHI)
- ☐ Manuscript preparation
- ☐ Reporting results
- ☐ Coordinating center

Other activity description

The description in the Other text box should be "primary awardee" or "funding recipient only" or something along those lines

Will this location use Ohio State as the IRB of record?*

Yes | No

This should be Yes

Approval documents

A letter of support, reliance agreement, and/or another IRB's approval should be provided, as necessary. Contact ORRP for more information.

UPLOADED FILES

No files have been uploaded.

This is where ORRP will upload the IRB Authorization Agreement before the submission is reviewed by the IRB

Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

SELECT FILES

Multi-site research for which Ohio State will act as the IRB of record requires the Ohio State IRB to assess relevant information about the participating site. Please provide information about the participating site by uploading a local context worksheet (completed by the site) into the section below.

Provide a local context form for this research site (required when Ohio State is the IRB of record for a site and the site will be recruiting or consenting participants, or if any research interventions or subject interactions will occur at the site)

UPLOADED FILES

No files have been uploaded.

Local context form is NOT needed in this scenario

Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

SELECT FILES

Upload any site-specific documents (e.g., consent forms, recruitment material, instruments) for this location that will be different from those used at Ohio State. If the same documents are used at Ohio State and this location, upload the documents on the appropriate pages throughout the Buck-IRB application.

UPLOADED FILES

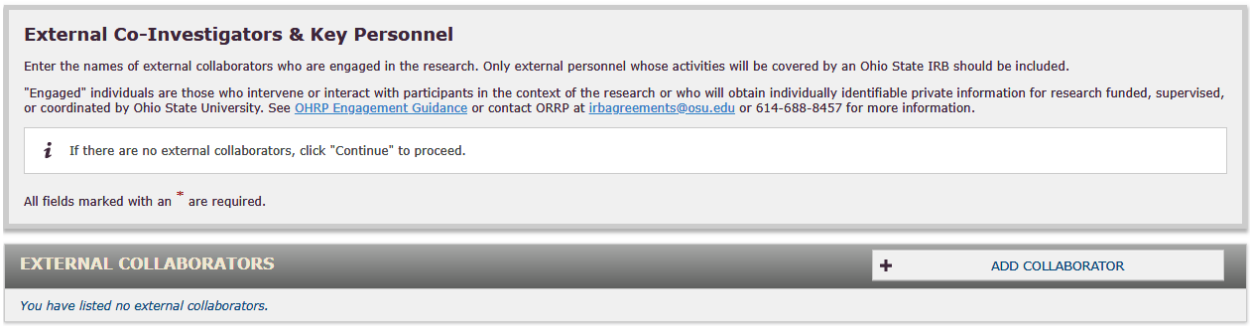
No files have been uploaded.

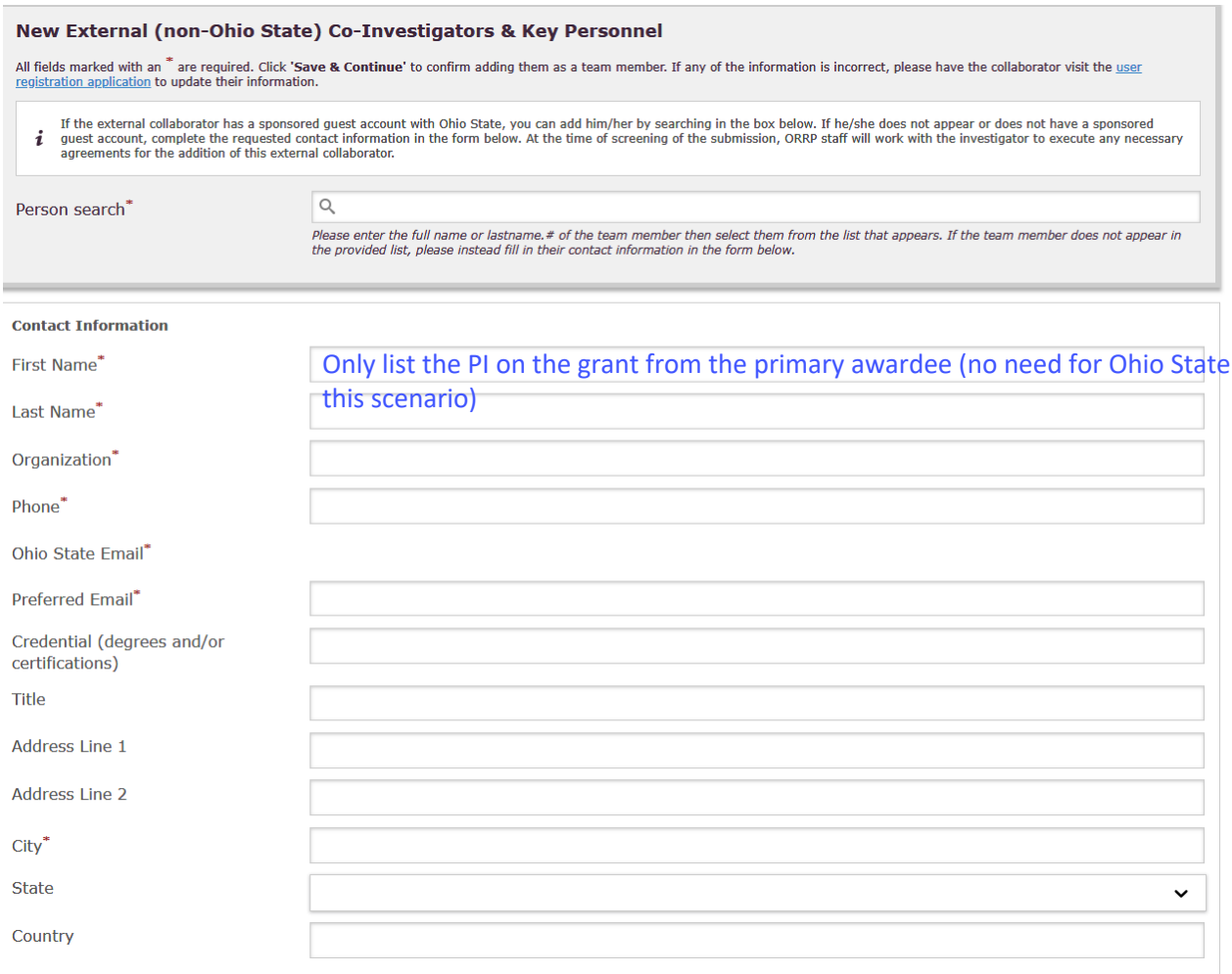
There should be no site specific documents

Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

SELECT FILES

External Collaborators page:





Only list the PI on the grant from the primary awardee (no need for Ohio State name.# in this scenario)

Research Involvement

Study team designation*

- ○ Co-Investigator
- ○ Key Personnel

Research role/activities performed for study*

- ☐ Protocol development/study design
- ☐ Recruitment
- ☐ Assess participant eligibility
- ☐ Obtain consent/parental permission/assent
- ☐ Interview participants/administer surveys
- ☐ Process biological specimens
- ☐ Conduct follow-up visits
- ☐ Data collection/entry/coding
- ☐ Data analysis/interpretation
- ☐ Reporting results
- ☐ Manuscript preparation
- ☐ Maintain regulatory documentation
- ☐ Access participant Protected Health Information (PHI)

Make sure activities checked are consistent with the type of study activities taking place. If no activities other than receiving funds then no boxes should be checked

Other activity description

The description in the Other text box should be "primary awardee" or "funding recipient only" or something along those lines.

Provide the external collaborator's resume/CV. This document is required in order for a reliance agreement to be drafted. Provide the external agreement when directed by ORRP staff. Contact ORRP with questions.

UPLOADED FILES

No files have been uploaded.

The CV is not needed in this Scenario. No documents need to be uploaded here.

Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

Funding page:

Funding and Financial Conflicts

If the research is federally funded and involves a subcontract to or from another entity, an IRB Authorization Agreement may be required. Contact ORRP for more information.

All fields marked with an * are required.

Is the research funded or has funding been requested?*

- (•) Yes
- ( ) No
- ( ) Pending

Add a sponsor*

Both the institution & source of the primary award (e.g., NIH) should be listed here.

Lookup a sponsor by name. If a sponsor to be added does not appear in the search, please contact ORRP to have the sponsor added to the system. Multiple sponsors can be added. For funding sources internal to Ohio State (e.g., departmental funds, start-up funds), select 'internal funds' as the funding source.

Is any support other than monetary (e.g., drugs, equipment, etc.) being provided for the study?*

- ( ) Yes
- ( ) No
- ( ) Pending

Provide a copy of the grant application or funding proposal.

UPLOADED FILES

No files have been uploaded.

The complete funding application should be uploaded here

Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

SELECT FILES

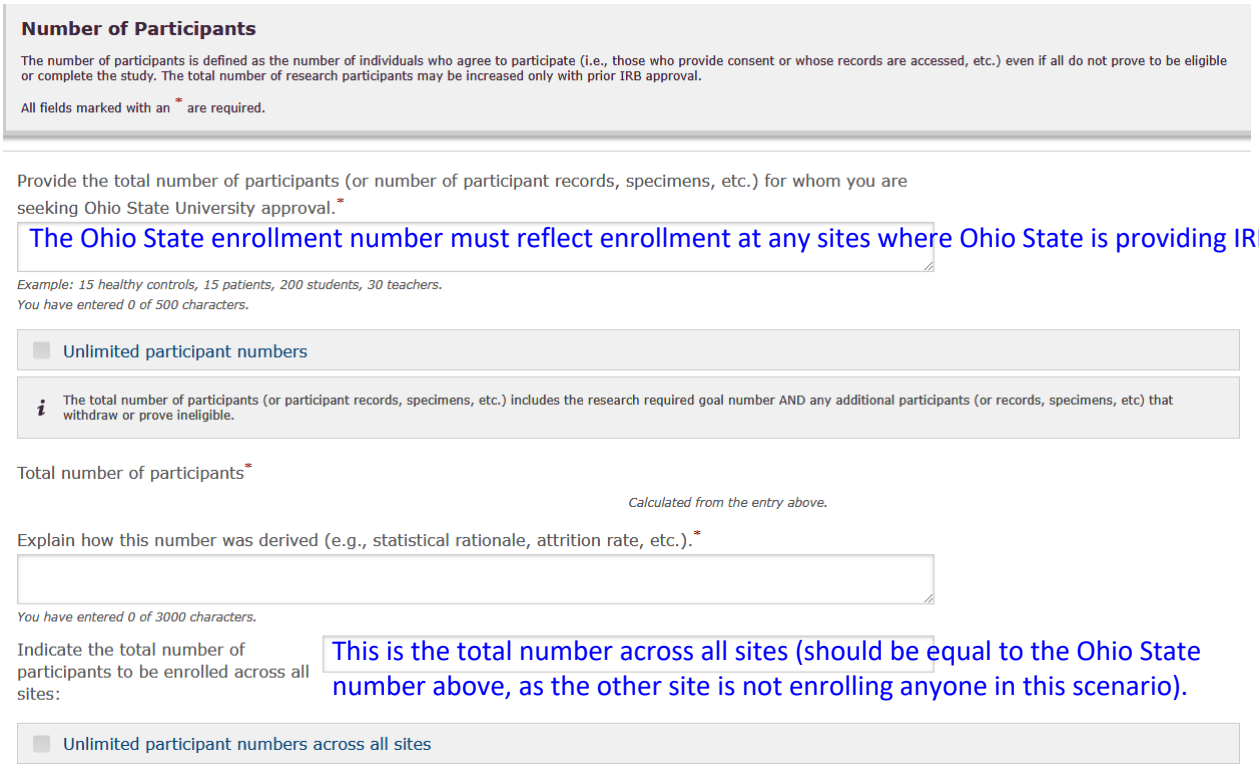
Financial Conflict of Interest

All Ohio State investigators and key personnel must have a current COI disclosure (updated as necessary for the proposed research) before IRB review. Examples of financial interests that must be disclosed include (but are not limited to) consulting fees or honoraria; stocks, stock options or other ownership interests; and patents, copyrights and royalties from such rights. For more information, see Office of Research Compliance COI Overview and eCOI.

Please indicate if any Ohio State University investigator (including principal or co-investigator), key personnel, or their immediate family members has a financial conflict (including salary or other payments for services, equity interests, or intellectual property rights) that would reasonably appear to be affected by the research, or a financial interest in any entity whose financial interest would reasonably appear to be affected by the research. Select 'none' if no financial conflicts exist.*

- [ ] None
- [ ] Michael Donovan

Number of Participants page (Covers both Ohio State lead site or not lead):



Number of Participants

The number of participants is defined as the number of individuals who agree to participate (i.e., those who provide consent or whose records are accessed, etc.) even if all do not prove to be eligible or complete the study. The total number of research participants may be increased only with prior IRB approval.

All fields marked with an * are required.

Provide the total number of participants (or number of participant records, specimens, etc.) for whom you are seeking Ohio State University approval.*

The Ohio State enrollment number must reflect enrollment at any sites where Ohio State is providing IRB oversight

Example: 15 healthy controls, 15 patients, 200 students, 30 teachers.
You have entered 0 of 500 characters.

☐ Unlimited participant numbers

i The total number of participants (or participant records, specimens, etc.) includes the research required goal number AND any additional participants (or records, specimens, etc) that withdraw or prove ineligible.

Total number of participants*

Calculated from the entry above.

Explain how this number was derived (e.g., statistical rationale, attrition rate, etc.).*

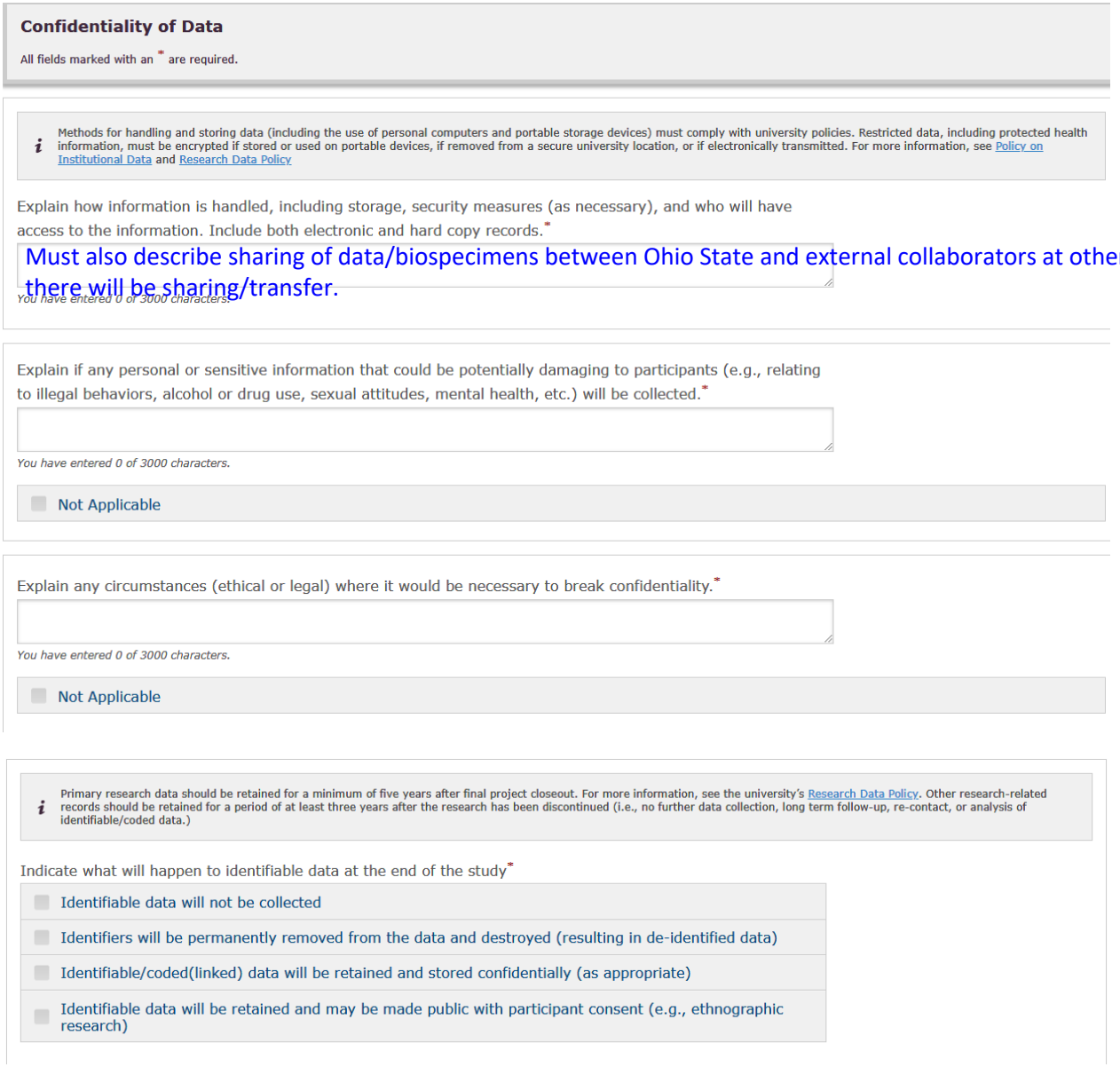
You have entered 0 of 3000 characters.

Indicate the total number of participants to be enrolled across all sites:

This is the total number across all sites (should be equal to the Ohio State number above, as the other site is not enrolling anyone in this scenario).

☐ Unlimited participant numbers across all sites

Confidentiality of Data page:



Confidentiality of Data

All fields marked with an * are required.

Methods for handling and storing data (including the use of personal computers and portable storage devices) must comply with university policies. Restricted data, including protected health information, must be encrypted if stored or used on portable devices, if removed from a secure university location, or if electronically transmitted. For more information, see Policy on Institutional Data and Research Data Policy

Explain how information is handled, including storage, security measures (as necessary), and who will have access to the information. Include both electronic and hard copy records.*

Must also describe sharing of data/biospecimens between Ohio State and external collaborators at other site if there will be sharing/transfer.

You have entered 0 of 3000 characters.

Explain if any personal or sensitive information that could be potentially damaging to participants (e.g., relating to illegal behaviors, alcohol or drug use, sexual attitudes, mental health, etc.) will be collected.*

You have entered 0 of 3000 characters.

Not Applicable

Explain any circumstances (ethical or legal) where it would be necessary to break confidentiality.*

You have entered 0 of 3000 characters.

Not Applicable

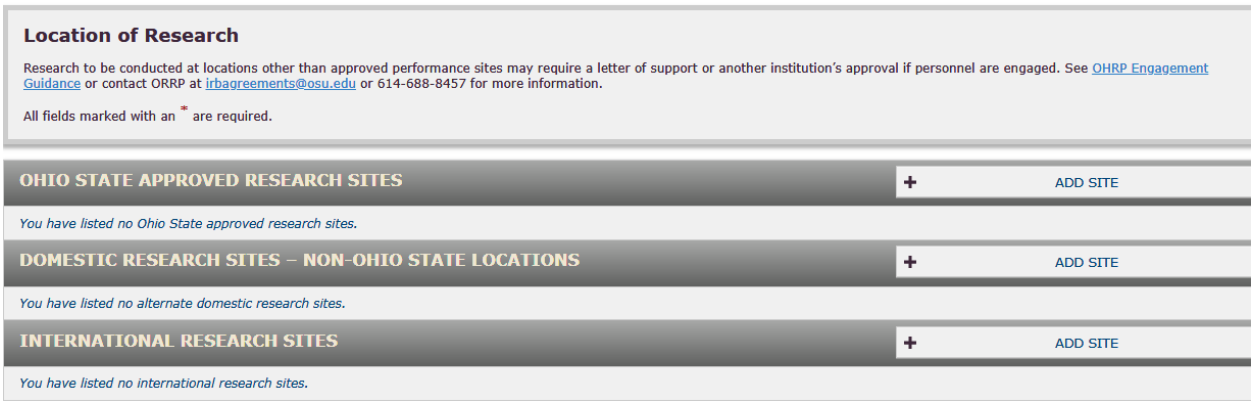
Primary research data should be retained for a minimum of five years after final project closeout. For more information, see the university's Research Data Policy. Other research-related records should be retained for a period of at least three years after the research has been discontinued (i.e., no further data collection, long term follow-up, re-contact, or analysis of identifiable/coded data.)

Indicate what will happen to identifiable data at the end of the study*

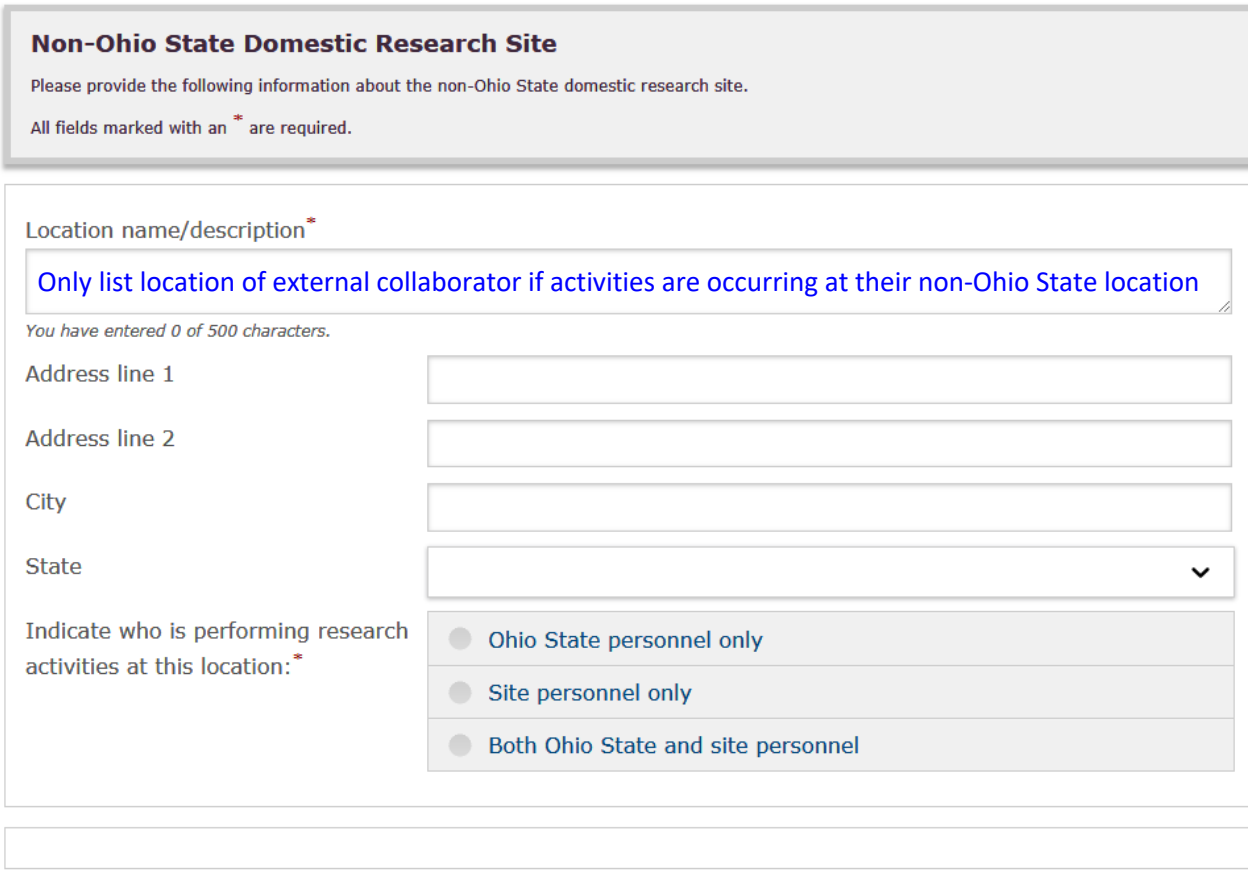
- Identifiable data will not be collected
- Identifiers will be permanently removed from the data and destroyed (resulting in de-identified data)
- Identifiable/coded(linked) data will be retained and stored confidentially (as appropriate)
- Identifiable data will be retained and may be made public with participant consent (e.g., ethnographic research)

Scenario 4: Ohio State is the IRB of record for an engaged individual

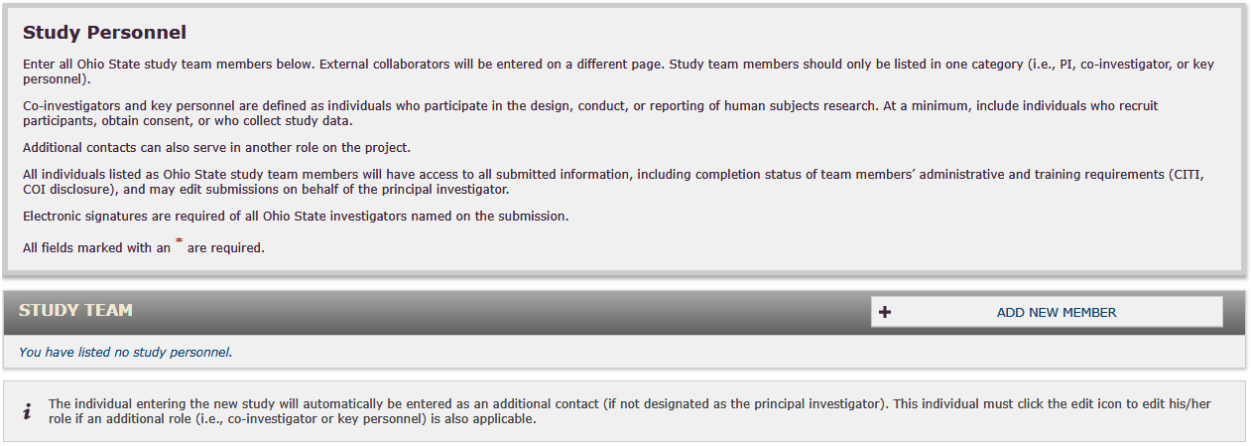
Location of Research page:



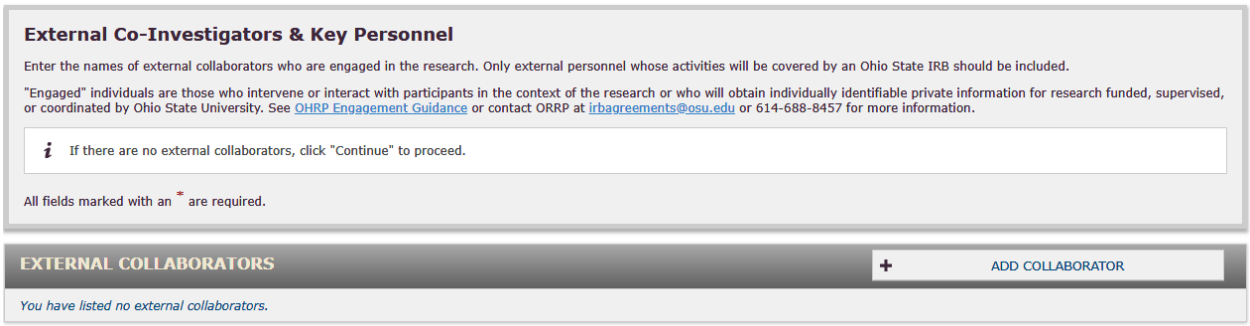
- **Domestic:**



Study Personnel page: Make sure non-Ohio State personnel are not listed on this page



External Collaborators page:



External Co-Investigators & Key Personnel

Enter the names of external collaborators who are engaged in the research. Only external personnel whose activities will be covered by an Ohio State IRB should be included.

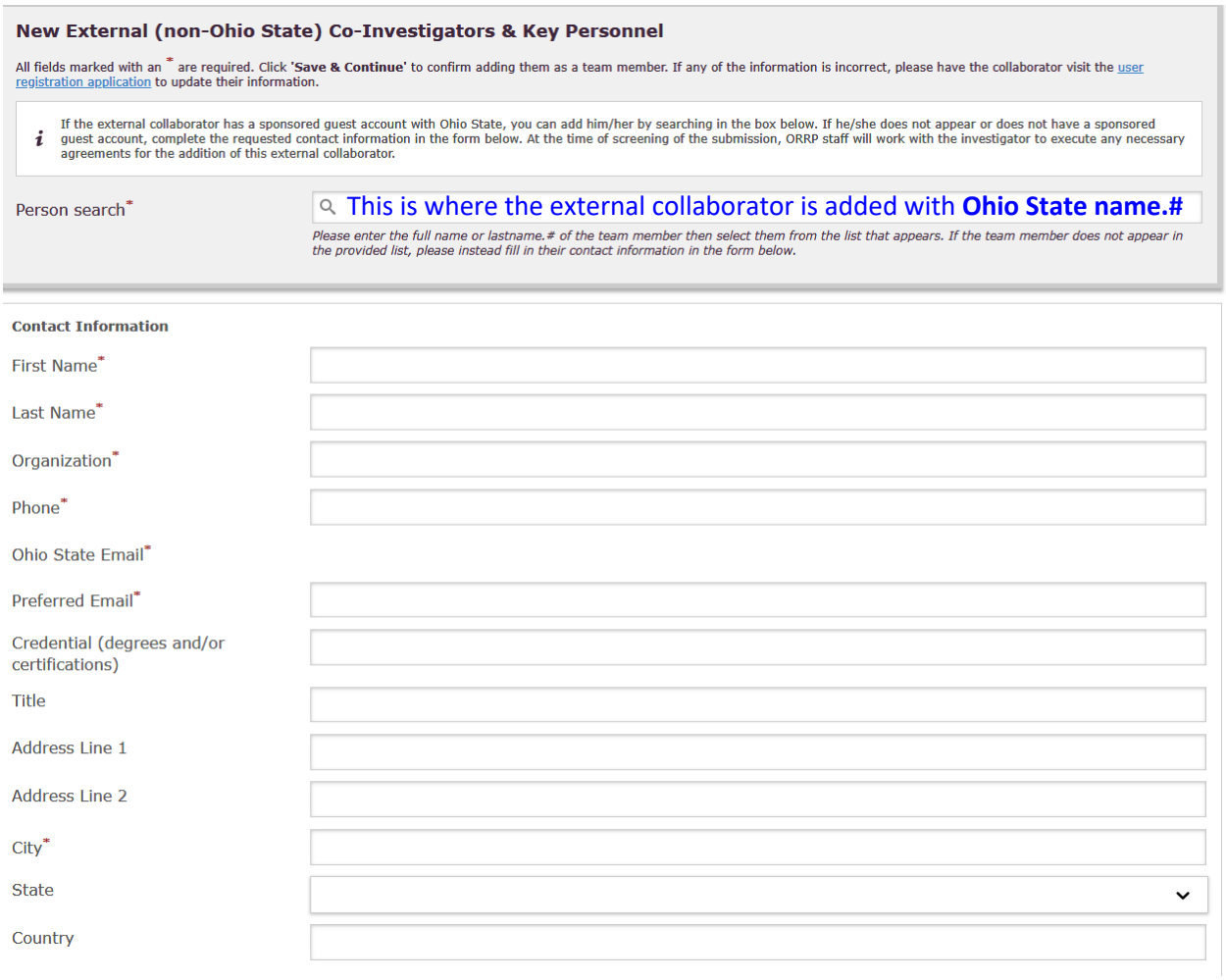
"Engaged" individuals are those who intervene or interact with participants in the context of the research or who will obtain individually identifiable private information for research funded, supervised, or coordinated by Ohio State University. See OHRP Engagement Guidance or contact ORRP at irbagreements@osu.edu or 614-688-8457 for more information.

If there are no external collaborators, click "Continue" to proceed.

All fields marked with an * are required.

EXTERNAL COLLABORATORS | + ADD COLLABORATOR

You have listed no external collaborators.



New External (non-Ohio State) Co-Investigators & Key Personnel

All fields marked with an * are required. Click '**Save & Continue**' to confirm adding them as a team member. If any of the information is incorrect, please have the collaborator visit the user registration application to update their information.

If the external collaborator has a sponsored guest account with Ohio State, you can add him/her by searching in the box below. If he/she does not appear or does not have a sponsored guest account, complete the requested contact information in the form below. At the time of screening of the submission, ORRP staff will work with the investigator to execute any necessary agreements for the addition of this external collaborator.

Person search* This is where the external collaborator is added with **Ohio State name.#**

Please enter the full name or lastname.# of the team member then select them from the list that appears. If the team member does not appear in the provided list, please instead fill in their contact information in the form below.

Contact Information

First Name*

Last Name*

Organization*

Phone*

Ohio State Email*

Preferred Email*

Credential (degrees and/or certifications)

Title

Address Line 1

Address Line 2

City*

State

Country

Research Involvement

Study team designation*

- ○ Co-Investigator
- ○ Key Personnel

Research role/activities performed for study*

Make sure activities checked are consistent with the type of study activities taking place.

- ☐ Protocol development/study design
- ☐ Recruitment
- ☐ Assess participant eligibility
- ☐ Obtain consent/parental permission/assent
- ☐ Interview participants/administer surveys
- ☐ Process biological specimens
- ☐ Conduct follow-up visits
- ☐ Data collection/entry/coding
- ☐ Data analysis/interpretation
- ☐ Reporting results
- ☐ Manuscript preparation
- ☐ Maintain regulatory documentation
- ☐ Access participant Protected Health Information (PHI)

Other activity description

Provide the external collaborator's resume/CV. This document is required in order for a reliance agreement to be drafted. Provide the external agreement when directed by ORRP staff. Contact ORRP with questions.

UPLOADED FILES

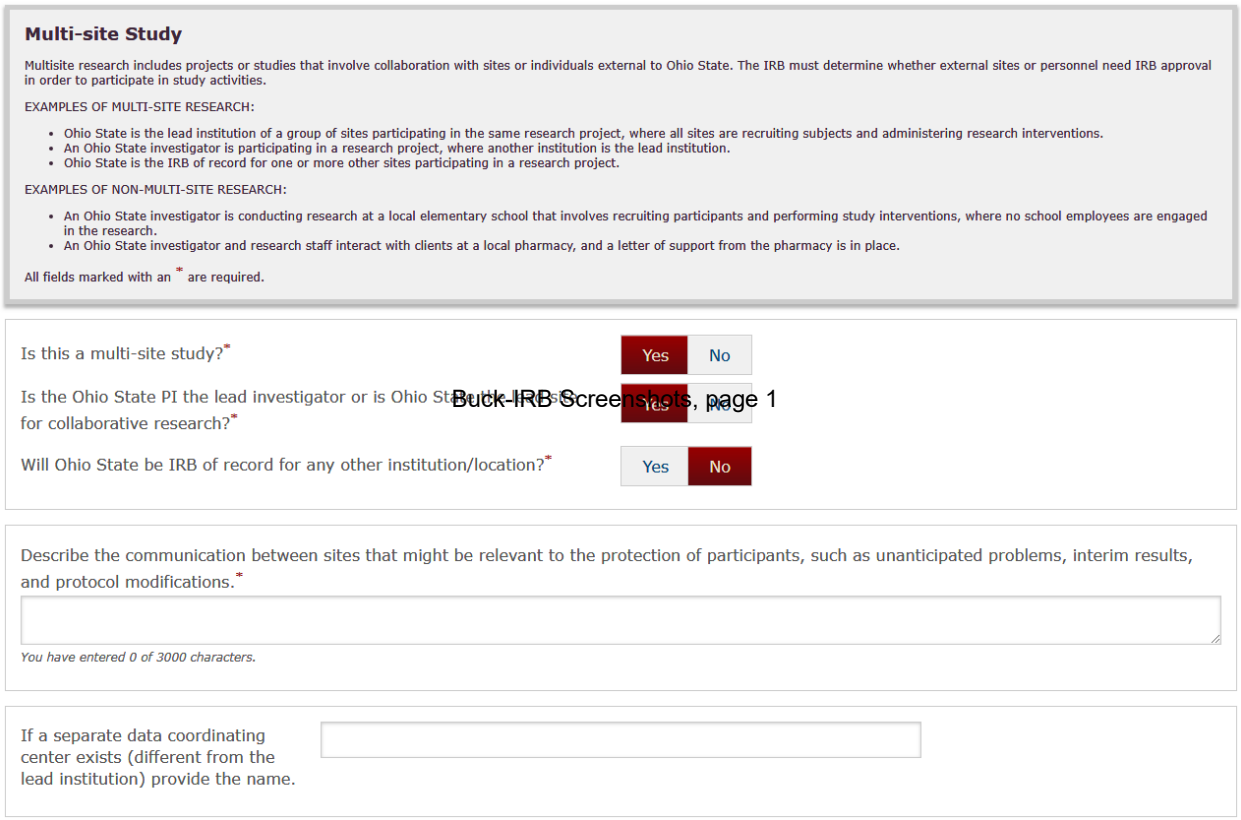
No files have been uploaded.

Upload the external collaborator's CV here. ORRP will upload the final Individual Investigator Agreement (IIA) prior to IRB review.

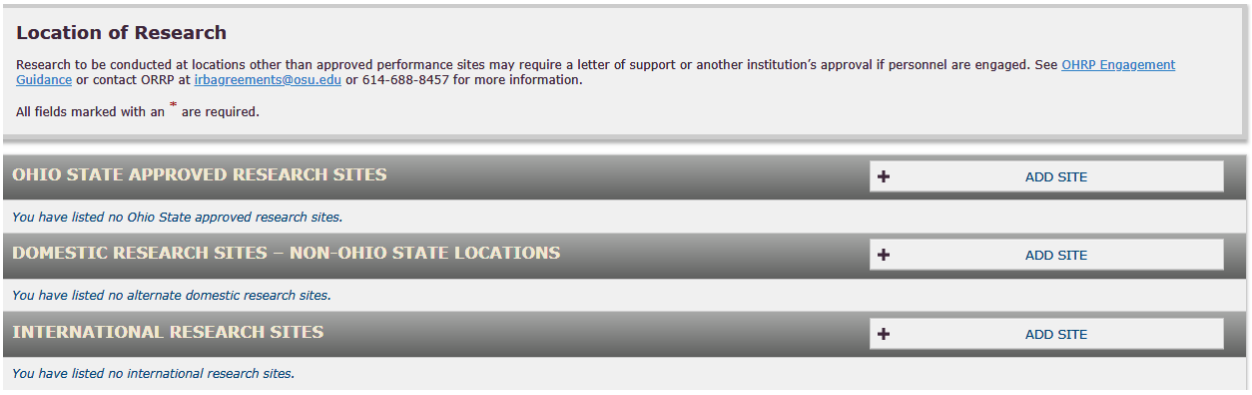
Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

Scenario 5: Ohio State is lead, external institution(s) do own review(s) (Ohio State not IRB of record for external institution)

Multi-Site Study page: The questions on this page should appear as below



Location of Research page:



- **Domestic:**

Non-Ohio State Domestic Research Site

Please provide the following information about the non-Ohio State domestic research site.

All fields marked with an * are required.

Location name/description*

List all sub-sites separately. If Ohio State will be receiving the data and writing manuscripts, Ohio State is likely the lead site.

You have entered 0 of 500 characters.

Address line 1

Address line 2

City

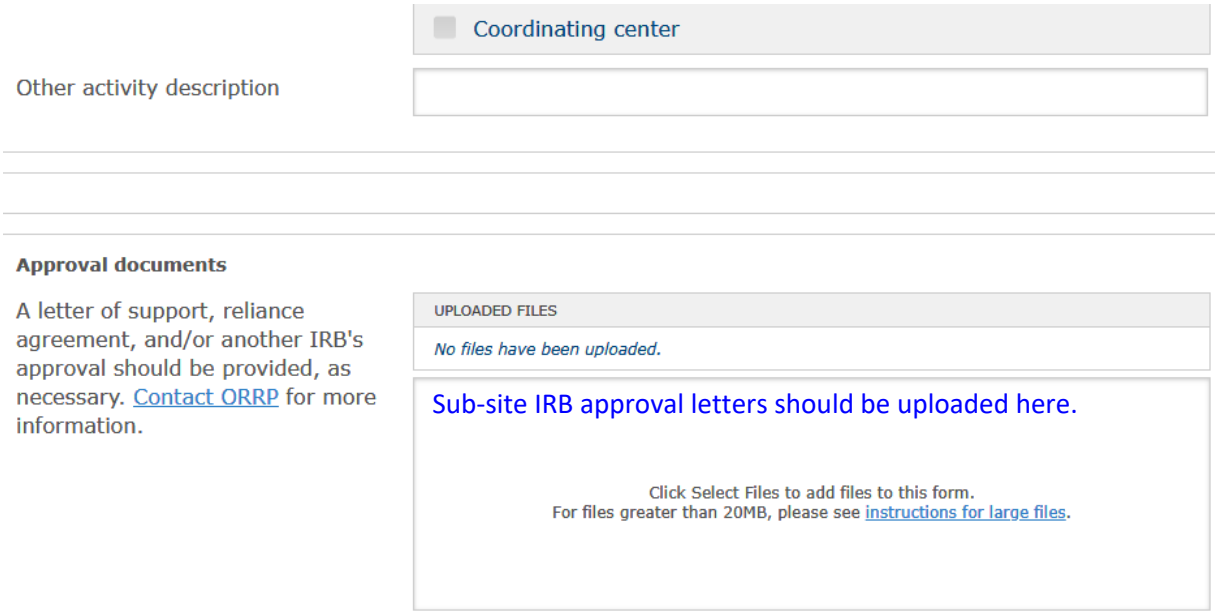
State

Indicate who is performing research activities at this location:*

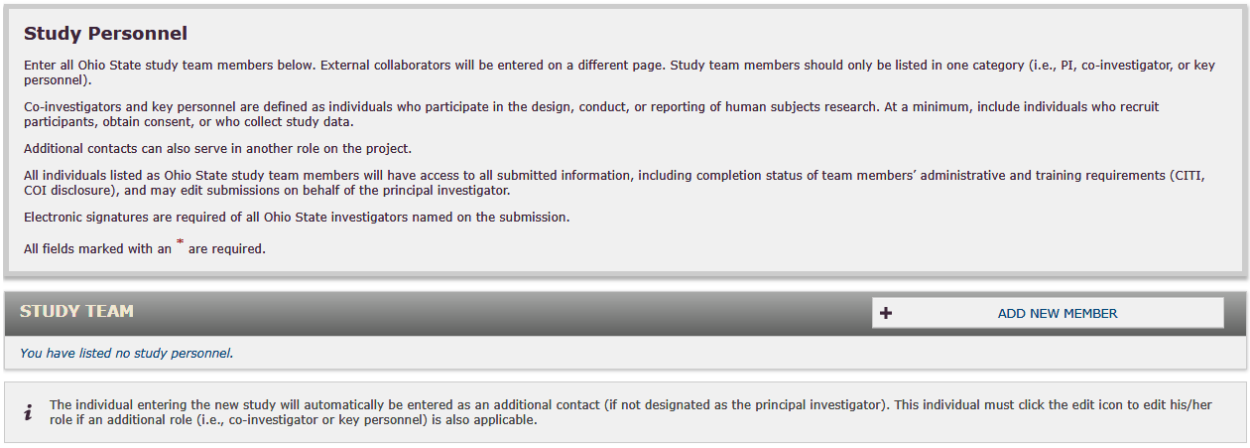
- ○ Ohio State personnel only
- ◉ Site personnel only
- ○ Both Ohio State and site personnel

Potential activities for this location (check all that apply)*

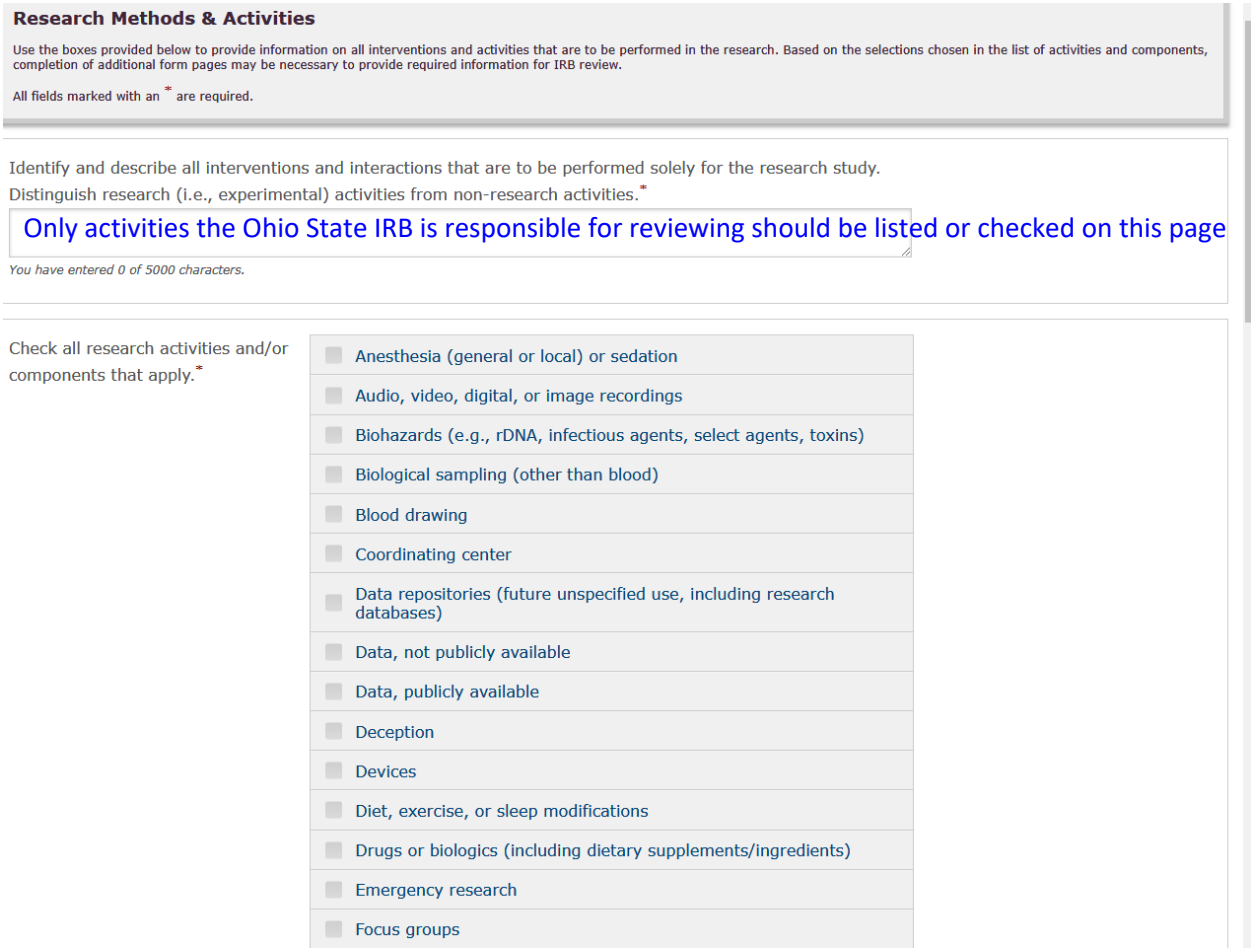
- ☐ Protocol development/study design
- ☐ Participant recruitment
- ☐ Obtaining consent/parental permission/assent
- ☐ Research interventions and subject interactions (administer questionnaires/interviews/surveys)
- ☐ Specimen collection
- ☐ Data collection/entry/coding
- ☐ Access participant protected health information (PHI)
- ☐ Manuscript preparation
- ☐ Reporting results



Study Personnel page: Make sure non-Ohio State personnel are not listed on this page



Research Methods & Activities page:



Research Methods & Activities

Use the boxes provided below to provide information on all interventions and activities that are to be performed in the research. Based on the selections chosen in the list of activities and components, completion of additional form pages may be necessary to provide required information for IRB review.

All fields marked with an * are required.

Identify and describe all interventions and interactions that are to be performed solely for the research study. Distinguish research (i.e., experimental) activities from non-research activities.*

Only activities the Ohio State IRB is responsible for reviewing should be listed or checked on this page

You have entered 0 of 5000 characters.

Check all research activities and/or components that apply.*

- Anesthesia (general or local) or sedation
- Audio, video, digital, or image recordings
- Biohazards (e.g., rDNA, infectious agents, select agents, toxins)
- Biological sampling (other than blood)
- Blood drawing
- Coordinating center
- Data repositories (future unspecified use, including research databases)
- Data, not publicly available
- Data, publicly available
- Deception
- Devices
- Diet, exercise, or sleep modifications
- Drugs or biologics (including dietary supplements/ingredients)
- Emergency research
- Focus groups

- [ ] Focus groups
- [ ] Food supplements
- [ ] Gene transfer
- [ ] Genetic testing
- [ ] Internet or e-mail data collection
- [ ] Magnetic resonance imaging (MRI)
- [ ] Materials that may be considered sensitive, offensive, threatening, or degrading
- [ ] Non-invasive medical procedures (e.g., EKG, Doppler)
- [ ] Observation of participants (including field notes)
- [ ] Oral history (does not include dental or medical history)
- [ ] Placebo
- [ ] Pregnancy testing
- [ ] Program Protocol (Umbrella Protocol)
- [ ] Radiation (e.g., CT or DEXA scans, X-rays, nuclear medicine procedures)
- [ ] Randomization
- [ ] Record review (which may include PHI)
- [ ] Specimen research
- [ ] Stem cell research
- [ ] Storage of biological materials (future unspecified use, including repositories)
- [ ] Surgical procedures (including biopsies)
- [ ] Surveys, questionnaires, or interviews (group)
- [ ] Surveys, questionnaires, or interviews (one-on-one)

Provide data collection forms, subject material, subject diaries, and/or other instruments, if applicable. Do not include case report forms for multi-site industry-initiated or cooperative group studies.

UPLOADED FILES

No files have been uploaded.

Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

SELECT FILES

Provide surveys, questionnaires, if applicable.

UPLOADED FILES

No files have been uploaded.

Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

SELECT FILES

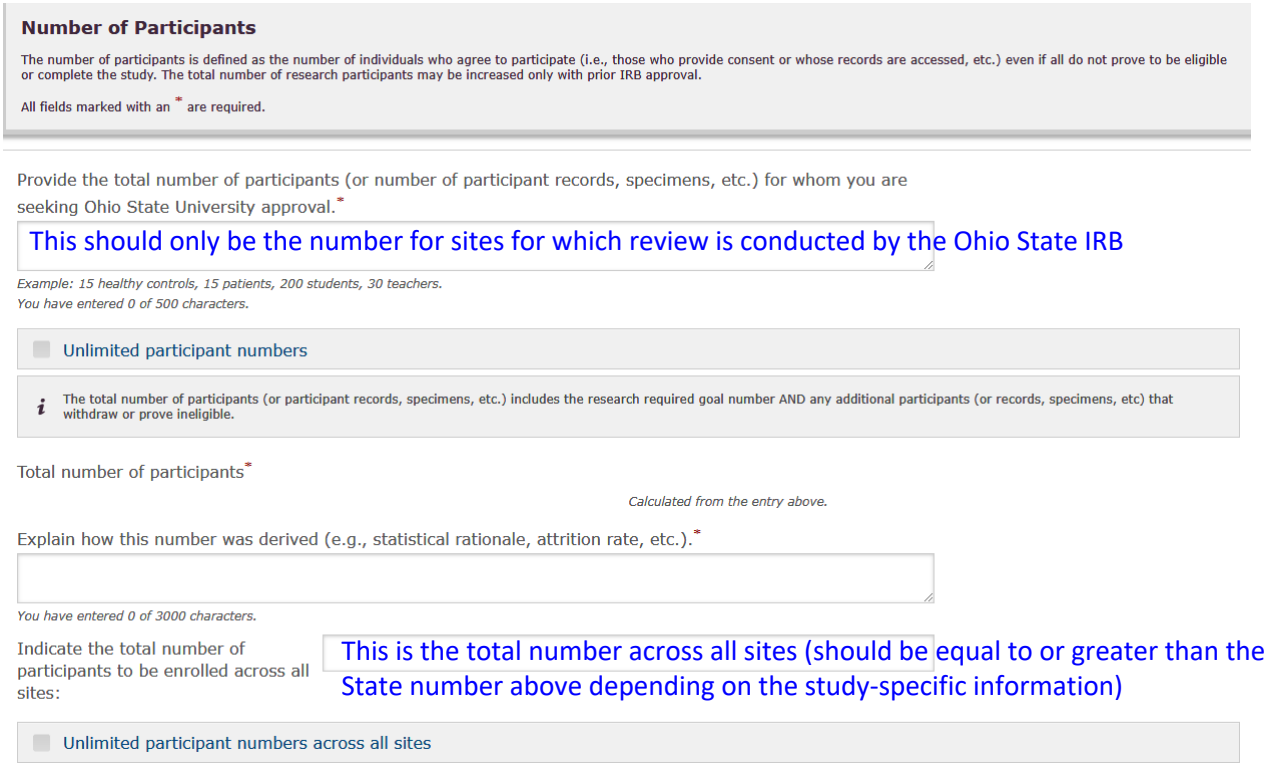
Provide subject information, such as newsletters, instruction sheets, appointment reminder cards, drug/device information, if applicable.

UPLOADED FILES

No files have been uploaded.

Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

Number of Participants page:



Number of Participants

The number of participants is defined as the number of individuals who agree to participate (i.e., those who provide consent or whose records are accessed, etc.) even if all do not prove to be eligible or complete the study. The total number of research participants may be increased only with prior IRB approval.

All fields marked with an * are required.

Provide the total number of participants (or number of participant records, specimens, etc.) for whom you are seeking Ohio State University approval.*

This should only be the number for sites for which review is conducted by the Ohio State IRB

Example: 15 healthy controls, 15 patients, 200 students, 30 teachers.
You have entered 0 of 500 characters.

☐ Unlimited participant numbers

The total number of participants (or participant records, specimens, etc.) includes the research required goal number AND any additional participants (or records, specimens, etc) that withdraw or prove ineligible.

Total number of participants*

Calculated from the entry above.

Explain how this number was derived (e.g., statistical rationale, attrition rate, etc.).*

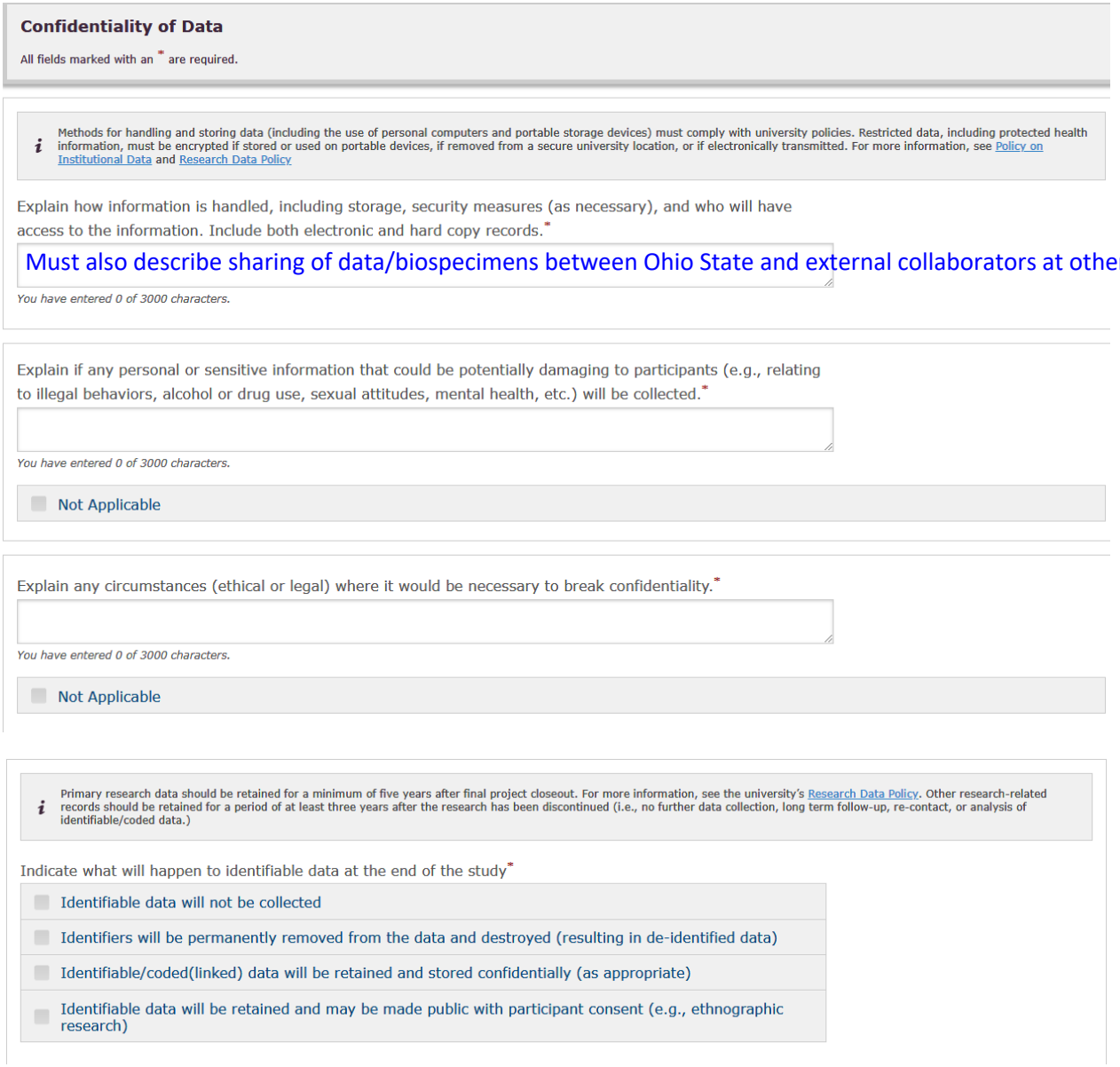
You have entered 0 of 3000 characters.

Indicate the total number of participants to be enrolled across all sites:

This is the total number across all sites (should be equal to or greater than the Ohio State number above depending on the study-specific information)

☐ Unlimited participant numbers across all sites

Confidentiality of Data page:



Confidentiality of Data

All fields marked with an * are required.

Methods for handling and storing data (including the use of personal computers and portable storage devices) must comply with university policies. Restricted data, including protected health information, must be encrypted if stored or used on portable devices, if removed from a secure university location, or if electronically transmitted. For more information, see Policy on Institutional Data and Research Data Policy

Explain how information is handled, including storage, security measures (as necessary), and who will have access to the information. Include both electronic and hard copy records.*

Must also describe sharing of data/biospecimens between Ohio State and external collaborators at other sites

You have entered 0 of 3000 characters.

Explain if any personal or sensitive information that could be potentially damaging to participants (e.g., relating to illegal behaviors, alcohol or drug use, sexual attitudes, mental health, etc.) will be collected.*

You have entered 0 of 3000 characters.

☐ Not Applicable

Explain any circumstances (ethical or legal) where it would be necessary to break confidentiality.*

You have entered 0 of 3000 characters.

☐ Not Applicable

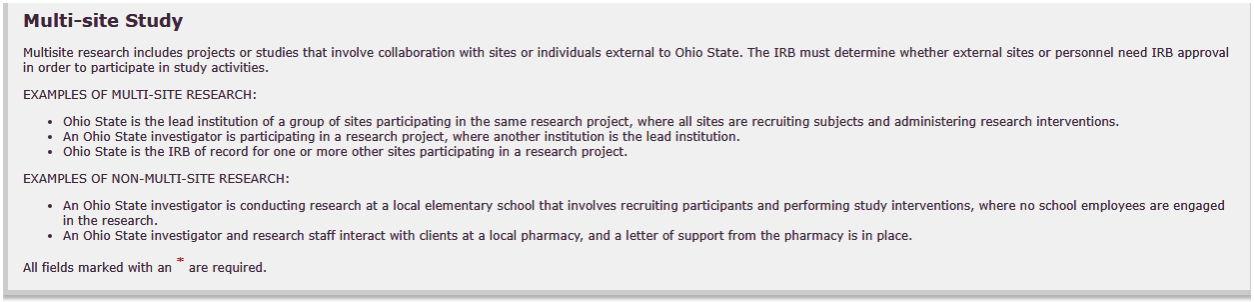
Primary research data should be retained for a minimum of five years after final project closeout. For more information, see the university's Research Data Policy. Other research-related records should be retained for a period of at least three years after the research has been discontinued (i.e., no further data collection, long term follow-up, re-contact, or analysis of identifiable/coded data.)

Indicate what will happen to identifiable data at the end of the study*

- ☐ Identifiable data will not be collected
- ☐ Identifiers will be permanently removed from the data and destroyed (resulting in de-identified data)
- ☐ Identifiable/coded(linked) data will be retained and stored confidentially (as appropriate)
- ☐ Identifiable data will be retained and may be made public with participant consent (e.g., ethnographic research)

Scenario 6: Ohio State is not lead, Ohio State only performing IRB review for Ohio State (not IRB of record for external institution)

Multi-Site Study page: The questions on this page should appear as below



Multi-site Study

Multisite research includes projects or studies that involve collaboration with sites or individuals external to Ohio State. The IRB must determine whether external sites or personnel need IRB approval in order to participate in study activities.

EXAMPLES OF MULTI-SITE RESEARCH:

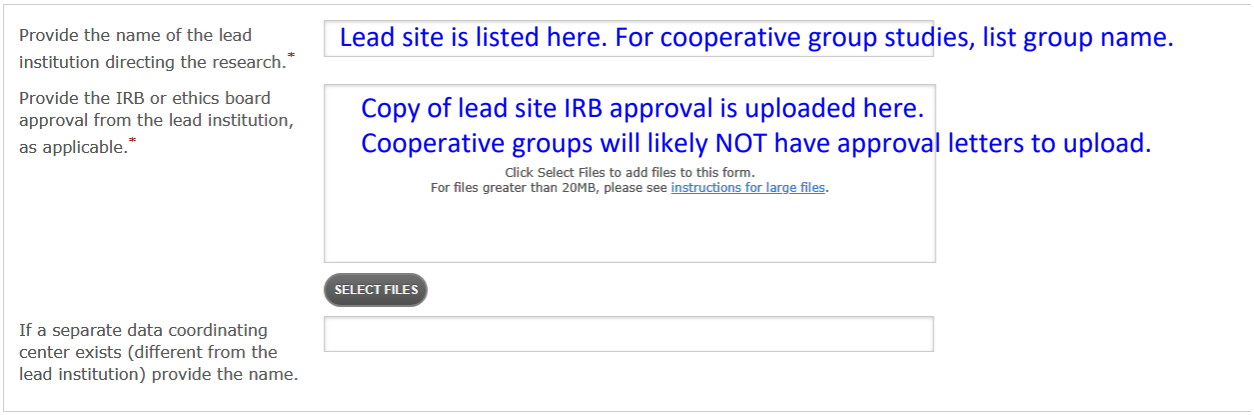
- Ohio State is the lead institution of a group of sites participating in the same research project, where all sites are recruiting subjects and administering research interventions.
- An Ohio State investigator is participating in a research project, where another institution is the lead institution.
- Ohio State is the IRB of record for one or more other sites participating in a research project.

EXAMPLES OF NON-MULTI-SITE RESEARCH:

- An Ohio State investigator is conducting research at a local elementary school that involves recruiting participants and performing study interventions, where no school employees are engaged in the research.
- An Ohio State investigator and research staff interact with clients at a local pharmacy, and a letter of support from the pharmacy is in place.

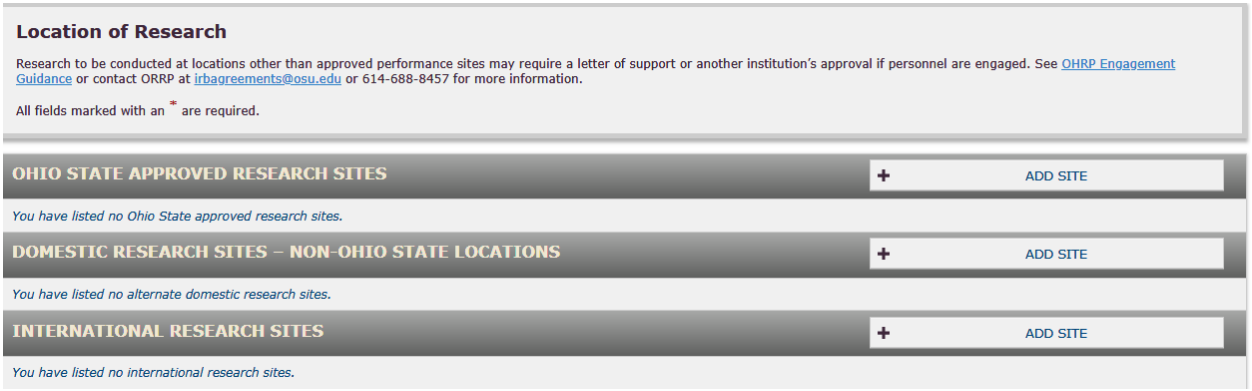
All fields marked with an * are required.

Is this a multi-site study?*	Yes / No
Is the Ohio State PI the lead investigator or is Ohio State the lead site for collaborative research?*	Yes / No
Will Ohio State be IRB of record for any other institution/location?*	Yes / No



Provide the name of the lead institution directing the research.*	Lead site is listed here. For cooperative group studies, list group name.
Provide the IRB or ethics board approval from the lead institution, as applicable.*	Copy of lead site IRB approval is uploaded here. Cooperative groups will likely NOT have approval letters to upload. Click Select Files to add files to this form. For files greater than 20MB, please see instructions for large files. SELECT FILES
If a separate data coordinating center exists (different from the lead institution) provide the name.	

Location of Research page: External sites (including the lead site) should NOT be listed on this page



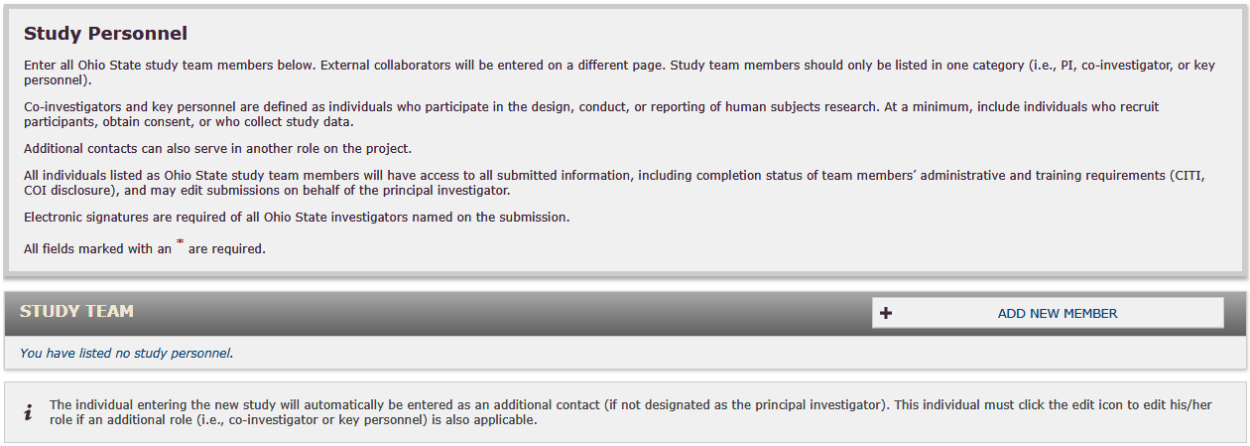
Location of Research

Research to be conducted at locations other than approved performance sites may require a letter of support or another institution's approval if personnel are engaged. See OHRP Engagement Guidance or contact ORRP at irbagreements@osu.edu or 614-688-8457 for more information.

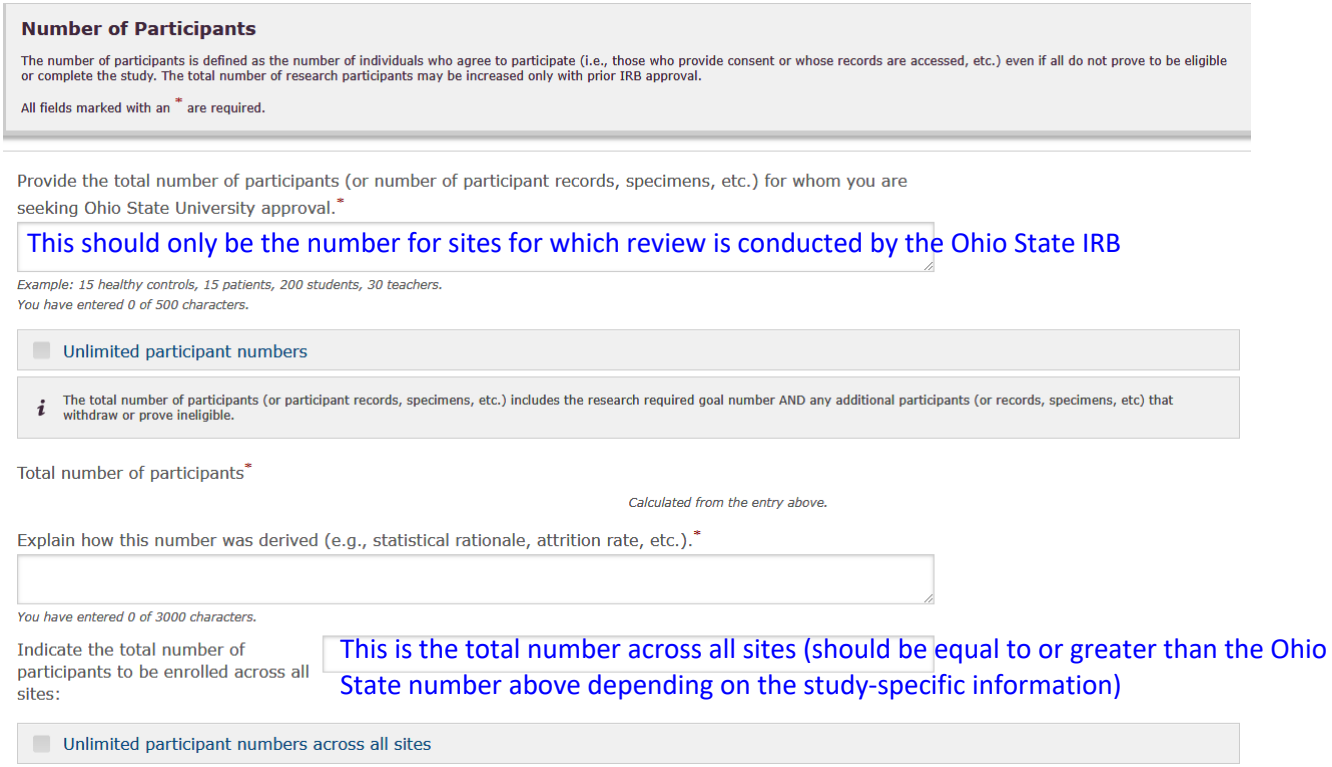
All fields marked with an * are required.

OHIO STATE APPROVED RESEARCH SITES	+ ADD SITE
You have listed no Ohio State approved research sites.	
DOMESTIC RESEARCH SITES – NON-OHIO STATE LOCATIONS	+ ADD SITE
You have listed no alternate domestic research sites.	
INTERNATIONAL RESEARCH SITES	+ ADD SITE
You have listed no international research sites.	

Study Personnel page: Make sure non-Ohio State personnel are not listed on this page



Number of Participants page:



Confidentiality of Data page:

Confidentiality of Data

All fields marked with an * are required.

Methods for handling and storing data (including the use of personal computers and portable storage devices) must comply with university policies. Restricted data, including protected health information, must be encrypted if stored or used on portable devices, if removed from a secure university location, or if electronically transmitted. For more information, see Policy on Institutional Data and Research Data Policy

Explain how information is handled, including storage, security measures (as necessary), and who will have access to the information. Include both electronic and hard copy records.*

Must also describe sharing of data/biospecimens between Ohio State and the lead site

You have entered 0 of 3000 characters.

Explain if any personal or sensitive information that could be potentially damaging to participants (e.g., relating to illegal behaviors, alcohol or drug use, sexual attitudes, mental health, etc.) will be collected.*

You have entered 0 of 3000 characters.

- [ ] Not Applicable

Explain any circumstances (ethical or legal) where it would be necessary to break confidentiality.*

You have entered 0 of 3000 characters.

- [ ] Not Applicable

Primary research data should be retained for a minimum of five years after final project closeout. For more information, see the university's Research Data Policy. Other research-related records should be retained for a period of at least three years after the research has been discontinued (i.e., no further data collection, long term follow-up, re-contact, or analysis of identifiable/coded data.)

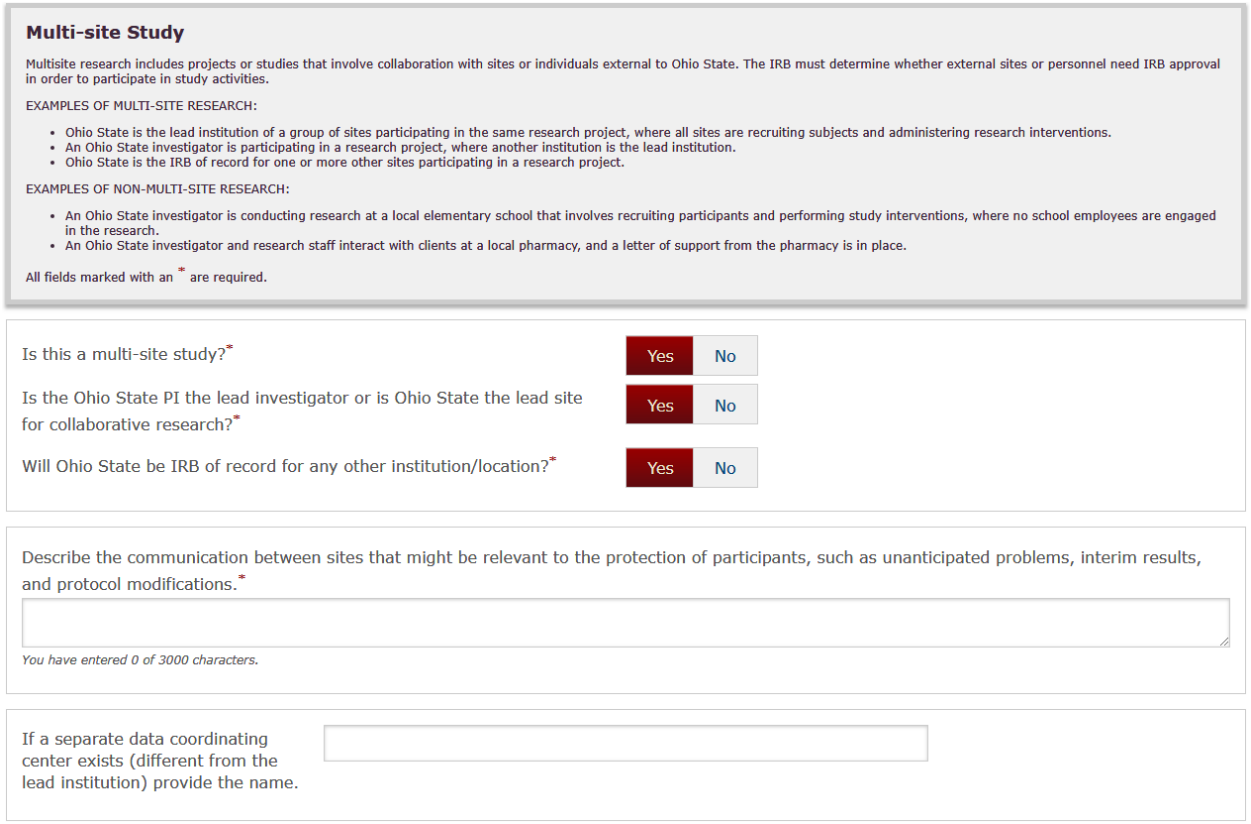
Indicate what will happen to identifiable data at the end of the study*

- [ ] Identifiable data will not be collected
- [ ] Identifiers will be permanently removed from the data and destroyed (resulting in de-identified data)
- [ ] Identifiable/coded(linked) data will be retained and stored confidentially (as appropriate)
- [ ] Identifiable data will be retained and may be made public with participant consent (e.g., ethnographic research)

Scenario 7: Ohio State is the IRB of record for the external institution (no direct participant interaction)

Multi-Site Study page (Ohio State is the lead site):

The questions on this page should appear as below



Multi-site Study

Multisite research includes projects or studies that involve collaboration with sites or individuals external to Ohio State. The IRB must determine whether external sites or personnel need IRB approval in order to participate in study activities.

EXAMPLES OF MULTI-SITE RESEARCH:

- Ohio State is the lead institution of a group of sites participating in the same research project, where all sites are recruiting subjects and administering research interventions.
- An Ohio State investigator is participating in a research project, where another institution is the lead institution.
- Ohio State is the IRB of record for one or more other sites participating in a research project.

EXAMPLES OF NON-MULTI-SITE RESEARCH:

- An Ohio State investigator is conducting research at a local elementary school that involves recruiting participants and performing study interventions, where no school employees are engaged in the research.
- An Ohio State investigator and research staff interact with clients at a local pharmacy, and a letter of support from the pharmacy is in place.

All fields marked with an * are required.

Is this a multi-site study?* Yes No

Is the Ohio State PI the lead investigator or is Ohio State the lead site for collaborative research?* Yes No

Will Ohio State be IRB of record for any other institution/location?* Yes No

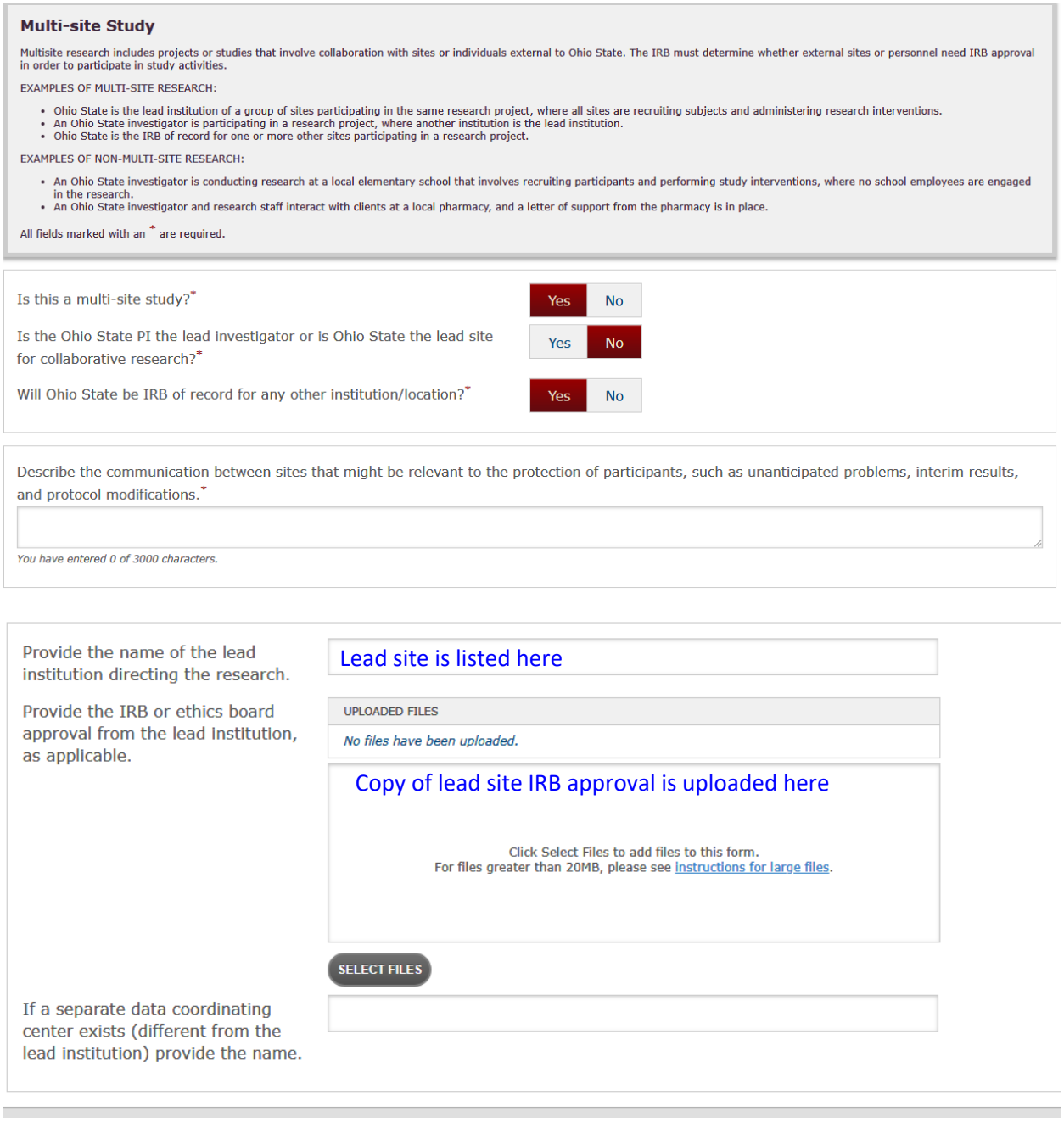
Describe the communication between sites that might be relevant to the protection of participants, such as unanticipated problems, interim results, and protocol modifications.*

You have entered 0 of 3000 characters.

If a separate data coordinating center exists (different from the lead institution) provide the name.

Multi-Site Study page (Ohio State is not the lead site):

The questions on this page should appear as below



Multi-site Study

Multisite research includes projects or studies that involve collaboration with sites or individuals external to Ohio State. The IRB must determine whether external sites or personnel need IRB approval in order to participate in study activities.

EXAMPLES OF MULTI-SITE RESEARCH:

- Ohio State is the lead institution of a group of sites participating in the same research project, where all sites are recruiting subjects and administering research interventions.
- An Ohio State investigator is participating in a research project, where another institution is the lead institution.
- Ohio State is the IRB of record for one or more other sites participating in a research project.

EXAMPLES OF NON-MULTI-SITE RESEARCH:

- An Ohio State investigator is conducting research at a local elementary school that involves recruiting participants and performing study interventions, where no school employees are engaged in the research.
- An Ohio State investigator and research staff interact with clients at a local pharmacy, and a letter of support from the pharmacy is in place.

All fields marked with an * are required.

Is this a multi-site study?* Yes No

Is the Ohio State PI the lead investigator or is Ohio State the lead site for collaborative research?* Yes No

Will Ohio State be IRB of record for any other institution/location?* Yes No

Describe the communication between sites that might be relevant to the protection of participants, such as unanticipated problems, interim results, and protocol modifications.*

You have entered 0 of 3000 characters.

Provide the name of the lead institution directing the research.

Lead site is listed here

Provide the IRB or ethics board approval from the lead institution, as applicable.

UPLOADED FILES

No files have been uploaded.

Copy of lead site IRB approval is uploaded here

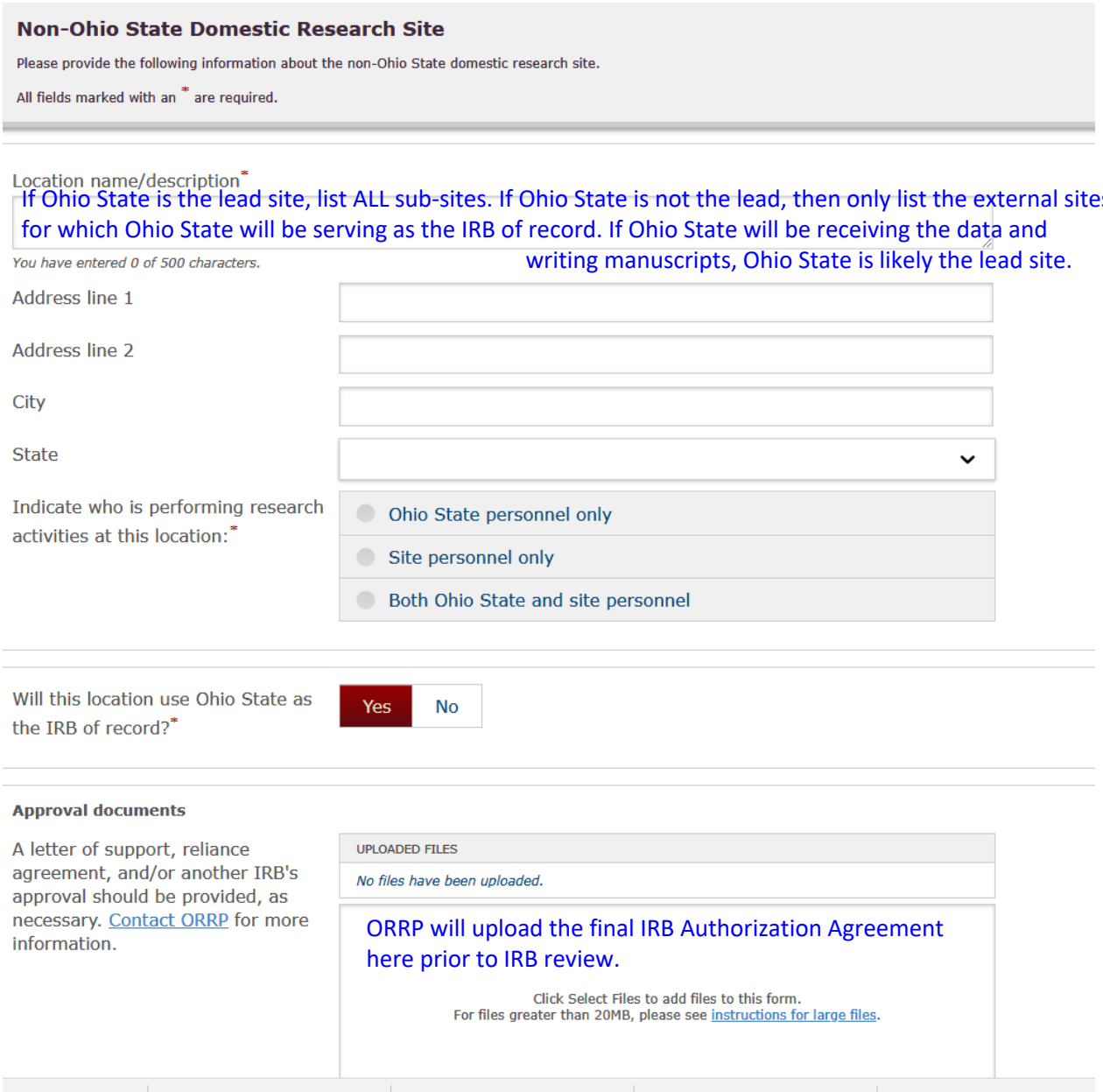
Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

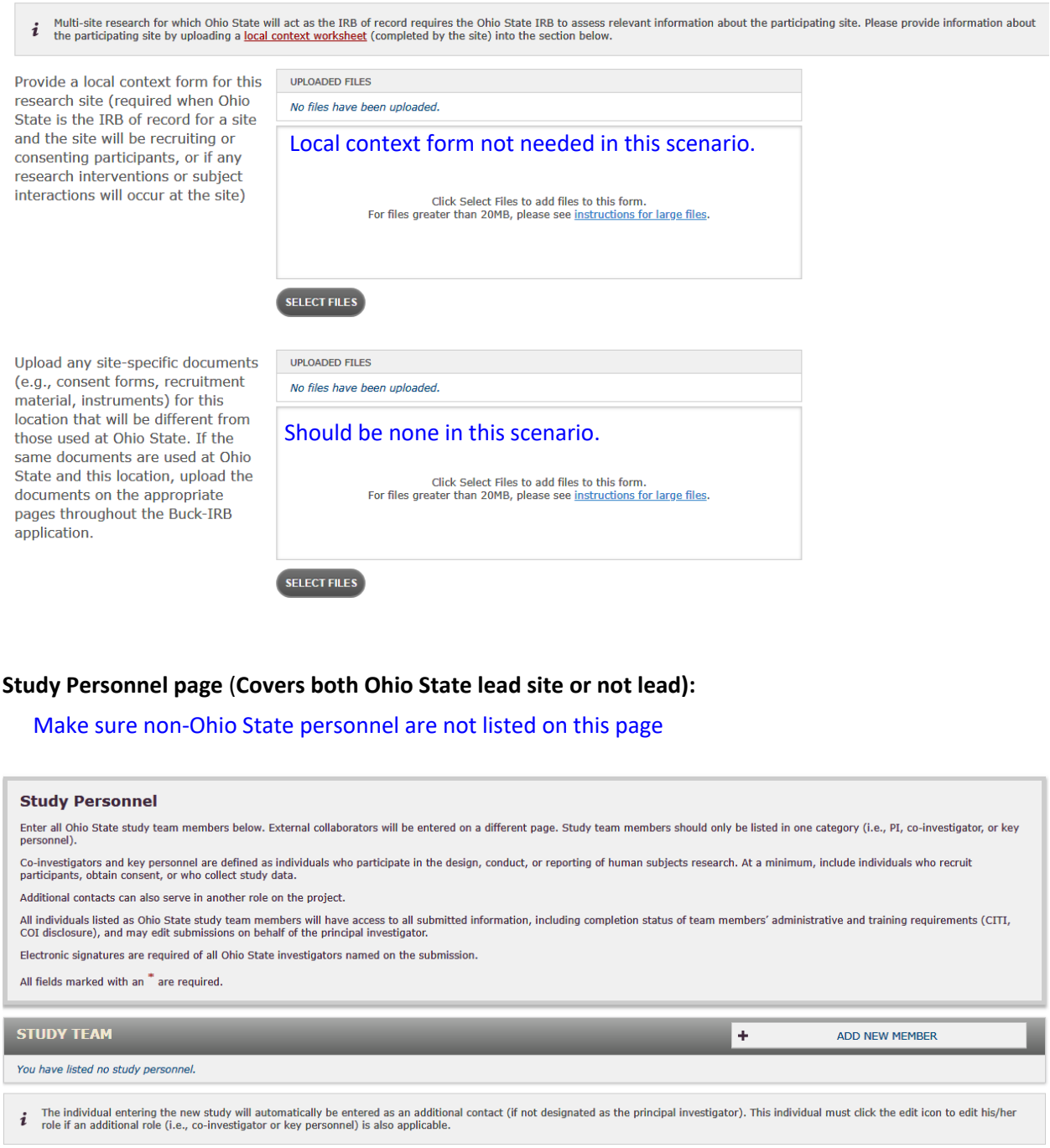
SELECT FILES

If a separate data coordinating center exists (different from the lead institution) provide the name.

Location of Research page (Covers both Ohio State lead site or not lead):

- **Domestic (Covers both Ohio State lead site or not lead):**



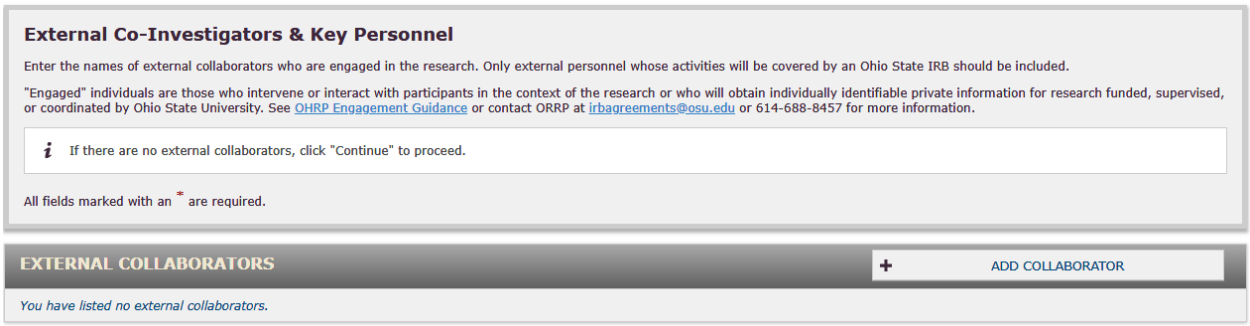


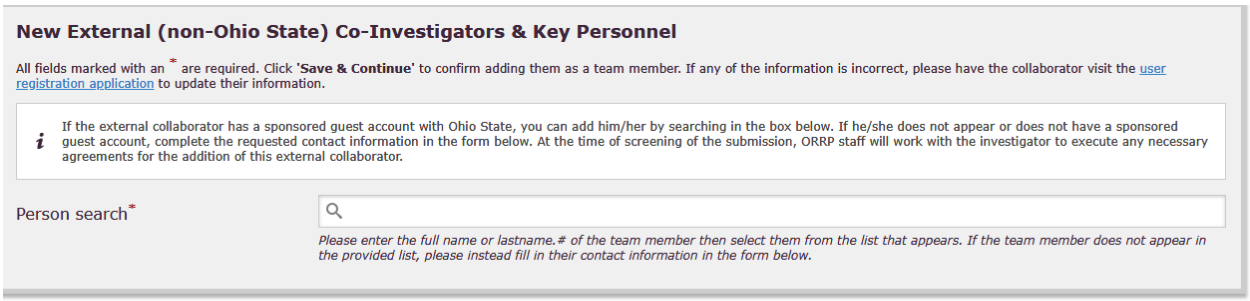
Study Personnel page (Covers both Ohio State lead site or not lead):

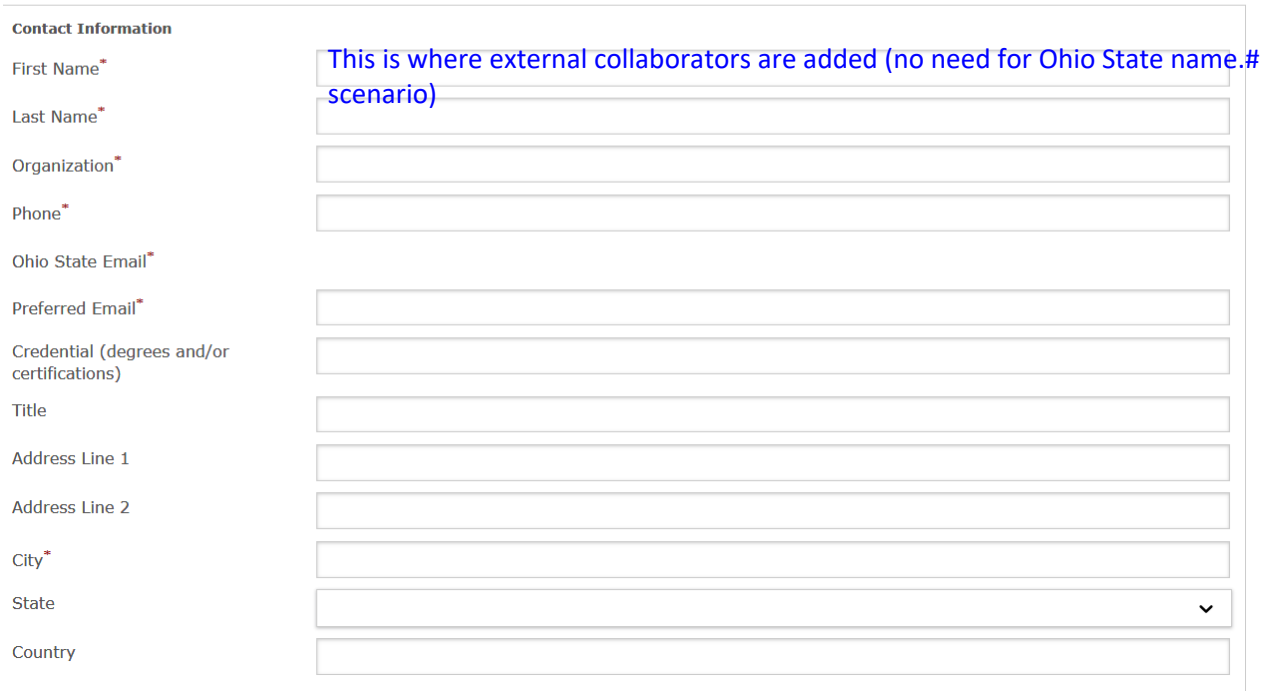
Make sure non-Ohio State personnel are not listed on this page

External Collaborators page (Covers both Ohio State lead site or not lead):

List only non-Ohio State personnel for whom the Ohio State IRB will serve as the IRB of Record







This is where external collaborators are added (no need for Ohio State name.# in this scenario)

Research Involvement

Study team designation*

- ○ Co-Investigator
- ○ Key Personnel

Research role/activities performed for study*

Make sure activities checked are consistent with the type of study activities taking place.

- ☐ Protocol development/study design
- ☐ Recruitment
- ☐ Assess participant eligibility
- ☐ Obtain consent/parental permission/assent
- ☐ Interview participants/administer surveys
- ☐ Process biological specimens
- ☐ Conduct follow-up visits
- ☐ Data collection/entry/coding
- ☐ Data analysis/interpretation
- ☐ Reporting results
- ☐ Manuscript preparation
- ☐ Maintain regulatory documentation
- ☐ Access participant Protected Health Information (PHI)

Other activity description

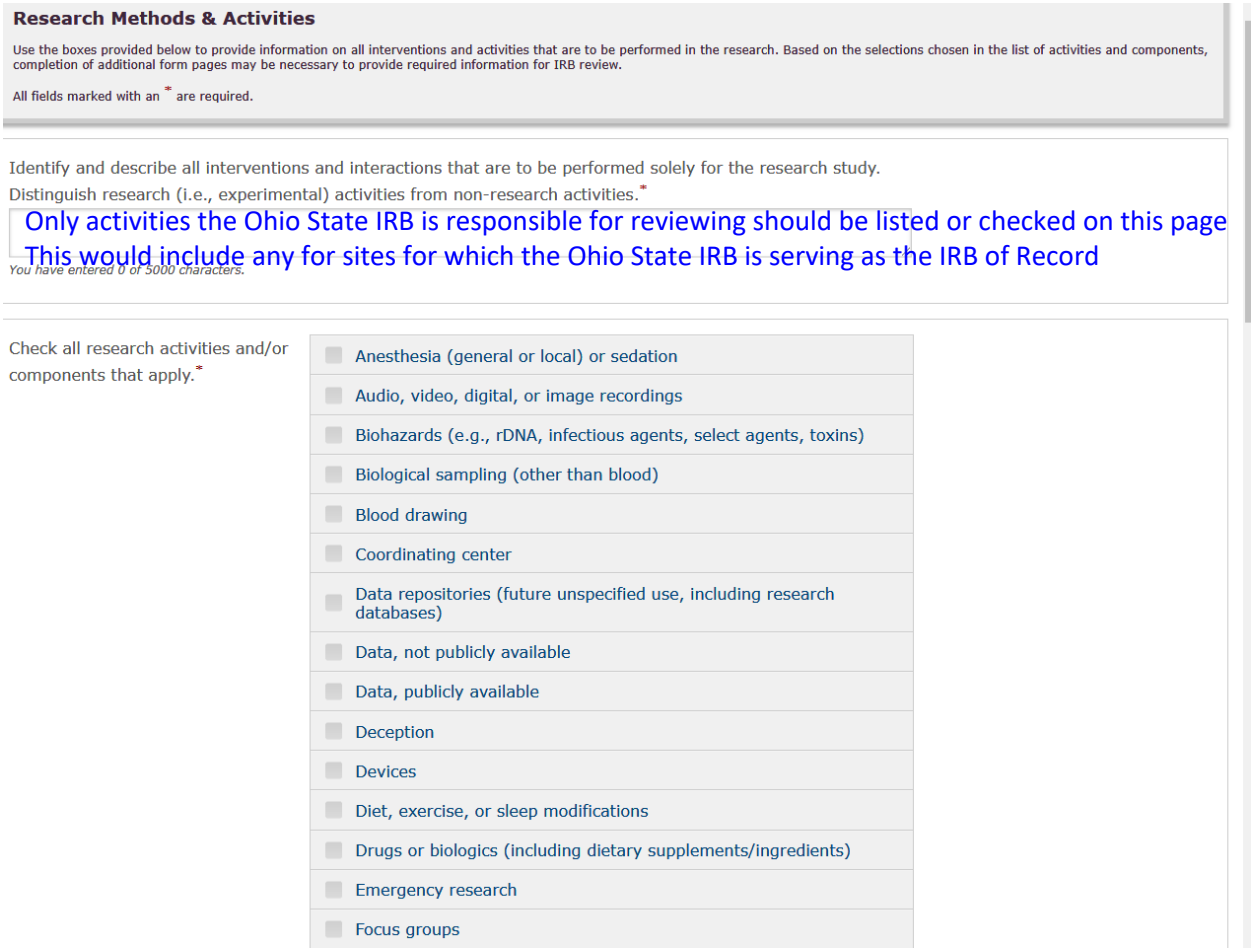
Provide the external collaborator's resume/CV. This document is required in order for a reliance agreement to be drafted. Provide the external agreement when directed by ORRP staff. Contact ORRP with questions.

UPLOADED FILES

No files have been uploaded.

Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

Research Methods & Activities page (Covers both Ohio State lead site or not lead):



Research Methods & Activities

Use the boxes provided below to provide information on all interventions and activities that are to be performed in the research. Based on the selections chosen in the list of activities and components, completion of additional form pages may be necessary to provide required information for IRB review.

All fields marked with an * are required.

Identify and describe all interventions and interactions that are to be performed solely for the research study. Distinguish research (i.e., experimental) activities from non-research activities.*

Only activities the Ohio State IRB is responsible for reviewing should be listed or checked on this page
This would include any for sites for which the Ohio State IRB is serving as the IRB of Record

You have entered 0 of 5000 characters.

Check all research activities and/or components that apply.*

- Anesthesia (general or local) or sedation
- Audio, video, digital, or image recordings
- Biohazards (e.g., rDNA, infectious agents, select agents, toxins)
- Biological sampling (other than blood)
- Blood drawing
- Coordinating center
- Data repositories (future unspecified use, including research databases)
- Data, not publicly available
- Data, publicly available
- Deception
- Devices
- Diet, exercise, or sleep modifications
- Drugs or biologics (including dietary supplements/ingredients)
- Emergency research
- Focus groups

- [ ] Focus groups
- [ ] Food supplements
- [ ] Gene transfer
- [ ] Genetic testing
- [ ] Internet or e-mail data collection
- [ ] Magnetic resonance imaging (MRI)
- [ ] Materials that may be considered sensitive, offensive, threatening, or degrading
- [ ] Non-invasive medical procedures (e.g., EKG, Doppler)
- [ ] Observation of participants (including field notes)
- [ ] Oral history (does not include dental or medical history)
- [ ] Placebo
- [ ] Pregnancy testing
- [ ] Program Protocol (Umbrella Protocol)
- [ ] Radiation (e.g., CT or DEXA scans, X-rays, nuclear medicine procedures)
- [ ] Randomization
- [ ] Record review (which may include PHI)
- [ ] Specimen research
- [ ] Stem cell research
- [ ] Storage of biological materials (future unspecified use, including repositories)
- [ ] Surgical procedures (including biopsies)
- [ ] Surveys, questionnaires, or interviews (group)
- [ ] Surveys, questionnaires, or interviews (one-on-one)

Provide data collection forms, subject material, subject diaries, and/or other instruments, if applicable. Do not include case report forms for multi-site industry-initiated or cooperative group studies.

UPLOADED FILES

No files have been uploaded.

Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

SELECT FILES

Provide surveys, questionnaires, if applicable.

UPLOADED FILES

No files have been uploaded.

Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

SELECT FILES

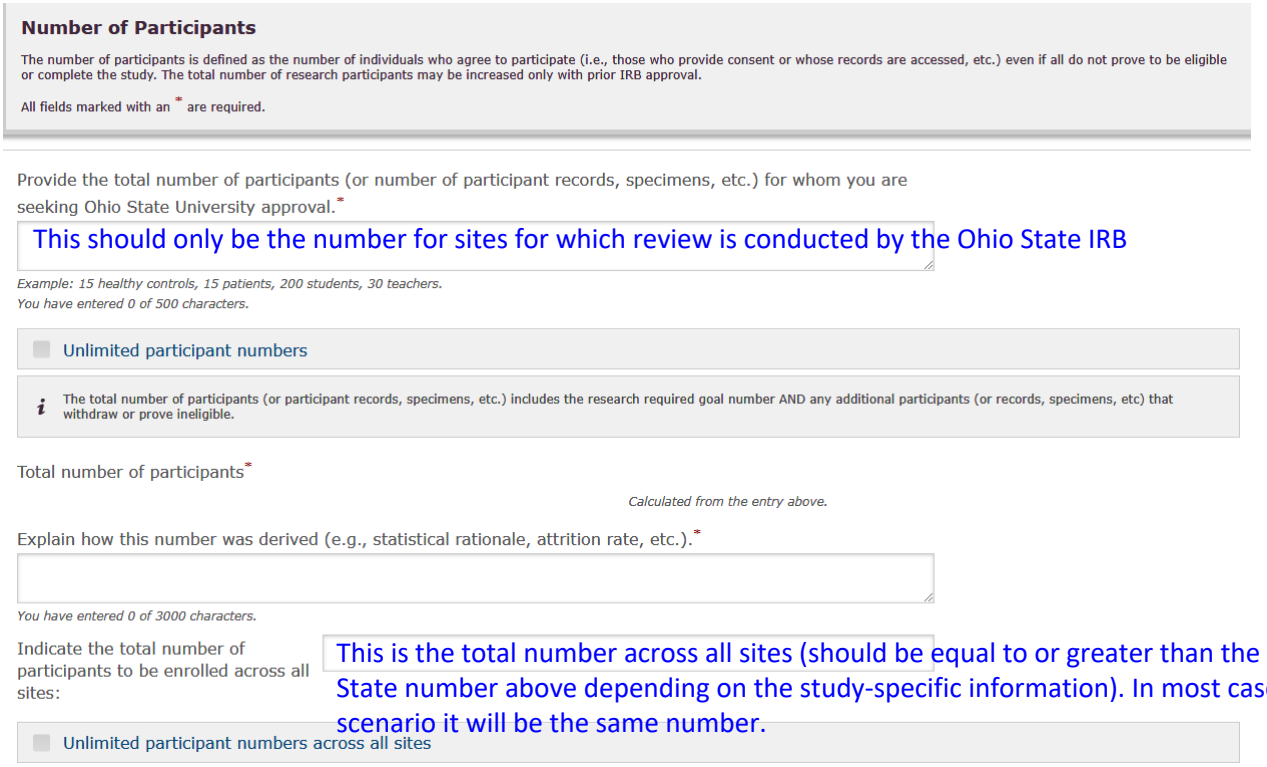
Provide subject information, such as newsletters, instruction sheets, appointment reminder cards, drug/device information, if applicable.

UPLOADED FILES

No files have been uploaded.

Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

Number of Participants page (Covers both Ohio State lead site or not lead):



Number of Participants

The number of participants is defined as the number of individuals who agree to participate (i.e., those who provide consent or whose records are accessed, etc.) even if all do not prove to be eligible or complete the study. The total number of research participants may be increased only with prior IRB approval.

All fields marked with an * are required.

Provide the total number of participants (or number of participant records, specimens, etc.) for whom you are seeking Ohio State University approval.*

This should only be the number for sites for which review is conducted by the Ohio State IRB

Example: 15 healthy controls, 15 patients, 200 students, 30 teachers.
You have entered 0 of 500 characters.

☐ Unlimited participant numbers

ℹ The total number of participants (or participant records, specimens, etc.) includes the research required goal number AND any additional participants (or records, specimens, etc) that withdraw or prove ineligible.

Total number of participants*

Calculated from the entry above.

Explain how this number was derived (e.g., statistical rationale, attrition rate, etc.).*

You have entered 0 of 3000 characters.

Indicate the total number of participants to be enrolled across all sites:

This is the total number across all sites (should be equal to or greater than the Ohio State number above depending on the study-specific information). In most cases in this scenario it will be the same number.

☐ Unlimited participant numbers across all sites

Confidentiality of Data page (Covers both Ohio State lead site or not lead):

Confidentiality of Data

All fields marked with an * are required.

Methods for handling and storing data (including the use of personal computers and portable storage devices) must comply with university policies. Restricted data, including protected health information, must be encrypted if stored or used on portable devices, if removed from a secure university location, or if electronically transmitted. For more information, see Policy on Institutional Data and Research Data Policy

Explain how information is handled, including storage, security measures (as necessary), and who will have access to the information. Include both electronic and hard copy records.*

Must also describe sharing of data/biospecimens between Ohio State and external collaborators at other sites

You have entered 0 of 3000 characters.

Explain if any personal or sensitive information that could be potentially damaging to participants (e.g., relating to illegal behaviors, alcohol or drug use, sexual attitudes, mental health, etc.) will be collected.*

You have entered 0 of 3000 characters.

☐ Not Applicable

Explain any circumstances (ethical or legal) where it would be necessary to break confidentiality.*

You have entered 0 of 3000 characters.

☐ Not Applicable

Primary research data should be retained for a minimum of five years after final project closeout. For more information, see the university's Research Data Policy. Other research-related records should be retained for a period of at least three years after the research has been discontinued (i.e., no further data collection, long term follow-up, re-contact, or analysis of identifiable/coded data.)

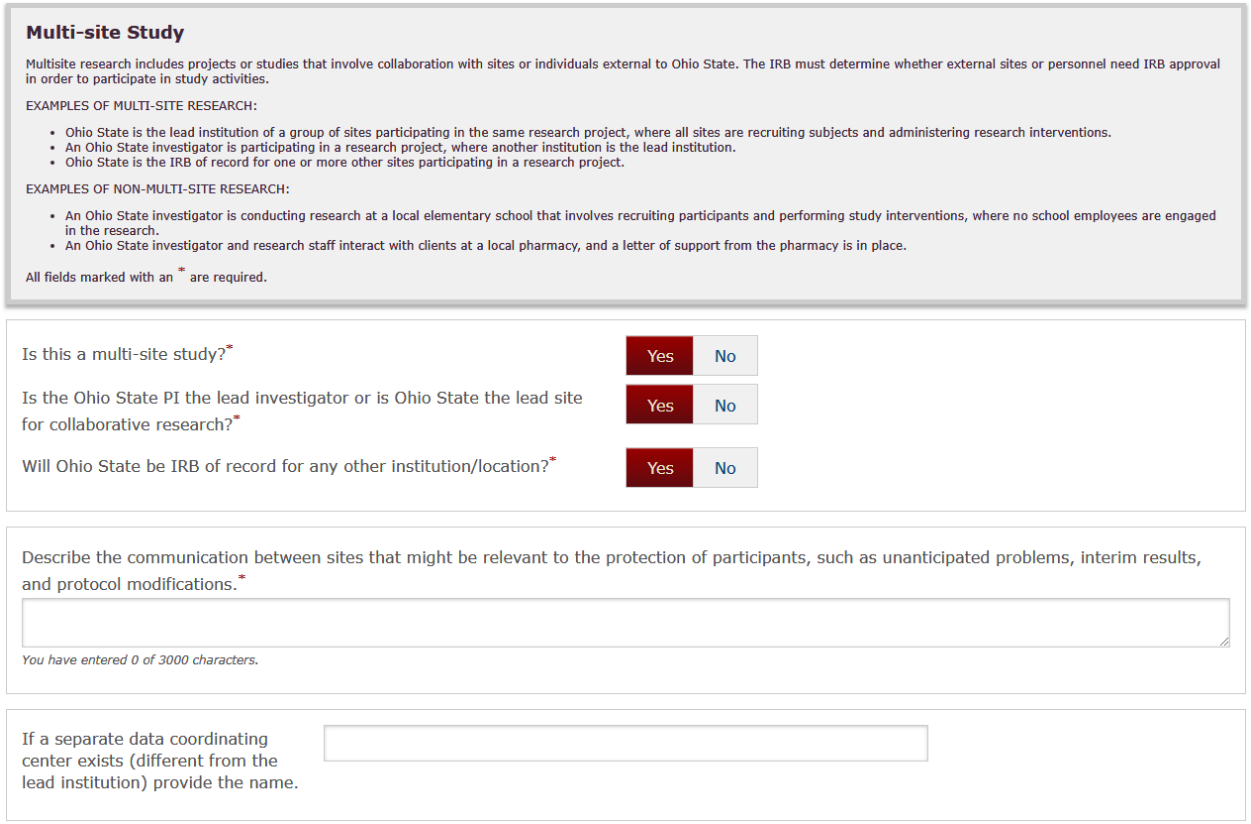
Indicate what will happen to identifiable data at the end of the study*

- ☐ Identifiable data will not be collected
- ☐ Identifiers will be permanently removed from the data and destroyed (resulting in de-identified data)
- ☐ Identifiable/coded(linked) data will be retained and stored confidentially (as appropriate)
- ☐ Identifiable data will be retained and may be made public with participant consent (e.g., ethnographic research)

Scenario 8: Ohio State is the IRB of record for the external institution (direct participant interaction at external site)

Multi-Site Study page (Ohio State is the lead site):

The questions on this page should appear as below



Multi-site Study

Multisite research includes projects or studies that involve collaboration with sites or individuals external to Ohio State. The IRB must determine whether external sites or personnel need IRB approval in order to participate in study activities.

EXAMPLES OF MULTI-SITE RESEARCH:

- Ohio State is the lead institution of a group of sites participating in the same research project, where all sites are recruiting subjects and administering research interventions.
- An Ohio State investigator is participating in a research project, where another institution is the lead institution.
- Ohio State is the IRB of record for one or more other sites participating in a research project.

EXAMPLES OF NON-MULTI-SITE RESEARCH:

- An Ohio State investigator is conducting research at a local elementary school that involves recruiting participants and performing study interventions, where no school employees are engaged in the research.
- An Ohio State investigator and research staff interact with clients at a local pharmacy, and a letter of support from the pharmacy is in place.

All fields marked with an * are required.

Is this a multi-site study?* Yes No

Is the Ohio State PI the lead investigator or is Ohio State the lead site for collaborative research?* Yes No

Will Ohio State be IRB of record for any other institution/location?* Yes No

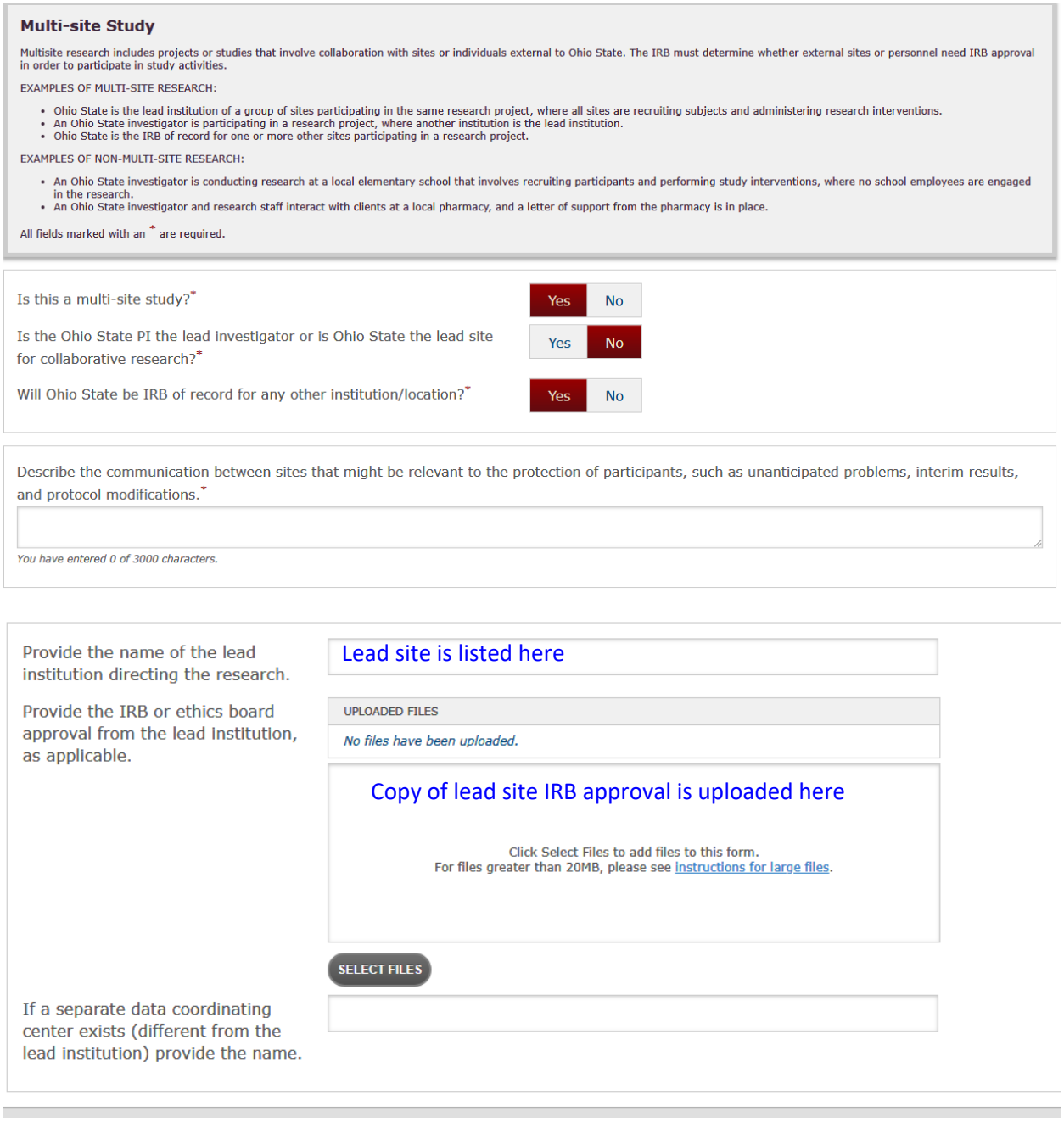
Describe the communication between sites that might be relevant to the protection of participants, such as unanticipated problems, interim results, and protocol modifications.*

You have entered 0 of 3000 characters.

If a separate data coordinating center exists (different from the lead institution) provide the name.

Multi-Site Study page (Ohio State is not the lead site):

The questions on this page should appear as below



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EXAMPLES OF MULTI-SITE RESEARCH:

- Ohio State is the lead institution of a group of sites participating in the same research project, where all sites are recruiting subjects and administering research interventions.
- An Ohio State investigator is participating in a research project, where another institution is the lead institution.
- Ohio State is the IRB of record for one or more other sites participating in a research project.

EXAMPLES OF NON-MULTI-SITE RESEARCH:

- An Ohio State investigator is conducting research at a local elementary school that involves recruiting participants and performing study interventions, where no school employees are engaged in the research.
- An Ohio State investigator and research staff interact with clients at a local pharmacy, and a letter of support from the pharmacy is in place.

All fields marked with an * are required.

Is this a multi-site study?* Yes No

Is the Ohio State PI the lead investigator or is Ohio State the lead site for collaborative research?* Yes No

Will Ohio State be IRB of record for any other institution/location?* Yes No

Describe the communication between sites that might be relevant to the protection of participants, such as unanticipated problems, interim results, and protocol modifications.*

You have entered 0 of 3000 characters.

Provide the name of the lead institution directing the research.

Lead site is listed here

Provide the IRB or ethics board approval from the lead institution, as applicable.

UPLOADED FILES

No files have been uploaded.

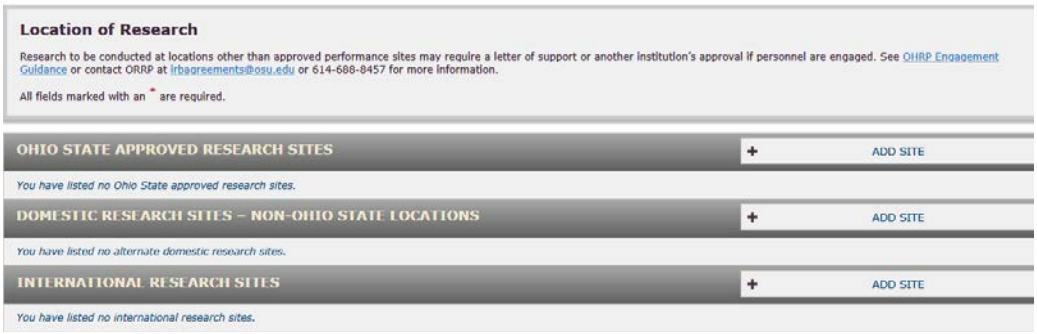
Copy of lead site IRB approval is uploaded here

Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

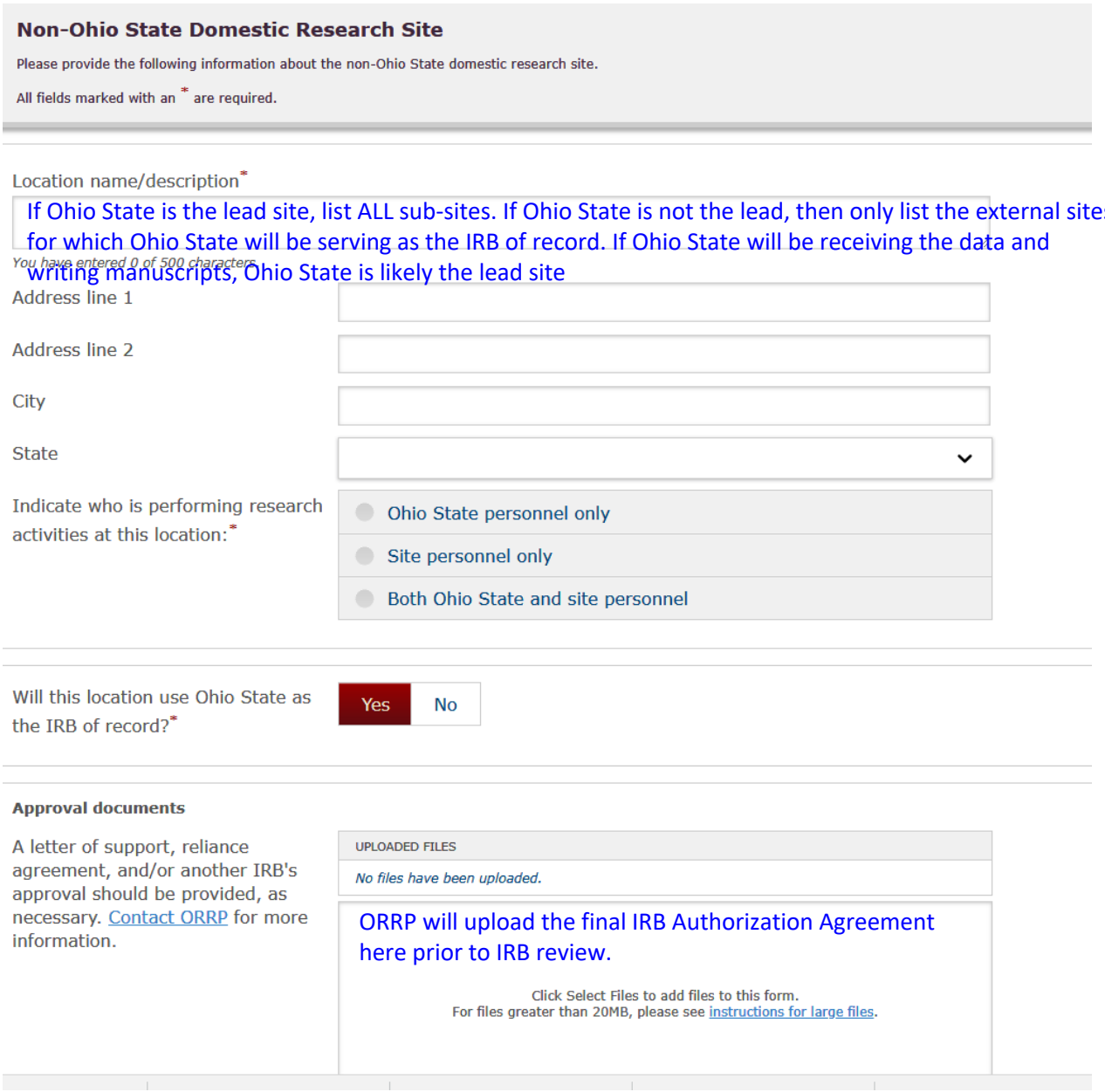
SELECT FILES

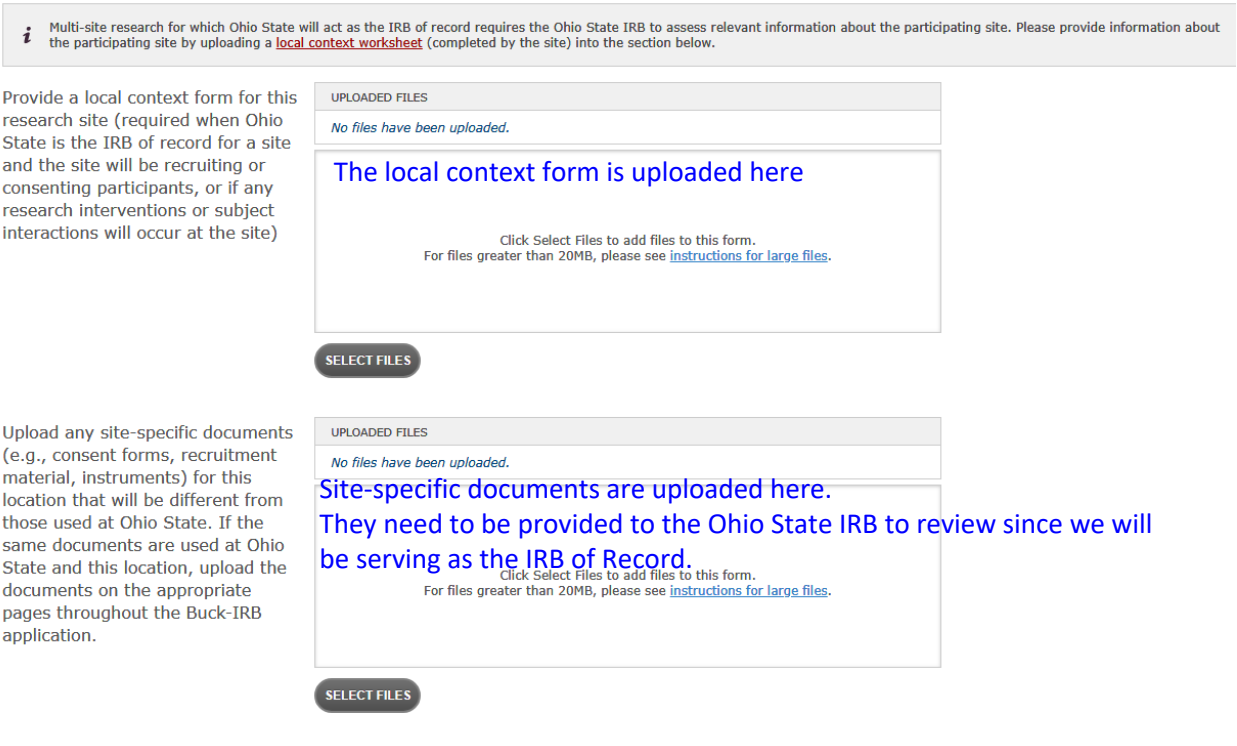
If a separate data coordinating center exists (different from the lead institution) provide the name.

Location of Research page (Covers both Ohio State lead site or not lead):



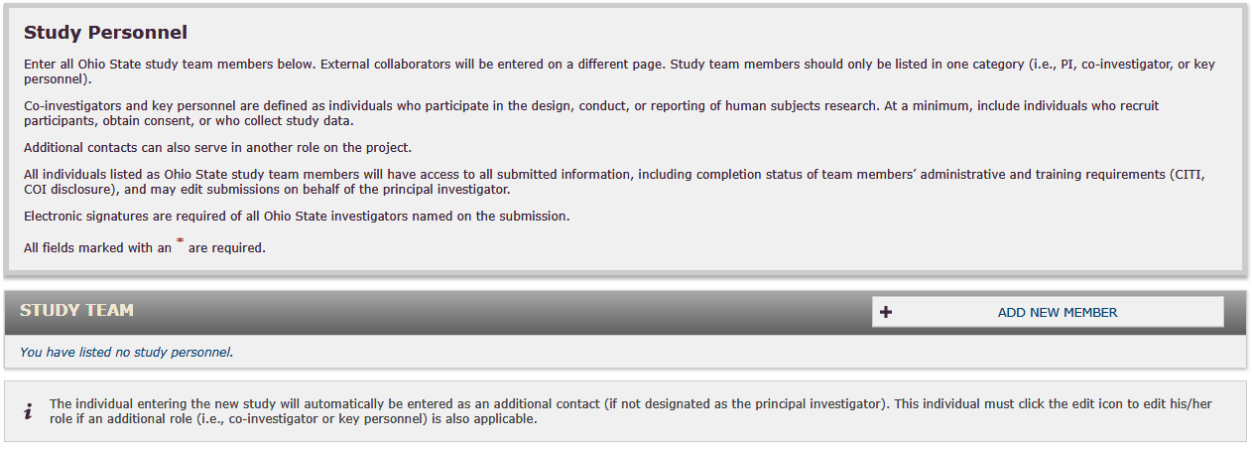
- **Domestic (Covers both Ohio State lead site or not lead):**





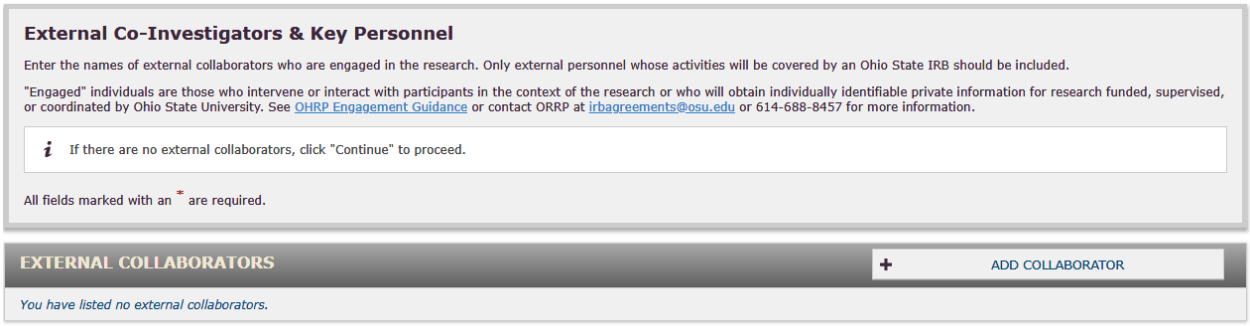
Study Personnel page (Covers both Ohio State lead site or not lead):

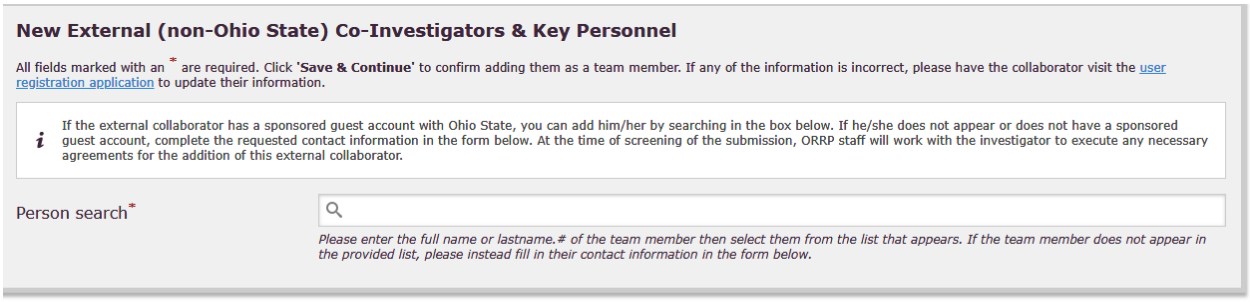
Make sure non-Ohio State personnel are not listed on this page

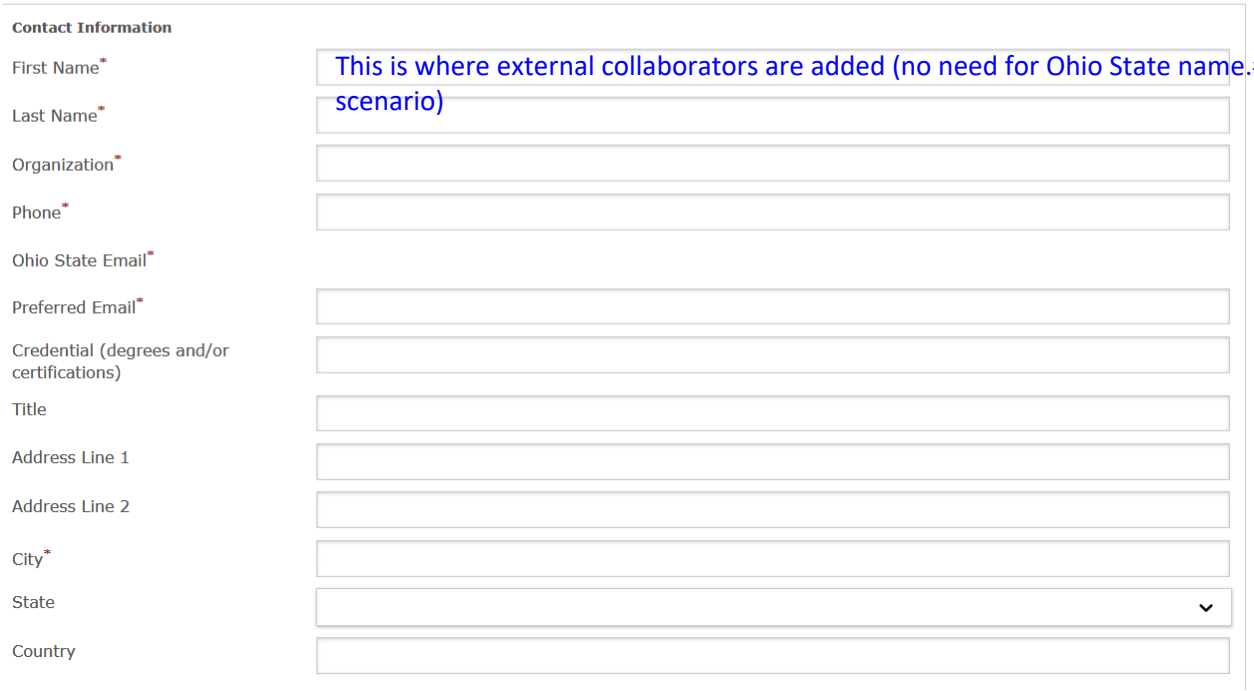


External Collaborators page (Covers both Ohio State lead site or not lead):

List only non-Ohio State personnel for whom the Ohio State IRB will serve as the IRB of Record







This is where external collaborators are added (no need for Ohio State name.# in this scenario)

Research Involvement

Study team designation*

- ○ Co-Investigator
- ○ Key Personnel

Research role/activities performed for study*

Make sure activities checked are consistent with the type of study activities taking place.

- ☐ Protocol development/study design
- ☐ Recruitment
- ☐ Assess participant eligibility
- ☐ Obtain consent/parental permission/assent
- ☐ Interview participants/administer surveys
- ☐ Process biological specimens
- ☐ Conduct follow-up visits
- ☐ Data collection/entry/coding
- ☐ Data analysis/interpretation
- ☐ Reporting results
- ☐ Manuscript preparation
- ☐ Maintain regulatory documentation
- ☐ Access participant Protected Health Information (PHI)

Other activity description

Provide the external collaborator's resume/CV. This document is required in order for a reliance agreement to be drafted. Provide the external agreement when directed by ORRP staff. Contact ORRP with questions.

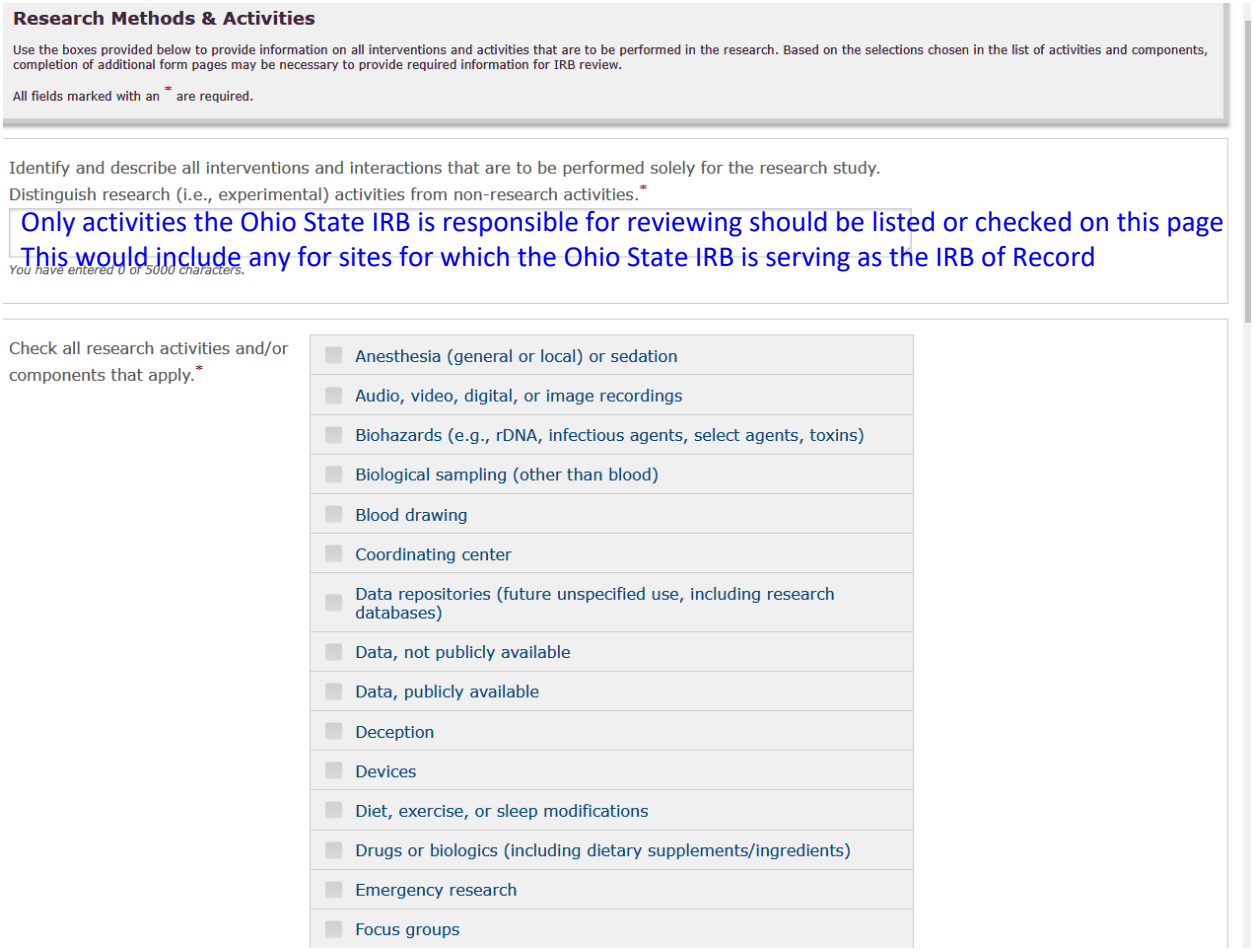
UPLOADED FILES

No files have been uploaded.

CV not needed in this scenario.

Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

Research Methods & Activities page (Covers both Ohio State lead site or not lead):



Research Methods & Activities

Use the boxes provided below to provide information on all interventions and activities that are to be performed in the research. Based on the selections chosen in the list of activities and components, completion of additional form pages may be necessary to provide required information for IRB review.

All fields marked with an * are required.

Identify and describe all interventions and interactions that are to be performed solely for the research study. Distinguish research (i.e., experimental) activities from non-research activities.*

Only activities the Ohio State IRB is responsible for reviewing should be listed or checked on this page
This would include any for sites for which the Ohio State IRB is serving as the IRB of Record

You have entered 0 of 5000 characters.

Check all research activities and/or components that apply.*

- Anesthesia (general or local) or sedation
- Audio, video, digital, or image recordings
- Biohazards (e.g., rDNA, infectious agents, select agents, toxins)
- Biological sampling (other than blood)
- Blood drawing
- Coordinating center
- Data repositories (future unspecified use, including research databases)
- Data, not publicly available
- Data, publicly available
- Deception
- Devices
- Diet, exercise, or sleep modifications
- Drugs or biologics (including dietary supplements/ingredients)
- Emergency research
- Focus groups

- [ ] Focus groups
- [ ] Food supplements
- [ ] Gene transfer
- [ ] Genetic testing
- [ ] Internet or e-mail data collection
- [ ] Magnetic resonance imaging (MRI)
- [ ] Materials that may be considered sensitive, offensive, threatening, or degrading
- [ ] Non-invasive medical procedures (e.g., EKG, Doppler)
- [ ] Observation of participants (including field notes)
- [ ] Oral history (does not include dental or medical history)
- [ ] Placebo
- [ ] Pregnancy testing
- [ ] Program Protocol (Umbrella Protocol)
- [ ] Radiation (e.g., CT or DEXA scans, X-rays, nuclear medicine procedures)
- [ ] Randomization
- [ ] Record review (which may include PHI)
- [ ] Specimen research
- [ ] Stem cell research
- [ ] Storage of biological materials (future unspecified use, including repositories)
- [ ] Surgical procedures (including biopsies)
- [ ] Surveys, questionnaires, or interviews (group)
- [ ] Surveys, questionnaires, or interviews (one-on-one)

Provide data collection forms, subject material, subject diaries, and/or other instruments, if applicable. Do not include case report forms for multi-site industry-initiated or cooperative group studies.

UPLOADED FILES

No files have been uploaded.

Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

SELECT FILES

Provide surveys, questionnaires, if applicable.

UPLOADED FILES

No files have been uploaded.

Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

SELECT FILES

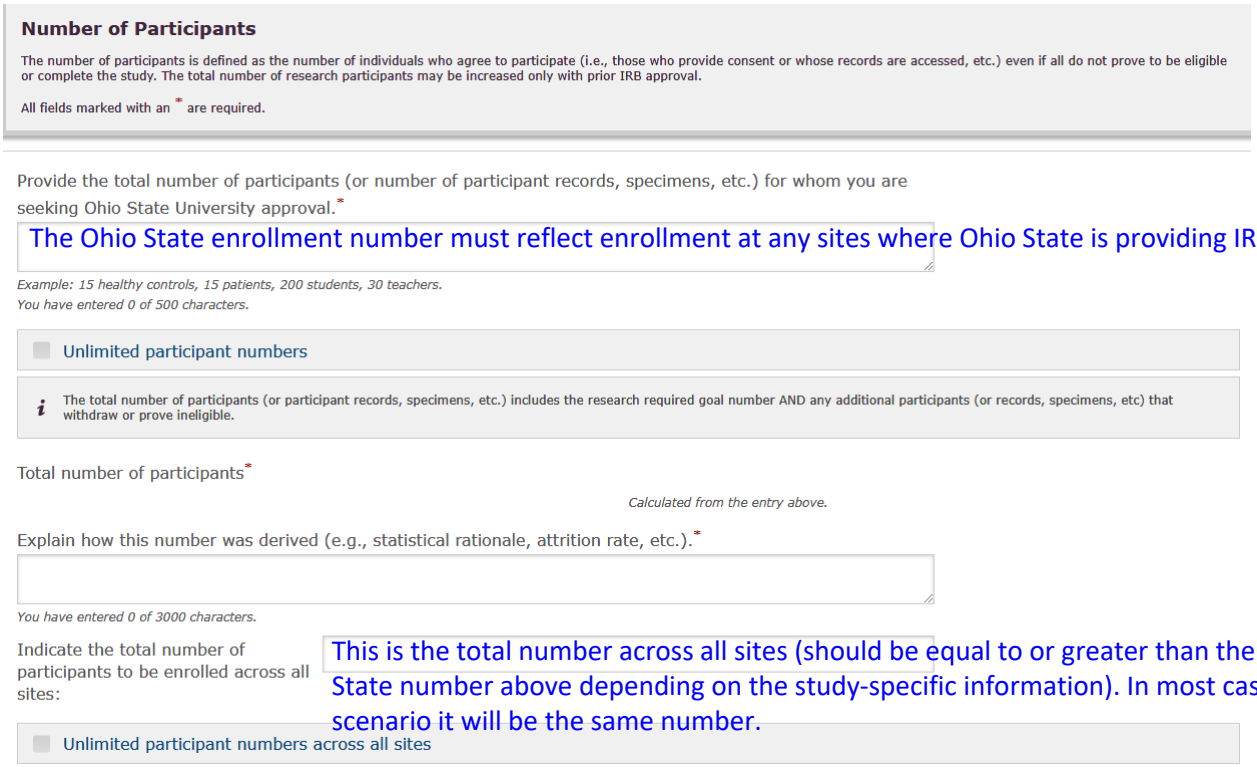
Provide subject information, such as newsletters, instruction sheets, appointment reminder cards, drug/device information, if applicable.

UPLOADED FILES

No files have been uploaded.

Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

Number of Participants page (Covers both Ohio State lead site or not lead):



Number of Participants

The number of participants is defined as the number of individuals who agree to participate (i.e., those who provide consent or whose records are accessed, etc.) even if all do not prove to be eligible or complete the study. The total number of research participants may be increased only with prior IRB approval.

All fields marked with an * are required.

Provide the total number of participants (or number of participant records, specimens, etc.) for whom you are seeking Ohio State University approval.*

The Ohio State enrollment number must reflect enrollment at any sites where Ohio State is providing IRB oversight

Example: 15 healthy controls, 15 patients, 200 students, 30 teachers.
You have entered 0 of 500 characters.

☐ Unlimited participant numbers

i The total number of participants (or participant records, specimens, etc.) includes the research required goal number AND any additional participants (or records, specimens, etc) that withdraw or prove ineligible.

Total number of participants*

Calculated from the entry above.

Explain how this number was derived (e.g., statistical rationale, attrition rate, etc.).*

You have entered 0 of 3000 characters.

Indicate the total number of participants to be enrolled across all sites:

This is the total number across all sites (should be equal to or greater than the Ohio State number above depending on the study-specific information). In most cases in this scenario it will be the same number.

☐ Unlimited participant numbers across all sites

Participant Population page (Covers both Ohio State lead site or not lead):

Make sure this captures the population at any sites for which Ohio State is serving as the IRB of Record

Participant Population

All fields marked with an * are required.

Specify the age(s) of the individuals who may be included in the research:*

If multiple age ranges are required, separate them with a comma. Example: 20-24 years, 40-45 years.

Specify the participant population(s). Check all participant groups that apply.*

- [ ] Adults
- [ ] Adults with decisional impairment
- [ ] Children
- [ ] Neonates (uncertain viability/nonviable)
- [ ] Non-English speaking
- [ ] Pregnant women/fetuses – only if pregnant women will be intentionally recruited and/or studied.
- [ ] Prisoners
- [ ] Student research pools (e.g., psychology, linguistics)
- [ ] Unknown (e.g., research using secondary data/specimens, non-targeted surveys, program protocols)

Describe the characteristics of the proposed participants, and explain how the nature of the research requires/justifies their inclusion.*

You have entered 0 of 3000 characters.

Will any participants be excluded based on age, gender, race/ethnicity, pregnancy status, language, education, or financial status?*

Yes | No

Are any of the participants likely to be vulnerable to coercion or undue influence?*

Yes | No

Consider students, employees, terminally ill persons, or others who may have limited autonomy.

Participant Identification page (Covers both Ohio State lead site or not lead):

Make sure this captures the recruitment process for any sites for which Ohio State is serving as the IRB of record

Participant Identification, Recruitment and Selection

All fields marked with an * are required.

Participant Identification

Provide evidence that you will be able to recruit the necessary number of participants to complete the study.*

You have entered 0 of 3000 characters.

Describe how potential participants will be identified (e.g., advertising, individuals known to the investigators, record review). Explain how the investigator(s) will gain access to this population, as applicable.*

You have entered 0 of 3000 characters.

Participant Recruitment and Selection

Select investigator(s) and/or key personnel who will recruit participants or identify records and/or specimens.*

- [ ] Michael Donovan

If the study team member is not listed here, please make sure to include them in the Study Team section of this form.

Describe the process that will be used to determine participant eligibility.*

You have entered 0 of 3000 characters.

Describe the recruitment process, including the setting in which recruitment will take place. Enter 'not applicable' if the research involves only record review and no participant interaction.*

You have entered 0 of 3000 characters.

⚠ The final versions of recruitment materials will be required before IRB approval.

Explain how the recruitment process respects potential participants' privacy.*

You have entered 0 of 3000 characters.

Provide copies of proposed recruitment materials (e.g., ads, fliers, website postings, and recruitment letters).

UPLOADED FILES

No files have been uploaded.

Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

SELECT FILES

Provide copies of consent materials used during the recruitment process (e.g., oral/written scripts).

UPLOADED FILES

No files have been uploaded.

Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

SELECT FILES

Informed Consent Process page (Covers both Ohio State lead site or not lead):

Make sure this captures the consent process for any sites for which Ohio State is serving as the IRB of record. The sub-site consent form(s) belong on the Location of Research page; only the Ohio State consent form is uploaded on this page.

Informed Consent Process

All fields marked with an * are required.

See Consent for Research for templates, HRPP policies Informed Consent Process and the Elements of Informed Consent, Documentation of the Informed Consent Process and Assent and Parental Permission or contact ORRP for more information.

Indicate the consent process(es) to be used in the study. Check all that apply.*

- [ ] Informed Consent - Form
- [ ] Informed Consent - Verbal Script/Online
- [ ] Informed Consent – Addendum
- [ ] Alteration of Consent Process
- [ ] Alteration of Parental Permission
- [ ] Assent - Form
- [ ] Debriefing Script
- [ ] Assent - Verbal Script/Online
- [ ] Parental Permission - Form
- [ ] Parental Permission - Verbal Script/Online
- [ ] Translated Consent/Assent - Form(s)
- [ ] Waiver of Assent
- [ ] Waiver of Consent Process
- [ ] Waiver of Consent Documentation
- [ ] Waiver of Parental Permission
- [ ] Waiver of Parental Permission Documentation

Select the investigator(s) and/or key personnel who will obtain consent from participants or their legally authorized representatives.*

- [ ] None
- [ ] Michael Donovan

If the study team member is not listed here, please make sure to include them in the Study Team section of this form.

Who will provide consent or permission (i.e., participant, legally authorized representative, parent and/or guardian)?*

You have entered 0 of 3000 characters.

- [ ] Not Applicable

Describe the consent process. Explain when and where consent will be obtained and how subjects and/or their legally authorized representatives will be provided sufficient opportunity (e.g., waiting period, if any) to consider participation.*

You have entered 0 of 3000 characters.

- [ ] Not Applicable

Explain how the possibility of coercion or undue influence will be minimized in the consent process.*

You have entered 0 of 3000 characters.

- [ ] Not Applicable

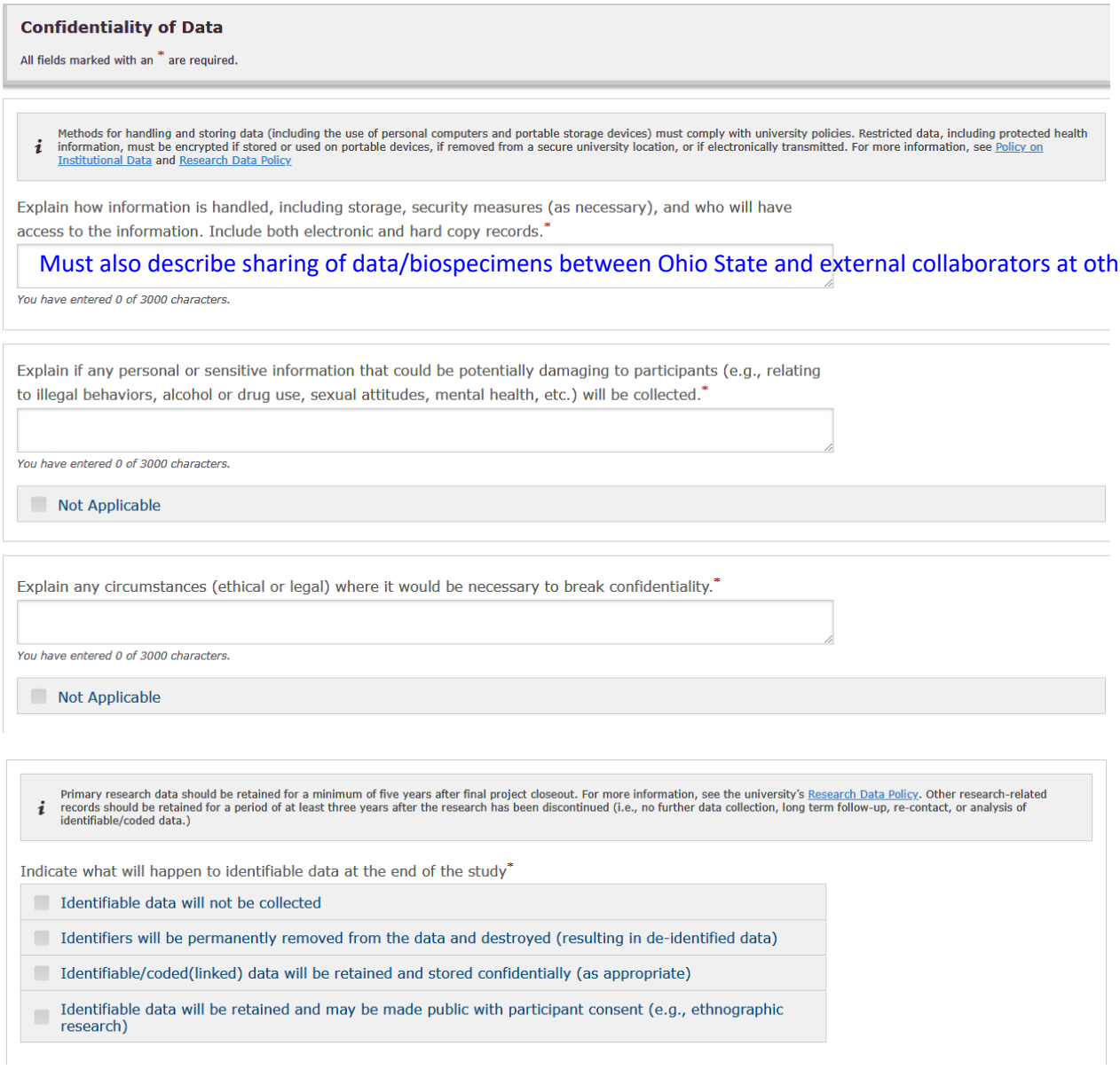
Will any other tools (e.g., quizzes, visual aids, information sheets) be used during the consent process to assist participant comprehension?*

Yes | No

Will any other consent forms be used (e.g., for clinical procedures such as MRI, surgery, etc.)?*

Yes | No

Confidentiality of Data page (Covers both Ohio State lead site or not lead):



Confidentiality of Data

All fields marked with an * are required.

Methods for handling and storing data (including the use of personal computers and portable storage devices) must comply with university policies. Restricted data, including protected health information, must be encrypted if stored or used on portable devices, if removed from a secure university location, or if electronically transmitted. For more information, see Policy on Institutional Data and Research Data Policy

Explain how information is handled, including storage, security measures (as necessary), and who will have access to the information. Include both electronic and hard copy records.*

Must also describe sharing of data/biospecimens between Ohio State and external collaborators at other sites

You have entered 0 of 3000 characters.

Explain if any personal or sensitive information that could be potentially damaging to participants (e.g., relating to illegal behaviors, alcohol or drug use, sexual attitudes, mental health, etc.) will be collected.*

You have entered 0 of 3000 characters.

Not Applicable

Explain any circumstances (ethical or legal) where it would be necessary to break confidentiality.*

You have entered 0 of 3000 characters.

Not Applicable

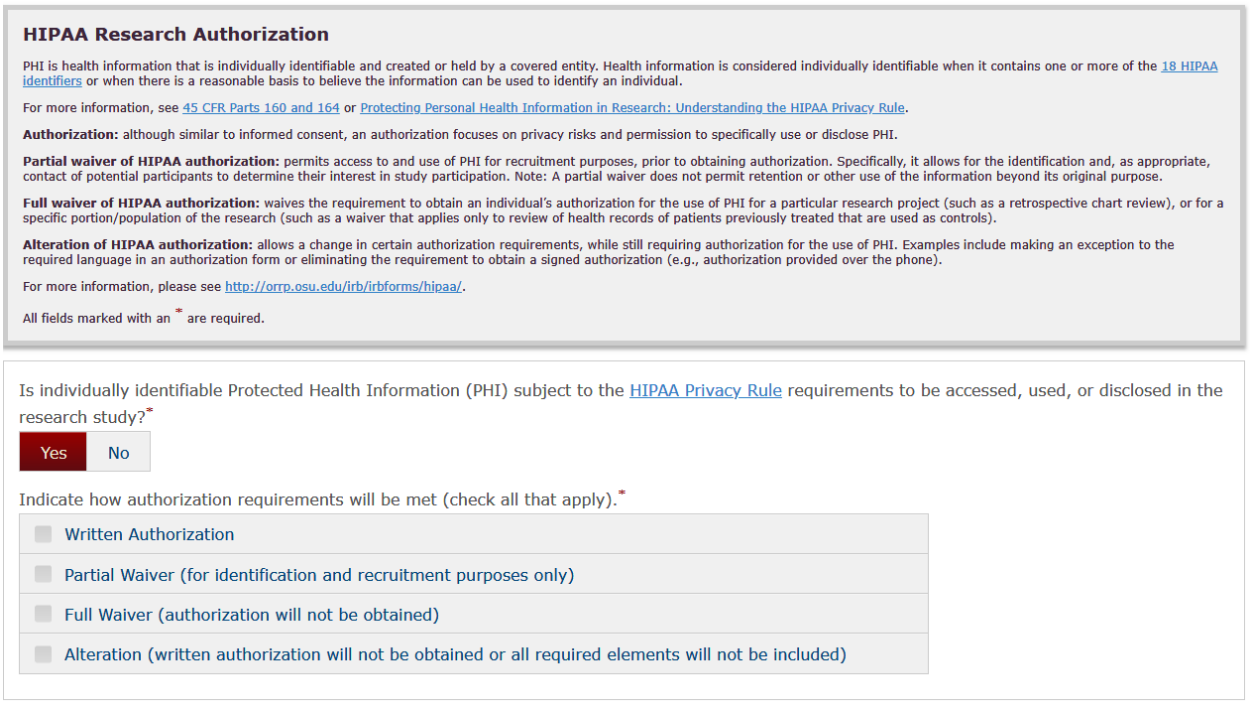
Primary research data should be retained for a minimum of five years after final project closeout. For more information, see the university's Research Data Policy. Other research-related records should be retained for a period of at least three years after the research has been discontinued (i.e., no further data collection, long term follow-up, re-contact, or analysis of identifiable/coded data.)

Indicate what will happen to identifiable data at the end of the study*

- Identifiable data will not be collected
- Identifiers will be permanently removed from the data and destroyed (resulting in de-identified data)
- Identifiable/coded(linked) data will be retained and stored confidentially (as appropriate)
- Identifiable data will be retained and may be made public with participant consent (e.g., ethnographic research)

HIPAA Research Authorization (If applicable; Covers both Ohio State lead site or not lead):

If applicable, this should also address any sites for which Ohio State is serving as the IRB of record



HIPAA Research Authorization

PHI is health information that is individually identifiable and created or held by a covered entity. Health information is considered individually identifiable when it contains one or more of the 18 HIPAA identifiers or when there is a reasonable basis to believe the information can be used to identify an individual.

For more information, see 45 CFR Parts 160 and 164 or Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule.

Authorization: although similar to informed consent, an authorization focuses on privacy risks and permission to specifically use or disclose PHI.

Partial waiver of HIPAA authorization: permits access to and use of PHI for recruitment purposes, prior to obtaining authorization. Specifically, it allows for the identification and, as appropriate, contact of potential participants to determine their interest in study participation. Note: A partial waiver does not permit retention or other use of the information beyond its original purpose.

Full waiver of HIPAA authorization: waives the requirement to obtain an individual's authorization for the use of PHI for a particular research project (such as a retrospective chart review), or for a specific portion/population of the research (such as a waiver that applies only to review of health records of patients previously treated that are used as controls).

Alteration of HIPAA authorization: allows a change in certain authorization requirements, while still requiring authorization for the use of PHI. Examples include making an exception to the required language in an authorization form or eliminating the requirement to obtain a signed authorization (e.g., authorization provided over the phone).

For more information, please see http://orrp.osu.edu/irb/irbforms/hipaa/.

All fields marked with an * are required.

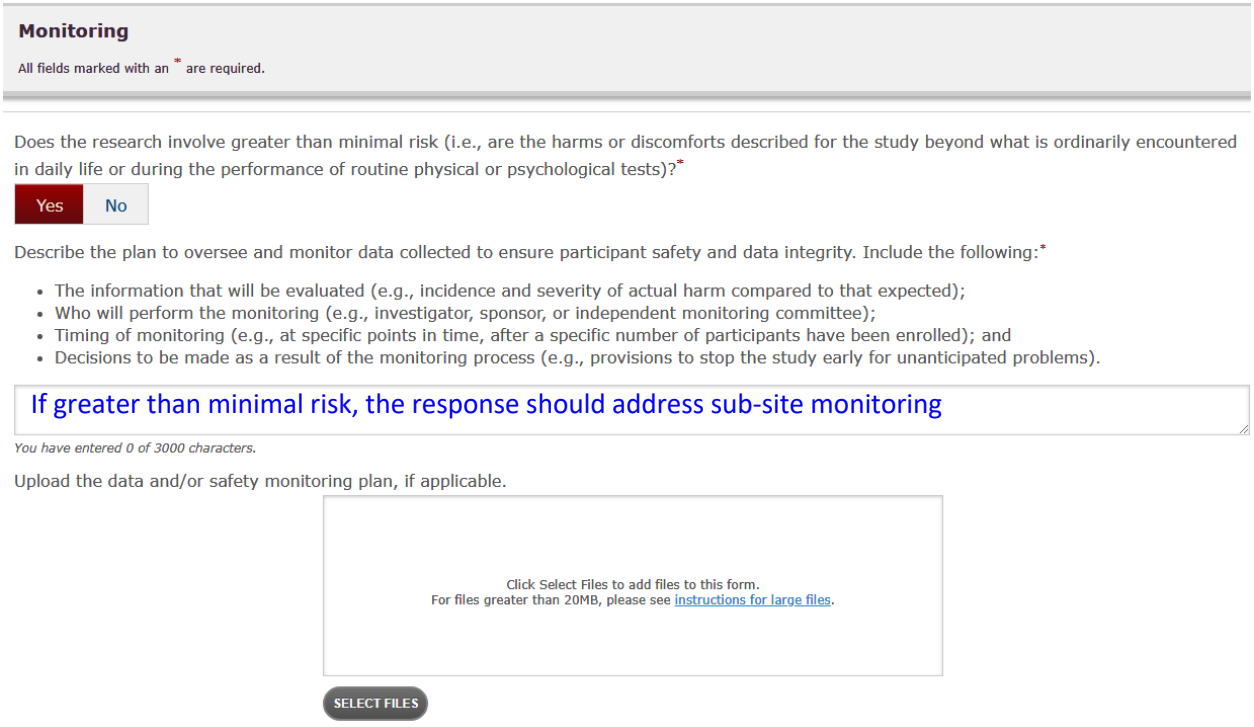
Is individually identifiable Protected Health Information (PHI) subject to the HIPAA Privacy Rule requirements to be accessed, used, or disclosed in the research study?*

Yes | No

Indicate how authorization requirements will be met (check all that apply).*

- ☐ Written Authorization
- ☐ Partial Waiver (for identification and recruitment purposes only)
- ☐ Full Waiver (authorization will not be obtained)
- ☐ Alteration (written authorization will not be obtained or all required elements will not be included)

Monitoring page (if greater than minimal risk; Covers both Ohio State lead site or not lead):



Monitoring

All fields marked with an * are required.

Does the research involve greater than minimal risk (i.e., are the harms or discomforts described for the study beyond what is ordinarily encountered in daily life or during the performance of routine physical or psychological tests)?*

Yes | No

Describe the plan to oversee and monitor data collected to ensure participant safety and data integrity. Include the following:*

- The information that will be evaluated (e.g., incidence and severity of actual harm compared to that expected);
- Who will perform the monitoring (e.g., investigator, sponsor, or independent monitoring committee);
- Timing of monitoring (e.g., at specific points in time, after a specific number of participants have been enrolled); and
- Decisions to be made as a result of the monitoring process (e.g., provisions to stop the study early for unanticipated problems).

If greater than minimal risk, the response should address sub-site monitoring

You have entered 0 of 3000 characters.

Upload the data and/or safety monitoring plan, if applicable.

Click Select Files to add files to this form.
For files greater than 20MB, please see instructions for large files.

SELECT FILES