

## IRB INITIAL SUBMISSION

### Study Identification

Title:

Principal Investigator: [look-up tool]

Study Department: [auto-fill or look-up tool]

### Type of Research

*Select the appropriate option below based on the type of review required for the research.*

**Exempt research:** *This option should be selected for research that involves human subjects that is not subject to regulations requiring IRB review and approval. Final determination is made by ORRP staff.*

**Expedited or full IRB-reviewed research:** *This option should be selected for review by the Biomedical Sciences, Behavioral and Social Sciences, or Cancer IRBs at Ohio State including research reviewed through either expedited or full board processes. This option should also be selected for any research which will be ceded to another non-Ohio State IRB, such as WIRB, NCI CIRB, or another external institution.*

**Don't know:** *This option should be selected if the investigator is uncertain whether the research is exempt or should be reviewed by an IRB.*

What type of review is required for your project?

- Exempt research  
*If Exempt selected, user taken to Exempt application*
- Expedited or full IRB-reviewed research (includes WIRB, NCI CIRB, and other external IRB review)  
*If Expedited or full IRB-reviewed research selected, user taken to Review Board page*
- Don't know (screening questions to determine if exempt research)  
*If Don't Know selected, user taken to Exempt Screening Questions page*

### Exempt Screening Questions

*Page displays only if "Don't Know" is selected on Type of Research page*

*Answer the following questions to help determine if your research potentially qualifies for exemption from federal regulations requiring IRB review. Please see [IRB Exemption Categories](#) for the list of exempt categories and their descriptions. Final determination will be made by designated ORRP staff.*

Will prisoners (or their data and/or specimens) be participants in the research? Yes/No

For research proposed under category 1, will the research be conducted outside of commonly accepted educational settings or deviate from normal educational practices? Yes/No/Not Applicable

For research proposed under category 2, will the research involve surveys or interview procedures with children? Yes/No/Not Applicable

For research proposed under category 2, will the research involve observations of the public behavior of children, during which an investigator participates in the activities being observed? Yes/No/Not Applicable

For research proposed under category 3, will benign behavioral interventions be conducted with children? Yes/No/Not Applicable

For research proposed under categories 1-5, is the research subject to FDA regulations? Yes/No/Not Applicable

## Review Board

*Research at Ohio State involving human subjects that requires Institutional Review Board (IRB) review is reviewed by one of three university IRBs or one of multiple external IRBs, including Western IRB (WIRB), National Cancer Institute Central IRB (CIRB), Ohio CTSA Consortium, and Nationwide Children’s Hospital (NCH) IRB. Board assignments are made to ensure that proposed research receives appropriate scientific or scholarly review by individuals with the qualifications to determine that the rights and welfare of research participants are protected. Final board assignment is determined by ORRP.*

*Selection of one of the three Ohio State IRBs below will connect to the initial review of human subjects research.*

*Selection of one of the external (non-Ohio State) IRBs will connect to an external review application which provides the necessary information for ORRP staff to perform pre-screening of the application to determine that institutional requirements have been met (e.g., COI disclosure, education) and that the research meets the conditions necessary to be forwarded for external IRB review. Final board assignment is determined by ORRP.*

Select the board to review this research.

- Ohio State Behavioral IRB
- Ohio State Biomedical IRB
- Ohio State Cancer IRB
- National Cancer Institute Central IRB (CIRB)
- Nationwide Children’s Hospital IRB
- Western IRB (WIRB)
- Ohio CTSA Consortium
- Quorum IRB
- Other external IRB

## 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.

Is this a multi-site study? Yes/No

*If Yes, asks question below and enables multi-site accrual goal question on Number of Participants page.*

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

*If Yes,*

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

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

*If No,*

Provide the name of the lead institution directing the research.  
Provide the IRB or ethics board approval from the lead institution, as applicable.  
[document upload box]

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

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

*If Yes and Ohio State is not the lead site,*

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

Location of Research
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*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 [irbinfo@osu.edu](mailto:irbinfo@osu.edu) or 614-688-8457 for more information.*

**Ohio State Approved Research Sites: [+ ADD SITE]**

**Domestic Research Sites:** [+ ADD SITE]

**International Research Sites:** [+ ADD SITE]

### Ohio State Approved Research Site

*Page displays each time corresponding [+ ADD SITE] button is selected.*

*Select the appropriate Ohio State approved research site by typing the building name or address in the search field below. If the specific Ohio State site is not listed, [contact ORRP](#) for assistance.*

*If you are adding a county extension office as a research location, enter the county name first when searching. If you are performing research in ALL county extension offices, select “Ohio State University Extension”.*

*To add a Columbus campus location, begin typing an academic building name below or enter “Ohio State Columbus Campus” in the search field and select that option when it appears.*

Search for a location [look-up tool]:

Address results auto-completed

### Non-Ohio State Domestic Research Site

*Page displays each time corresponding [+ ADD SITE] button is selected.*

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

Location name/description

Address line 1/Address line 2/City/State

#### **Approval Documents**

A letter of support and/or another IRB’s approval should be provided, as necessary. [Contact ORRP](#) for more information. [document upload box]

### International Research Site

*Page displays each time corresponding [+ ADD SITE] button is selected.*

*Provide information about the local context in which the research will be conducted. For more information, see HRPP policy [Research Performance Sites and Collaborative Off-Site Research](#).*

*Procedures:*

- *Determine if local research and/or ethics reviews are also required. If so, attach a copy of the approval/review.*
- *Provide local letters of support from host or participating organizations, if applicable.*

*For information about federal requirements for IRB review of international research, see [45 CFR 46.107](#) and the [OHRP International Program](#).*

*For a list of regulations, laws, and guidelines pertaining to international human subjects research for selected countries, see [International Compilation of Human Research Protections](#).*

*For information about international travel health, safety, and security, see [The Ohio State University Department of Public Safety and Office of International Affairs - International Travel Health and Safety](#).*

Location name and description

Local contact name/phone/email

List the language(s) in which the research will be conducted (list all applicable languages) [look-up tool]:

Is a team member fluent in the language of the potential participants? Yes/No

*If No*, Describe the provisions in place to provide translation services throughout the duration of the study.

Describe any cultural, political, religious, or other local influences that may affect conduct of the proposed research and how these will be addressed (e.g., issues posing potential threats, requiring changes in recruitment methods, etc.).

- Not Applicable [optional check-box]

Describe any local exceptions to the required consent process (e.g., the age at which legally effective informed consent can be provided, a request from an outsider to sign documents would be treated with suspicion based on customs, etc.). Provide a plan for addressing these differences.

- Not Applicable [optional check-box]

Will children be enrolled in the study? Yes/No

*If Yes*, Describe any local exceptions regarding the requirements for adult permission and child assent and how these will be addressed.

Will compensation be offered? Yes/No

*If Yes*, Provide the amount and explain its appropriateness for the setting.

Explain any benefits to the local community that will remain with the community once the research is complete.

Describe the researchers' training/experience with conducting research (or studying or residing) in the research setting, including any relationship(s) with the community from which participants will be recruited.

Provide contact details for two individuals who are **not affiliated** with the research (or researchers), are knowledgeable about the location and population, and could serve as a consultant(s) regarding the proposed research.

First consultant contact: Name/Title/Phone Email

Second consultant contact: Name/Title/Phone/Email

Describe communication and oversight plans between the IRB and the researchers(s) who will be on-site. *Note: Consider how issues will be handled that might be relevant to the protection of participants (e.g., unanticipated problems, complaints, noncompliance, etc.)*

Describe procedures for data storage in the local setting and for transfer of data to Ohio State.

Will the research involve medical procedures and/or treatment? Yes/No

*If Yes*,

Indicate if any planned research procedures are considered to be standard of care in the country or location

Describe provisions for emergency treatment that are available in the location.

Provide local research and/or ethics review approval and/or local letters of support, as applicable.  
[document upload box]

## 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, RCR, 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.*

### Study Team

[+ ADD NEW MEMBER]

*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.*

## New Study Team Member

*Page displays each time [+ ADD NEW MEMBER] button is selected.*

Team member search [look-up tool]:

Team member designation:

- Co-Investigator
- Key Personnel
- Additional Contact (receives study correspondence from ORRP)

*If 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

### 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](mailto:irbagreements@osu.edu) or 614-688-8457 for more information.*

#### External Collaborators

[+ ADD NEW COLLABORATOR]

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

*Page displays each time [+ ADD NEW COLLABORATOR] button is selected.*

*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: [look-up tool]

*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

*If collaborator does not have an OSU guest account, provide the following information*

First Name/Last Name/Organization

Phone/Email/Address/City/State/Country

## Research Involvement

Study team designation:

- Co-Investigator
- Key Personnel

Research role/activities performed for study:

- Protocol development/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 [text box]

## 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.*

Is the research funded or has funding been requested? Yes/No/Pending

*If Yes or Pending, Add a sponsor: [look-up tool]*

Is any support other than monetary (e.g., drugs, equipment, etc.) being provided for the study?  
Yes/No/Pending

*If Yes or Pending, Please specify the support and provider:*

Provide a copy of the grant application or funding proposal. [document upload box]

## 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 reasonable appear to be affected by the research. Select “none” if no financial conflicts exist.

- None
- [auto-populated list of team members]

## Expedited Review

*The Federal Regulations establish two main criteria for an expedited review:*

- The research may not involve more than "minimal risk." "Minimal risk" means that "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (45 CFR 46.102(i) and 21 CFR 56.102(i)).*
- The entire research project must be consistent with one or more of the federally defined categories.*

*The expedited review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.*

*The expedited review procedure may not be used for classified research involving human subjects. Investigators are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review (i.e., expedited or convened) utilized by the IRB.*

*Protocols involving the collection, storage, and/or distribution of data and/or specimens for future research uses do not qualify for expedited IRB review. Convened review is required.*

*For more information regarding the expedited review procedures, see the [Expedited Review Procedures](#) policy.*

Are you requesting Expedited Review? Yes/No

*If Yes, enables [Expedited Review Categories](#) page*

## Expedited Review Categories

*Page displays only if Expedited Review requested on previous page.*

*Select the appropriate category(ies) for expedited review that describe the proposed research. Check all that apply. If the research meets the conditions for expedited review, the review of the protocol will be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. See [45 CFR 46](#) and [21 CFR 56](#) for more information.*

*The categories in this list apply regardless of the age of the participants, except as noted.*

*Select ALL categories that apply.*

- **Apply for Category #1**

[If researchers have previously requested review by the Ohio State Behavioral IRB the box will not appear and instead the language "Category # 1 may not be used with Ohio State Behavioral and Social Sciences IRB" will appear]

Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

- a. Research on drugs for which an investigational new drug application ([21 CFR 312](#)) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
- b. Research on medical devices for which (i) an investigational device exemption application ([21 CFR 812](#)) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

- **Apply for Category #2**

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- a. From healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week.
- b. From other adults and children (defined as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. [45 CFR 46.402\(a\)](#)), considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

- **Apply for Category #3**

Prospective collection of biological specimens for research purposes by non-invasive means.

- a. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

- **Apply for Category #4**

Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

- a. Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- **Apply for Category #5**  
Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).  
*(NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)*
- **Apply for Category #6**  
Collection of data from voice, video, digital or image recordings made for research purposes.
- **Apply for Category #7**  
Research made on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.  
*(NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt.)*

<b>Institutional Approvals</b>
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*Check all that apply and provide applicable documentation.*

*See websites listed below for information on obtaining approvals. IRB review cannot be conducted until required institutional approvals or exemptions are obtained, except as noted.*

- No institutional approval
- [Comprehensive Cancer Center \(CCC\) Clinical Scientific Review Committee \(CSRC\)](#)  
Approval or exemption required prior to IRB review for all cancer-related research.
- [Institutional Biosafety Committee \(IBC\)](#)  
Approval required prior to IRB review for research involving biohazards (recombinant DNA, infectious or select agents, viruses, toxins), gene transfer, or xenotransplantation.  
Note: Laboratories processing clinical research samples (i.e., blood, serum, tissue, urine, feces, saliva, bile) must be registered with the IBC. As applicable, contact [IBCinfo@osu.edu](mailto:IBCinfo@osu.edu) to confirm laboratory registration.
- [Human Gene Transfer \(HGT\) Institutional Review](#), *only displays if IBC is selected*

If any other than “No institutional approval” is selected, Upload approval letters for all applicable committees above. [document upload box]

## Summary, Background, and Objectives

Summarize the proposed research using **non-technical** language that can be readily understood by someone outside the discipline. **Use complete sentences (limit 300 words).**

Summarize existing knowledge and previous work that support the expectation of obtaining useful results without undue risk to human subjects. **Use complete sentences (limit 300 words).**

List the objectives and/or specific scientific or scholarly aims of the research study.

Upload research protocol [document upload box]

*A research protocol provides information such as the study objectives, background, detailed plan for conducting the research, and discussion of how the research findings will be analyzed.*

## 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.*

Identify and describe all interventions and interactions that are to be performed solely for the research study.

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), *Enables* Data Repositories *page*
- Data, not publicly available
- Data, publicly available
- Deception, *Enables* Deception *page*
- Devices, *Enables* Devices *page*
- Diet, exercise, or sleep modifications
- Drugs or biologics (including dietary supplements/ingredients), *Enables* Drugs or Biologics *page* and Drugs (Supplemental Questions) *page*
- Emergency research
- Focus groups
- Food supplements
- Gene transfer

- Genetic testing, *Enables* Genetic Testing *page*
- 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), *Enables* Radiation, Radiation Exams/Procedures, and Radiation Dosage Totals pages
- Randomization
- Record review (which may include PHI)
- Specimen research
- Stem cell research
- Storage of biological materials (future unspecified use, including repositories), *Enables* Storage of Biological Materials *page*
- Surgical procedures (including biopsies)
- Surveys, questionnaires, or interviews (group)
- Surveys, questionnaires, or interviews (one-on-one)
- Other (Specify), *If Yes* Specify the other activity

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. [document upload box]

Provide surveys, questionnaires, if applicable. [document upload box]

Provide subject information, such as newsletters, instruction sheets, appointment reminder cards, drug/device information, if applicable. [document upload box]

#### Duration

Estimate the time required from each participant, including individual interactions, total time commitment, and long-term follow-up, if any. For studies with no subject time involvement, such as record review studies with a waiver of consent or observational studies, enter 'not applicable.'

#### 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.*

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

Example: 15 healthy controls, 15 patients, 200 students, 30 teachers.

- Unlimited participant numbers [optional check-box]

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 [auto-calculated field]

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

Indicate the total number of participants to be enrolled across all sites. *Question will only appear Multi-site Study page indicates the research is multi-site*

- Unlimited participant numbers across all sites [optional check-box]; *will only appear Multi-site Study page indicates the research is multi-site*

## Participant Population

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, *Enables Adults with decisional impairment page*
- Children, *Enables Children page*
- Neonates (uncertain viability/nonviable), *Enables Neonates page*
- Non-English speaking, *Enables Non-English speaking page*
- Pregnant women/fetuses – only if pregnant women will be intentionally recruited and/or studied, *Enables Pregnant women/fetuses page*
- Prisoners, *Enables Prisoners page*
- Student research pools (e.g., psychology, linguistics)  
*If Student research pools is selected, Specify the student research pool(s)*
  - Economics
  - REP (Psychology)
  - LOC (Linguistics)
  - CREP (Communication)
  - Political Science
  - Music
  - ESSREP (Environmental & Social Sustainability)
- 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.

Will any participants be excluded based on age, gender, race/ethnicity, pregnancy status, language, education, or financial status? Yes/No

*If Yes, Explain the criteria and reason(s) for each exclusion.  
Consider the study's scientific or scholarly aims and risks.*

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.*

*If Yes, Describe additional safeguards to protect participants' rights and welfare.  
Consider strategies to ensure voluntary participation.*

## Participant Identification, Recruitment, and Selection

### **Participant Identification**

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

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.

### **Participant Recruitment and Selection**

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

- [checkbox list populated with research personnel]

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

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

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.

*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). [document upload box]

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

## Incentives to Participate

*For more information regarding incentives for participation, see the ORRP policy, [Recruiting Methods](#), [Recruiting Materials](#), and [Participant Compensation](#).*

Will participants receive compensation or other incentives (e.g., free services, cash payments, gift certificates, classroom credit) to participate in the research study? Yes/No  
*Compensation plans should be pro-rated (not contingent upon study completion) and should consider participation withdrawals, as applicable.*

*If Yes*, Describe the incentive, including the amount and timing of all payments, the form of payment (e.g., cash, check, gift card) and how payment will be received (e.g., mailed, in person, online).

### Alternatives to Participation

Other than choosing not to participate, are there any alternatives to participating in the research?  
Yes/No

*If Yes*, List the specific alternatives to participation, including available procedures or treatments that may be advantageous to the subject.

### Informed Consent Process

*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, *Automatically selects Waiver of Consent Documentation box on this page and enables Waiver of Consent Documentation page*
- Informed Consent – Addendum
- Alteration of Consent Process, *Enables Alteration of Consent Process page*
- Alteration of Parental Permission, *Enables Alteration of Parental Permission page*
- Assent - Form
- Debriefing Script
- Assent - Verbal Script/Online
- Parental Permission - Form
- Parental Permission - Verbal Script/Online, *Automatically selects Waiver of Parental Permission Documentation box on this page and enables Waiver of Parental Permission Documentation page*
- Translated Consent/Assent - Form(s)
- Waiver of Assent, *Enables Waiver of Assent page*
- Waiver of Consent Process, *Enables Waiver of Consent Process page*
- Waiver of Consent Documentation, *Automatically selects Informed Consent – Verbal Script/Online box on this page and enables Waiver of Consent Documentation page*
- Waiver of Parental Permission, *Enables Waiver of Parental Permission page*
- Waiver of Parental Permission Documentation, *Automatically selects Parental Permission – Verbal Script/Online and enables Waiver of Parental Permission Documentation page*



*If anything on list above is checked EXCEPT waiver of assent, waiver of consent process, or waiver of parental permission AND deception was not selected as a research activity on the Research Methods & Activities page:* Provide copies of all documents, as applicable. [document upload box]

*If anything on list above is checked EXCEPT waiver of assent, waiver of consent process, or waiver of parental permission AND deception was selected as a research activity on the Research Methods & Activities page:* Provide copies of all documents, as applicable. Attach the debriefing script or information sheet to be used to explain the research to the participants. [document upload box]

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

- None
- [check-box list auto-populated with study team members]

*If the study team member is not listed here, please make sure to add 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 [optional check-box]

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 [optional check-box]

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

- Not Applicable [optional check-box]

Will any other tools (e.g., quizzes, visual aids, information sheets) be used during the consent process to assist participant comprehension? Yes/No

*If Yes,* Provide copies of these tools [document upload box]

Will any other consent forms be used (e.g., for clinical procedures such as MRI, surgery, etc. and/or consent forms from other institutions)? Yes/No

*If Yes,* Provide copies of these forms [document upload box]

## Privacy of Participants

*Privacy of Participants: It is important to note the distinction between “privacy” and “confidentiality”. In general, privacy concerns are about the people involved in the research (a person’s desire to control the access of others to themselves), whereas confidentiality is associated with a participant’s data collected for research purposes. This section should specifically address provisions to protect participants’ privacy interests (e.g., limiting the number of people screening private records for recruitment, any interactions will be conducted in a way to avoid being witnessed or overheard, sensitive or medical information will be discussed in a private setting, etc.). For more information, please see the policy [Privacy and Confidentiality](#).*

Describe the provisions to protect the privacy interests of the participants.

*Consider the circumstances and nature of information to be obtained, taking into account factors (e.g., age, gender, ethnicity, education level, etc.) that may influence participants' expectations of privacy.*

Does the research require access to personally identifiable, private information? Yes/No

*If Yes*, Describe the personally identifiable private information involved in the research. List the information source(s) (e.g., educational records, surveys, medical records, etc.).

### Confidentiality of Data

*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.

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 [optional check box]

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

- Not Applicable [optional check box]

*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)

### Certificate of Confidentiality

*NIH automatically provides Certificates of Confidentiality (CoC) to NIH-funded research studies. Please remember to insert the [standard CoC language](#) into the study's consent document.*

If your study is not NIH-funded, will you be requesting a Certificate of Confidentiality from the NIH?  
Yes/No

*If Yes*, Provide a copy of the certificate of confidentiality. [document upload box]

See HRPP policy [Privacy and Confidentiality](#) for more information.

## 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://orpp.osu.edu/irb/investigator-guidance/hipaa/>*

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

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

- Written Authorization
- Partial Waiver (for identification and recruitment purposes only), *Enables* Partial Waiver of HIPAA Research Authorization [page](#)
- Full Waiver (authorization will not be obtained), *Enables* Full Waiver of HIPAA Research Authorization [page](#)
- Alteration (written authorization will not be obtained or all required elements will not be included), *Enables* Alteration of HIPAA Research Authorization [page](#)

## General Authorization Forms

*Page displays only if written authorization or alteration is checked on the HIPAA Research Authorization page*

### Combined HIPAA and Consent Forms

If your HIPAA authorization is combined within a consent form file, please select the file(s) below. Select all documents which contain both consent and HIPAA language combined. Otherwise, use the file upload field to upload your HIPAA authorization form.

- [Auto-populated list of documents uploaded on the informed consent page; previously selected documents will remain selected, but the checkboxes are editable]

### HIPAA Written Authorization Forms

Provide a copy of the authorization form. [document upload box]

### Alteration of HIPAA Authorization Forms

Provide a copy of the authorization form. [document upload box]

## Reasonably Anticipated Benefits

List the potential benefits that participants may expect as a result of this research study. State if there are no direct benefits to individual participants.

*Compensation is not to be considered a benefit.*

List the potential benefits that society and/or others may expect as a result of this research study.

## Risks, Harms & Discomforts

Describe all reasonably expected risks, harms, and/or discomforts that may apply to the research.

Discuss severity and likelihood of occurrence. As applicable, include potential risks to an embryo or fetus if a woman is or may become pregnant.

*Consider the range of risks, including physical, psychological, social, legal, and economic.*

Describe how risks, harms, and/or discomforts will be minimized.

*If testing will be performed to identify individuals who may be at increased risk (e.g., pregnant women, individuals with HIV/AIDS, depressive disorders, etc.), address timing and method of testing; include how positive test results will be handled.*

## Assessment of Risks & Benefits

Discuss how risks to participants are reasonable when compared to the anticipated benefits to participants (if any) and the importance of the knowledge that may reasonably be expected to result.

## Monitoring

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

*If Yes,* 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).

Upload the data and/or safety monitoring plan, if applicable. [document upload box]

### Participant Costs/Reimbursements

Are there any additional costs that may result from study participation (e.g., parking, study drugs, diagnostic tests, etc.)? Yes/No

*Note: Answer "Yes" regardless of who will bear these costs.*

*If Yes,*

Describe any potential costs participants (or their insurers) will incur as a result of study participation.

Specify costs to participants that will be covered by the research study.

### Uploaded Files Review

*To access or upload a file, click on a page below.*

*All uploaded documents display under the appropriate page header.*

### Other Files/Comments

*This page should be used to provide ORRP or the IRB with additional information related to the current submission.*

*The general comments text area can be used to provide clarification to ORRP staff or the IRB members. The general upload box below should be used to upload any additional documents necessary for this submission that were not already captured previously in the form. Examples of documents which may be uploaded include the detailed cover letter response for modifications or deferrals, IRB approvals for external sites at the time of continuing review, or a memo to IRB reviewers from the investigator.*

Uploaded files [document upload box for miscellaneous documents]

Additional comments for this submission.

## Find Errors

*You have completed the IRB initial submission (non-exempt) form. To ensure a faster approval process, your study submission has been checked for errors or incomplete information. These must be remedied prior to study submission.*

Please remedy the following prior to submission.

*Provides list of remaining errors/incomplete information which links to respective pages, if applicable.*