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.
Is Ohio State a SUB-RECIPIENT of federal funding?

Will external personnel actively OBTAIN INFORMED CONSENT from human subjects for the research?

Will external personnel INTERVENE with research participants by performing invasive or non-invasive procedures or by manipulating subjects' environment?

Will external personnel INTERACT for research purposes with any human subjects for the research? (e.g., conducting interviews, administering questionnaires, engaging in protocol-dictated communication)

Will activities be LIMITED TO:
- informing prospective subjects about the project;
- providing prospective subjects with information about the research and/or investigators' contact information;
- OR
- seeking or obtaining prospective subjects' permission for investigators to contact them?

Do the interventions/interactions performed by external personnel meet the definition of a COMMERCIAL SERVICE?
For an activity to be considered a commercial service, all of the following must be true:
- the external personnel will not receive professional recognition or publication privileges for the services provided;
- the external personnel typically perform the services for non-research purposes;
- AND
- the external personnel will not administer any intervention being tested or evaluated under the protocol

Will external personnel RELEASE existing, identifiable materials (private information or biological specimens) to the external personnel, in the study?
(e.g., schools that release identifiable test scores; hospitals that release identifiable human biological specimens)

Will external personnel COLLECT or OBTAIN identifiable materials (private information or biological specimens) from any source for the research?
(e.g., observing or recording private behavior; using, studying, or analyzing identifiable materials provided by another institution or materials already in possession of the investigators)

Will the identifiable materials be CODED?

Will external personnel have access to the CODE KEY?

STOP External personnel are NOT ENGAGED

STOP Primary awardee institution is engaged

STOP External personnel ARE engaged*

Besides releasing materials, will the external personnel be involved in the Ohio State research IN ANY OTHER WAY, including but not limited to analyzing data or receiving authorship credit/professional recognition?

Will external personnel have access to the CODE KEY?

DUA/MTA required prohibiting release of code key to external personnel

* 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.
DECISION TREE:
COLLABORATIVE RESEARCH SCENARIOS

Are external personnel involved in the research?

No

Yes

Are external personnel ENGAGED* in non-exempt human subjects research?

No

Yes

Are external personnel affiliated with Ohio State (OSU Physicians, Inc., visiting scholar, adjunct professor)?

No

Yes

Are they acting as an employee or agent of another institution/organization?

No

Yes

Individual Investigator Agreement (IIA)

Does their institution/organization have a Federalwide Assurance (FWA)?

No

Yes

Will their institution/organization receive a federal subaward flowing through Ohio State?

No

Yes

Site must obtain FWA

Will Ohio State serve as the IRB of Record for the external institution?

No

Yes


Is Ohio State the lead site?

No

Yes

Will subjects be recruited or enrolled at the external site?

No

Yes


Scenario 1

Scenario 2

Scenario 3

Scenario 4

Scenario 5

Scenario 6

Scenario 7

Scenario 8

* 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

<table>
<thead>
<tr>
<th>Flowchart Scenario #</th>
<th>Description</th>
<th>Collaborative Research Agreement Type</th>
<th>Buck-IRB Application Pages</th>
<th>Documents Required</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scenario 1</strong></td>
<td>External individuals/institutions receive de-identified or coded (without code key) data and/or biospecimens; site is not engaged</td>
<td>No reliance agreement required</td>
<td>• Not applicable – does not need to be noted in application</td>
<td>• Not applicable</td>
</tr>
<tr>
<td><strong>Scenario 2</strong></td>
<td>Ohio State personnel conduct off-site research; site is not engaged</td>
<td>No reliance agreement required</td>
<td>• Location of Research</td>
<td>• Letter of Support</td>
</tr>
<tr>
<td><strong>Scenario 3</strong></td>
<td>External institution is primary awardee of federal funds but no human subject research activities occurring at external institution; Ohio State is IRB of record</td>
<td>IRB Authorization Agreement (IAA)</td>
<td>• Multi-Site Study</td>
<td>• Grant application</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ORRP will coordinate agreement process</td>
<td>• Location of Research</td>
<td>• Ohio State ICF &amp; HIPAA*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• External Collaborators</td>
<td>• Executed IAA**</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>o List PI named on grant application</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Funding</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Number of Participants</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>o Multi-site accrual number should match Ohio State number of participants</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Confidentiality of Data</td>
<td></td>
</tr>
<tr>
<td><strong>Scenario 4</strong></td>
<td>Ohio State provides IRB oversight for engaged individual</td>
<td>Individual Investigator Agreement (IIA)</td>
<td>• Location of Research</td>
<td>• CV/résumé</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ORRP will coordinate agreement process</td>
<td>o If research is occurring at a location that is not engaged/does not have a Federalwide Assurance</td>
<td>• Letter of Support, if applicable</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• External Collaborators</td>
<td>• Executed IIA**</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>o Add collaborator with Ohio State name.# lookup tool</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>▪ Human research protections training (CITI)</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>▪ Responsible Conduct of Research training (CITI)</td>
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<td></td>
<td></td>
<td></td>
<td>▪ eCOI disclosure</td>
<td></td>
</tr>
</tbody>
</table>

* If applicable, document must reflect collaboration  ** ORRP Reliance Team facilitates
### Buck-IRB Cheat Sheet: Collaborative Research

**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

**Documents Required**
- 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

**Documents Required**
- 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)

**ORRP will coordinate agreement process**

- Multi-Site Study
- Location of Research
- External Collaborators
- Research Methods and Activities
- Number of Participants
- Confidentiality of Data

**Documents Required**
- 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

**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)

**Documents Required**
- 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**
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.

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location name(description)*</td>
<td>Domestic location listed here</td>
</tr>
<tr>
<td>Address line 1</td>
<td></td>
</tr>
<tr>
<td>Address line 2</td>
<td></td>
</tr>
<tr>
<td>City</td>
<td></td>
</tr>
<tr>
<td>State</td>
<td></td>
</tr>
<tr>
<td>Indicate who is performing research activities at this location:*</td>
<td>Ohio State personnel only</td>
</tr>
</tbody>
</table>

**Approval documents**

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

**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.

<table>
<thead>
<tr>
<th>Location name/description*</th>
</tr>
</thead>
<tbody>
<tr>
<td>List institution of external collaborator here</td>
</tr>
</tbody>
</table>

You have entered 0 of 500 characters.

<table>
<thead>
<tr>
<th>Address line 1</th>
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</table>

<table>
<thead>
<tr>
<th>Address line 2</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>City</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>State</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Indicate who is performing research activities at this location:*</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Ohio State personnel only</td>
</tr>
<tr>
<td>☐ Site personnel only</td>
</tr>
<tr>
<td>☐ Both Ohio State and site personnel</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Potential activities for this location (check all that apply):*</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Protocol development/study design</td>
</tr>
<tr>
<td>☐ Participant recruitment</td>
</tr>
<tr>
<td>☐ Obtaining consent/parental permission/assent</td>
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<td>☐ Research interventions and subject interactions (administer questionnaires/interviews/surveys)</td>
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<td>☐ Specimen collection</td>
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<td>☐ Data collection/entry/coding</td>
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<tr>
<td>☐ Access participant protected health information (PHI)</td>
</tr>
<tr>
<td>☐ Manuscript preparation</td>
</tr>
<tr>
<td>☐ Reporting results</td>
</tr>
<tr>
<td>☐ Coordinating center</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other activity description</th>
</tr>
</thead>
<tbody>
<tr>
<td>The description in the Other text box should be &quot;primary awardee&quot; or &quot;funding recipient only&quot; or something along those lines</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Will this location use Ohio State as the IRB of record:*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>This should be Yes</td>
</tr>
</tbody>
</table>
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.

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.

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.
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 [IRB Engagement Guidance](https://research.osu.edu) or contact IRBP at [research@osu.edu](mailto:research@osu.edu) or 614-688-9157 for more information.

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

All fields marked with an "*" are required.

### 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](https://research.osu.edu) 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, IRBP staff will work with the investigator to execute any necessary agreements for the addition of this external collaborator.

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Person search*</td>
<td>Please enter the full name or last name 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.</td>
</tr>
</tbody>
</table>

---

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

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

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

Look up a sponsor by name. If a sponsor to be added does not appear in the search, please contact ORBP 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.

- **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.

**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 Exercise and policy.

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):

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

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:

- Unlimited participant numbers 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).
Confidentiality of Data page:

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.**

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.

[Not Applicable]

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

[Not Applicable]

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:

| 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 CNRP Engagement Guidance or contact ORR at labarements@osu.edu or 614-688-8457 for more information. |  |  |
| All fields marked with an * are required. |  |  |

**OHIO STATE APPROVED RESEARCH SITES**  
You have listed no Ohio State approved research sites.

**DOMESTIC RESEARCH SITES – NON-OHIO STATE LOCATIONS**  
You have listed no alternate domestic research sites.

**INTERNATIONAL RESEARCH SITES**  
You have listed no international research sites.

- **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**  
Only list location of external collaborator if activities are occurring at their non-Ohio State location

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
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 IRB Engagement Guidance or contact DRIP at T: (614) 247-6677 or 614-688-9457 for more information.

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

All fields marked with an * are required.

EXTERNAL COLLABORATORS
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, DRIP 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 last name 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
Make sure activities checked are consistent with the type of study activities taking place.

### 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)

#### 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.

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

<table>
<thead>
<tr>
<th>Location name/description*</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Address line 1</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Address line 2</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>City</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>State</th>
</tr>
</thead>
</table>

| Indicate who is performing research activities at this location:* |

<table>
<thead>
<tr>
<th>Ohio State personnel only</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Site personnel only</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Both Ohio State and site personnel</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>Protocol development/study design</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Participant recruitment</th>
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<table>
<thead>
<tr>
<th>Obtaining consent/parental permission/assent</th>
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<table>
<thead>
<tr>
<th>Research interventions and subject interactions (administer questionnaires/interviews/surveys)</th>
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<table>
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<th>Specimen collection</th>
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<tr>
<th>Access participant protected health information (PHI)</th>
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<table>
<thead>
<tr>
<th>Manuscript preparation</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Reporting results</th>
</tr>
</thead>
</table>
Study Personnel page: Make sure non-Ohio State personnel are not listed on this page
Only activities the Ohio State IRB is responsible for reviewing should be listed or checked on this page.
<table>
<thead>
<tr>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focus groups</td>
</tr>
<tr>
<td>Food supplements</td>
</tr>
<tr>
<td>Gene transfer</td>
</tr>
<tr>
<td>Genetic testing</td>
</tr>
<tr>
<td>Internet or e-mail data collection</td>
</tr>
<tr>
<td>Magnetic resonance imaging (MRI)</td>
</tr>
<tr>
<td>Materials that may be considered sensitive, offensive, threatening,</td>
</tr>
<tr>
<td>or degrading</td>
</tr>
<tr>
<td>Non-invasive medical procedures (e.g., EKG, Doppler)</td>
</tr>
<tr>
<td>Observation of participants (including field notes)</td>
</tr>
<tr>
<td>Oral history (does not include dental or medical history)</td>
</tr>
<tr>
<td>Placebo</td>
</tr>
<tr>
<td>Pregnancy testing</td>
</tr>
<tr>
<td>Program Protocol (Umbrella Protocol)</td>
</tr>
<tr>
<td>Radiation (e.g., CT or DEXA scans, X-rays, nuclear medicine</td>
</tr>
<tr>
<td>procedures)</td>
</tr>
<tr>
<td>Randomization</td>
</tr>
<tr>
<td>Record review (which may include PHI)</td>
</tr>
<tr>
<td>Specimen research</td>
</tr>
<tr>
<td>Stem cell research</td>
</tr>
<tr>
<td>Storage of biological materials (future unspecified use, including</td>
</tr>
<tr>
<td>repositories)</td>
</tr>
<tr>
<td>Surgical procedures (including biopsies)</td>
</tr>
<tr>
<td>Surveys, questionnaires, or interviews (group)</td>
</tr>
<tr>
<td>Surveys, questionnaires, or interviews (one-on-one)</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>SELECT FILES</th>
<th>UPLOADED FILES</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No files have been uploaded.</td>
</tr>
</tbody>
</table>

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

Provide surveys, questionnaires, if applicable.

<table>
<thead>
<tr>
<th>SELECT FILES</th>
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</thead>
<tbody>
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<td>No files have been uploaded.</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
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</tbody>
</table>

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:

- ✔️ Unlimited participant numbers 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)
Confidentiality of Data page:

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

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.*

Not Applicable

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

Not Applicable

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.  

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

Lead site is listed here. For cooperative group studies, list group name.

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.

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 Guidance or contact OHRP at hhs.gov or 814-688-8457 for more information.

All fields marked with an * are required.

OHIO STATE APPROVED RESEARCH SITES
You have listed no Ohio State approved research sites.

DOMESTIC RESEARCH SITES – NON-OHIO STATE LOCATIONS
You have listed no alternate domestic research sites.

INTERNATIONAL RESEARCH SITES
You have listed no international research sites.
Study Personnel page: Make sure non-Ohio State personnel are not listed on this page

The individual entering the new study will automatically be entered as an additional contact (if not designated as the principal investigator). This individual must click the edit icon to edit his/her role if an additional role (i.e., co-investigator or key personnel) is also applicable.

Number of Participants page:

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

Example: 13 healthy controls, 15 patients, 200 students, 30 teachers.
You have entered 0 of 500 characters.

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)
Confidentiality of Data page:

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

<table>
<thead>
<tr>
<th>Multi-site Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multi-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.</td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>Is this a multi-site study?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Is the Ohio State PI the lead investigator or is Ohio State the lead site for collaborative research?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Will Ohio State be IRB of record for any other institution/location?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

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**

Multi-site 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.
- Ohio State is the lead institution of a research project, where one or more other institutions are 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?*

Is the Ohio State PI the lead investigator or is Ohio State the lead site for collaborative research?*

Will Ohio State be IRB of record for any other institution/location?*

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.

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

**Lead site is listed here**

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

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

  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 *
  
  If Ohio State is the lead site, list ALL sub-sites. If Ohio State is not the lead, then only list the external sites for which Ohio State will be serving as the IRB of record. If Ohio State will be receiving the data and writing manuscripts, Ohio State is likely the lead site.

  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

  Will this location use Ohio State as the IRB of record? *
  
  Yes  No

  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.

  ORRP will upload the final IRB Authorization Agreement here prior to IRB review.

  Click Select Files to add files to this form. For files greater than 20MB, please see instructions for large files.
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)
Make sure activities checked are consistent with the type of study activities taking place.
Research Methods & Activities page (Covers both Ohio State lead site or not lead):

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.

<table>
<thead>
<tr>
<th>Check all research activities and/or components that apply.</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Anesthesia (general or local) or sedation</td>
</tr>
<tr>
<td>- Audio, video, digital, or image recordings</td>
</tr>
<tr>
<td>- Biohazards (e.g., rDNA, infectious agents, select agents, toxins)</td>
</tr>
<tr>
<td>- Biological sampling (other than blood)</td>
</tr>
<tr>
<td>- Blood drawing</td>
</tr>
<tr>
<td>- Coordinating center</td>
</tr>
<tr>
<td>- Data repositories (future unspecified use, including research databases)</td>
</tr>
<tr>
<td>- Data, not publicly available</td>
</tr>
<tr>
<td>- Data, publicly available</td>
</tr>
<tr>
<td>- Deception</td>
</tr>
<tr>
<td>- Devices</td>
</tr>
<tr>
<td>- Diet, exercise, or sleep modifications</td>
</tr>
<tr>
<td>- Drugs or biologics (including dietary supplements/ingredients)</td>
</tr>
<tr>
<td>- Emergency research</td>
</tr>
<tr>
<td>- Focus groups</td>
</tr>
<tr>
<td>Focus groups</td>
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<td>--------------------------------------</td>
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<td>Stem cell research</td>
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<td>Storage of biological materials (future unspecified use, including repositories)</td>
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<td>Surgical procedures (including biopsies)</td>
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<td>Surveys, questionnaires, or interviews (group)</td>
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<tr>
<td>Surveys, questionnaires, or interviews (one-on-one)</td>
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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.

<table>
<thead>
<tr>
<th>Select Files</th>
<th>Upload Files</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No files have been uploaded.</td>
</tr>
</tbody>
</table>

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

Provide surveys, questionnaires, if applicable.

<table>
<thead>
<tr>
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</tr>
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<tbody>
<tr>
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Provide subject information, such as newsletters, instruction sheets, appointment reminder cards, drug/device information, if applicable.

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

<table>
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<tbody>
<tr>
<td>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.</td>
</tr>
<tr>
<td>All fields marked with an * are required.</td>
</tr>
</tbody>
</table>

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 500 characters.

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

- [ ] Unlimited participant numbers 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.
Confidentiality of Data page (Covers both Ohio State lead site or not lead):

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

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.

Not Applicable

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

Not Applicable

Primary research data should be retained for a minimum of five years after final project closure. 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

<table>
<thead>
<tr>
<th><strong>Multi-site Study</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
<tr>
<td><strong>EXAMPLES OF MULTI-SITE RESEARCH:</strong></td>
</tr>
<tr>
<td>• 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.</td>
</tr>
<tr>
<td>• An Ohio State investigator is participating in a research project, where another institution is the lead institution.</td>
</tr>
<tr>
<td>• Ohio State is the IRB of record for one or more other sites participating in a research project.</td>
</tr>
<tr>
<td><strong>EXAMPLES OF NON-MULTI-SITE RESEARCH:</strong></td>
</tr>
<tr>
<td>• 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.</td>
</tr>
<tr>
<td>• 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.</td>
</tr>
</tbody>
</table>

All fields marked with an “*” are required.

<table>
<thead>
<tr>
<th><strong>Is this a multi-site study?</strong></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Is the Ohio State PI the lead investigator or is Ohio State the lead site for collaborative research?</strong></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td><strong>Will Ohio State be IRB of record for any other institution/location?</strong></td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

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**

Multi-site 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?*

Is the Ohio State PI the lead investigator or is Ohio State the lead site for collaborative research?*

Will Ohio State be IRB of record for any other institution/location?*

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.

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

**Lead site is listed here**

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

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

  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*
  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

  Will this location use Ohio State as the IRB of record?*
  Yes  No

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

  ORRP will upload the final IRB Authorization Agreement here prior to IRB review.
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.

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

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

**Study Personnel**

Enter all Ohio State study team members below. External collaborators will be entered on a different page. Study team members should only be listed in one category (i.e., PI, co-investigator, or key personnel).

Co-investigators and key personnel are defined as individuals who participate in the design, conduct, or reporting of human subjects research. At a minimum, include individuals who recruit participants, obtain consent, or who collect study data.

Additional contacts can also serve in another role on the project.

All individuals listed as Ohio State study team members will have access to all submitted information, including completion status of team members’ administrative and training requirements (CITI, COI disclosure), and may edit submissions on behalf of the principal investigator.

Electronic signatures are required of all Ohio State investigators named on the submission.

All fields marked with an "*" are required.

**STUDY TEAM**

You have listed no study personnel.

The individual entering the new study will automatically be entered as an additional contact (if not designated as the principal investigator). This individual must click the edit icon to edit his/her role if an additional role (i.e., co-investigator or key personnel) is also applicable.
### 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

#### 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 [ORIR Engagement Guidance](#) or contact ORIR at [irbproposals@osu.edu](mailto:irbproposals@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

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, ORIR staff will work with the investigator to execute any necessary agreements for the addition of this external collaborator.

Person search*

Please enter the full name or last name. # 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.

<table>
<thead>
<tr>
<th>Contact Information</th>
<th>This is where external collaborators are added (no need for Ohio State name. # in this scenario)</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name*</td>
<td></td>
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<tr>
<td>Last Name*</td>
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<tr>
<td>Organization*</td>
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<tr>
<td>Phone*</td>
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<tr>
<td>Ohio State Email*</td>
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<tr>
<td>Preferred Email*</td>
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<tr>
<td>Credential (degrees and/or certifications)</td>
<td></td>
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<tr>
<td>Title</td>
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<td>Address Line 1</td>
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<tr>
<td>Address Line 2</td>
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</tr>
<tr>
<td>City*</td>
<td></td>
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<tr>
<td>State</td>
<td></td>
</tr>
<tr>
<td>Country</td>
<td></td>
</tr>
</tbody>
</table>
**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)

**Other activity description**

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**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.
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.
| 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.

<table>
<thead>
<tr>
<th>SELECT FILES</th>
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</thead>
<tbody>
<tr>
<td><strong>UPLOADS</strong></td>
</tr>
<tr>
<td>No files have been uploaded.</td>
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<td><strong>SELECT FILES</strong></td>
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</tr>
</tbody>
</table>

Provide surveys, questionnaires, if applicable.

Provide subject information, such as newsletters, instruction sheets, appointment reminder cards, drug/device information, if applicable.
Number of Participants page (Covers both Ohio State lead site or not lead):

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

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**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.

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.

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.
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.

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)?

- 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.

- Not Applicable

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

- 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.

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 closure. 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

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**HIPAA Research Authorization**

HIPAA 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 **16 CFR Parts 160 and 164** or **Protection 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://www.osu.edu/irb/informs/hipaa/](http://www.osu.edu/irb/informs/hipaa/).

All fields marked with an "*" are required.

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**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)

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

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**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 unexpected 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.

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Click Select Files to add files to this form.

For files greater than 20MB, please see [instructions for large files](#).