## IRB Project Review Form Instructions

|  |  |
| --- | --- |
| **1** | **Complete this form using Microsoft Word** |

You may use Microsoft Word to fill all requested information. *Please DO NOT leave a question blank. If a question does not apply to your research, please write “N/A”.*

|  |  |
| --- | --- |
| **2** | **Prepare all necessary supporting documents and accompanying materials** |

1. Documentation of consent procedures (one or more of the following must be provided):
	1. Consent form(s) ☐
	2. Verbal Consent Script ☐
	3. Cover letter ☐
	4. Any survey instruments or questionnaires to be used ☐
2. A list of interview questions or topics, in as much detail as possible (if interviews are used) ☐
3. An electronic copy of NIH Protecting Human Research Participants certificate for ☐

the Principal Investigator and Faculty Mentor.

1. Any other supplementary materials (e.g. letter of support from research site/location/ agencies, etc.) specifically requested in this application form. ☐

|  |  |
| --- | --- |
| **3** | **Email this form and supporting documentation to the appropriate address** |

### If you are a student Principal Investigator, email the entire application package to your faculty mentor / research advisor for evaluation before IRB submission. After your faculty has reviewed and given consent to your application and any documents (e.g. interview protocol, consent forms), you then email [irb@eastern.edu](http://../../../../Library/Containers/com.apple.mail/Data/Library/Rebecca/AppData/Tara/AppData/Local/Temp/irb%40eastern.edu) with your intent to submit. The IRB chair will enroll you in the IRB course site on Brightspace and send you a link to send to your faculty mentor/research advisor to get their digital approval for your application. All email communication with the IRB must be from your secure EU email address.

### Faculty applicants: Email the IRB (irb@eastern.edu) with your intent to submit and the name and email address of either your dean or department chair. Once you have been enrolled in the course site on Brightspace, you will be able to then submit all your documents via Brightspace. You will also be sent a link to send to department chair or dean to get their digital approval for your application

### Please note that, although most applications can be reviewed and approved simply with an electronic signature, the IRB may, at its discretion, request submission of a signed hard copy. Whereas there is a space for your signature, it is not required. Applying through the secure Brightspace course site serves as your signature. Faculty and/or department chair approval through a Google form serves as their signature. All approvals will be sent as electronic emails, you can print that in case you need a hard copy to show to the research site.

**Review Timeline**

When your packet has been received by the IRB, it will be checked for completeness. If not complete, you will be requested to submit additional materials necessary for the review. Upon approval, you will receive approval from the IRB by email. **Do not begin collecting data until you receive this approval.**

* + **Exempt** reviews will generally take no more than 10 business days to be reviewed.
	+ **Expedited** reviews will take about 10 business days
	+ **Full Board** reviews will be conducted at the next meeting of the IRB, provided that the completed application has been received by the IRB at least 10 working days prior to the scheduled meeting date. The IRB meets on a monthly basis during the fall/spring academic semesters.
	+ **(Winter Break and June-August Exempt, Expedited and Full Board Reviews):** Please note that the IRB board does not review applications regularly during the summer months, so review times may take longer (approximately 3-4 weeks). Applicants should plan appropriately for such potential delays.

**Contact Information**

Website: http://www.eastern.edu/offices-and-centers/institutional-review-board

Mailing address: IRB, Eastern University Phone: 610-341-1547

 1300 Eagle Road Email: irb@eastern.edu

 St. Davids, PA 19087

**PART I: Project Description**

|  |  |
| --- | --- |
| **Principal Investigator(s)** (PI): (*please list all names*) |  |
|       |
| **PI:** Please email irb@eastern.edu to get enrolled in the ethics training module on our Brightspace course. If you have an NIH certificate or CITI certificate regarding research ethics, please email us that and we’ll see if we can accept that instead.  |
| Department: |       | Campus: |       |
| Status: | ☐ Faculty | ☐ Adjunct faculty | ☐ Staff | ☐ Graduate Student | ☐ Undergraduate student |
| **Faculty Mentor** (*if PI is a student*): |       | **Course Number** (if applicable): |       |
| **Faculty Mentor:** Please email irb@eastern.edu to get enrolled in the ethics training module on our Brightspace course. If you have an NIH certificate or CITI certificate regarding research ethics, please email us that and we’ll see if we can accept that instead. If you have previously sent us your NIH certificate, we should still have it on file. |
| E-mail: |       | Phone: |       | Fax: |       |
| Mail correspondence to: |       |
| **Project Title:** |       |
| Estimated Project Start Date: (mm / dd / yyyy) |       | Estimated Data Collection Completion Date (Note: IRB approval cannot exceed one year): (mm/dd/ yyyy) |       |
| Is there, or will there be, extramural funding that directly supports this research? | If yes: | Funding agency: |       |
| YES ☐ NO ☐ | PI on grant: |       |
| **Are you conducting your study with Eastern University students**?YES ☐ NO ☐If yes, *and you plan to contact/use more than* ***100*** *students in your research,* you will need permission from the Vice President for Student Development and the Department of Institutional Review. You may submit your application for review prior to receiving their approval. |
| **Are you conducting your study off the premises of Eastern University such as an agency or school or recruiting participants from a business, agency, school, etc.?**YES ☐ NO ☐If yes, assurance of oversight by that entity must be provided to the IRB in the form of (please attach to application). A letter of permission from the lead administrator (or his/her designee) to conduct the study, which shows evidence that the administrator or official oversight group has reviewed the protocol and accepted its use at that institution  |
| **IRB #:** |       *(For Administrative Use Only)* |
| ***ABSTRACT and REFERENCES:*** Please describe the 1) purpose, 2) hypothesis/research objective, 3) research design, and 4) methods/procedures of your study, including methods for data analysis. Specify what the participants will do and how they will be recruited. Explain how your research is novel or how it adds to existing knowledge. Cite relevant publications, as appropriate. ***Additional information about methods and references:***Are there published articles/books/materials that affirm the safety and/or appropriateness of your methods? If so, list them below (please use professional form when listing citations). If you are utilizing methods, surveys, interview questions, or other instruments developed by someone else, please list them here: |

**PART II: What level of IRB review is needed for your project?**

1. To determine whether your project is *exempt* from a full or expedited review by the IRB, please answer the following questions. *If you answered YES to any of these questions, then your project is NOT exempt.*

|  |  |
| --- | --- |
| Yes ☐ No ☐  | 1. Are the subjects’ data directly or indirectly identifiable and could these data place subjects at risk for criminal or civil liability or might they be damaging to the subjects’ financial standing, employability, or reputation?
 |
| Yes ☐ No ☐ | 1. Will subjects be asked to report their own or others’ sexual experiences, alcohol or drug use, and will you know their identities?
 |
| Yes ☐ No ☐ | 1. Are subjects used who may not be legally competent (under 18 years old, or subjects with certain conditions of intellectual, emotional or developmental disability?)
 |
| Yes ☐ No ☐ | 1. Are personal records (medical, academic, etc.) used with identifiers and without written consent?
 |
| Yes ☐ No ☐ | 1. Are any subjects confined in a correctional or detention facility?
 |
| Yes ☐ No ☐ | 1. Will alcohol or drugs be administered?
 |
| Yes ☐ No ☐ | 1. Will blood/body fluids be drawn?
 |
| Yes ☐ No ☐ | 1. Will specimens obtained from an autopsy be used?
 |
| Yes ☐ No ☐ | 1. Will you be including pregnant women by design?
 |
| Yes ☐ No ☐ | 1. Are live fetuses subjects in this research?
 |
| Yes ☐ No ☐ | 1. Will Non-English speakers be included?
 |
| Yes ☐ No ☐ | 1. Will economically or educationally disadvantaged populations be targeted?
 |
| Yes ☐ No ☐ | 1. Will members from minority groups be targeted?
 |
|  |  |

1. If you answered YES to *any* of the 13 questions above, please do not check anything here and proceed to the Expedited Review Criteria Section (p. 6). If you answered NO to *all* of the questions above, then your research qualifies for exempt review IF it fits into at least one of the following categories. *Please check all that apply:*

|  |  |
| --- | --- |
| ☐ | **Educational Research** |
| Research in established or commonly accepted educational settings, involving normal educational practices. This is for research that is concerned with improving educational practice. |
| ☐ | **Surveys, Questionnaires, Interviews, or Observation of Public Behavior** |
| The subject matter must not involve “sensitive” topics, such as criminal or sexual behavior, alcohol or drug use on the part of the subjects, unless they are conducted in a manner that guarantees anonymity for the subjects |
| ☐ | **Surveys, Questionnaires, Interviews or Observation of Public Behavior** |
| Surveys that involve sensitive information and subjects’ identities are known to the researcher may still be exempt if: (1) the subjects are elected to appointed candidates for public office; or (2) federal statute(s) specify without exception that confidentiality will be maintained throughout the research and thereafter. |
| ☐ | **Archival Research** |
| Research involving the collection or study of existing data, documents, records, pathological or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. These data/samples must be preexisting, which means they were collected prior to the current project. |
| ☐ | **Research Examining Public Benefit or Public Service Programs** |
| To qualify for this exemption, the research must also be conducted by (or subject to review by) an authorized representative of the program in question. Studies in this category are still exempt if they include pregnant women by design and their purpose is to examine benefit programs specifically for pregnant women. |
| ☐ | **Taste Evaluation Research** |
| Studies of taste and food quality evaluation. Studies of taste evaluation qualify for this exemption only if (1) wholesome foods without additives are consumed; or (2) a food is consumed that contains a food additive present at or below the level that has been found to be safe. |

|  |  |
| --- | --- |
|  |   |
|  |  |

*If you determined that your project is exempt from expedited or full board review, then please proceed to page 7, Part III. Data Collection Procedures. Otherwise, please answer the following questions to determine whether your project qualifies for expedited review.*

#### Expedited Review Criteria

1. To meet expedited review criteria, your project must meet the following conditions:
	* No more than minimal risk to the subjects

The federal definition of minimal risk is: *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.*

* + Subjects must not be confined in a correctional or detention facility
	+ Subjects must be participating in one or more of the ways described in the following section (see #2).
1. Your project qualifies for expedited review IF subjects are participating in one or more of the following ways. *Please check all that apply*.

|  |  |
| --- | --- |
| ☐ | **Collection of excreta and external secretions** |
| This includes sweat, saliva, placenta, and/or amniotic fluid. None of these may be collected by “invasive” procedures, such as those that use cannulae or hypodermic needles, such as amniocentesis. |
| ☐ | **Recording of data using noninvasive procedures routinely employed in clinical practice.** |
| This includes but is not limited to the use of ‘contact’ recording electrodes, weighing, tests of sensory acuity, electrocardiography and electroencephalography, and measure of naturally occurring radioactivity.IMPORTANT EXCLUSIONS: This does NOT include procedures which: (a) impart matter or significant amounts of energy to the subjects; (b) invade the subjects’ privacy; or (c) expose subjects to significant amounts of energy outside the visible range (e.g. ultraviolet light from tanning beds). |
| ☐ | **Collection of hair or nail clippings, or teeth from patients whose care requires the extraction or collection of plaque and/or calculus** |
| Collection of dental material must use routine procedures for the cleaning of teeth. |
| ☐ | **Voice recordings** |
| Recordings made for research purposes such as the investigation of speech defects and speech pathology. |
| ☐ | **Moderate exercise** |
| Moderate exercise performed by healthy volunteers. |
| ☐ | **Experimental procedures (i.e., manipulation of an independent variable)** |
| Research performed to investigate individual or group behavior or the characteristics of individuals, such as studies of perception, cognition, game theory, or test development.IMPORTANT EXCLUSIONS: This does NOT include studies that (a) involve significant stress to the subjects or (b) that are intended to produce a relatively lasting change in behavior. |
| ☐ | **Educational research with subjects under 18 years of age**Research in established or commonly accepted educational settings, involving normal educational practices and involving subjects are under 18 years of age. This is for research that is concerned with improving educational practice. |
| ☐ | **Studies of archived data, records or diagnostic specimens** |
| This category would include studies of these specimens that do not qualify for exempt review. |
| ☐ | **Research 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, ethnography, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. |
| ☐ | **Collection of blood samples** |
| Studies involving the collection of blood samples by venipuncture, in amounts not exceeding 550 mL (about one pint) in an eight-week period and no more than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant. |

If your study fits into one or more of the ten types of participation and meets the required criteria, then your project can receive EXPEDITED REVIEW from the IRB. If your study does not meet expedited review criteria, then it qualifies for FULL BOARD review. *The IRB will determine which level of review is appropriate for your project, based upon the information you provide in this form.*

#### Full Board Reviews

Research projects that require full board review have the potential for more than minimal risks (physical, psychological, or social) to subjects and/or include populations with special considerations (including research on prisoners, persons who are not legally competent, emotionally, cognitively or developmentally disabled populations).

*The IRB will determine which level of review is appropriate for your project, based upon the information you provide in this form.*

**PART III: Data Collection Procedures**

1. Please indicate the method(s) to be used: (*check all that apply*)

|  |  |
| --- | --- |
| ☐ *Survey administered by*: | ☐ Investigator ☐ Subject ☐ Mail ☐ Phone ☐ In Person ☐ Internet / E-mail |
| *Please submit a copy of the survey that you will use.* |
| ☐ *Interview* | ☐ One-on-one ☐ Focus Group ☐ Oral History ☐ Other *(specify)*:  |       |
| *Please submit a copy of the interview questions that you will use.*  |
| ☐ *Observation of Public Behavior* | ☐ Classroom ☐ Public Setting ☐ Other *(specify)*: |       |
| ☐ *Archived Data or Records* | ☐ Academic ☐ Medical ☐ Legal ☐ Other *(specify)*: |       |
| ☐ *Taste or Sensory Evaluation* | ☐ Food Tasting ☐ Olfactory |
| ☐ *Therapeutic Evaluation* | ☐ Biomedical ☐ Psychological ☐ Physical Therapy |
| ☐ *Experimental Procedures* | ☐ Biomedical ☐ Psychological ☐ Other *(specify)*: |       |
| ☐ *Ethnography* |
| ☐ *Examination of Pathological or Diagnostic Tissue Specimens* |
| ☐ Other *(briefly describe)*: |       |

1. Please indicate how the data will be handled: *(see the IRB manual, p. 45)*

Anonymous is defined as: data are recorded such that no identifier whatsoever exists to link a subject’s identity to that subject’s response. No one can link an individual person to the response of that person, including the investigator(s). Face-to-face interviews and data collection are never anonymous. In order for internet surveys to qualify as anonymous, they must NOT collect IP addresses, email addresses, Facebook or LinkedIn accounts, etc.

Confidential is defined as: there exists a documented linkage between a subject’s identify and her/his response in the research. The investigator provides assurance in the protocol and in the informed consent that the identity of any individual subject will not be revealed in any report of the study. Confidentiality means that the investigator can (or could) identify individuals who participated in a study, perhaps through a code.

|  |
| --- |
| ☐ Anonymous ☐ Confidential ☐ Intentionally identified |

1. What form of consent will be obtained? *(refer to the “Informed Consent Form Guidelines” document)*

|  |
| --- |
| ☐ Written *(please attach consent form).* *If you are not using written consent please provide a brief rationale (e.g. not standard to my discipline, internet survey, working with a population that does not read, etc.) and then select the appropriate type of consent below:*☐ Implied *(please attach cover letter or describe terms on a separate page)* |
| ☐ Verbal *(please attach consent script)* |
| ☐ Seeking Waiver of Consent *(please contact IRB for further information)* |
| ☐ Consent Not Applicable *(please explain reasons on a separate page)* |

1. If the data will be handled in an *anonymous* or *confidential* manner, how will confidentiality be maintained? *(please check all that apply)*

|  |
| --- |
| ☐ Coded to a master list and separated from the data |
| ☐ Stored in a locked cabinet |
| ☐ Stored in a locked office |
| ☐ Stored in a restricted (password-protected) computer |
| ☐ Other *(specify)*:       |  |
| ☐ N/A – the subjects will be intentionally identified |  |

1. Who will have access to the data?

|  |
| --- |
|       |

1. Will any of the following be collected? Please check yes or no *for each* of these 3 categories below

|  |  |
| --- | --- |
| ☐ Yes ☐ No | Video recordings (either tape or digital) |
| ☐ Yes ☐ No | Audio recordings (either tape or digital) |
| ☐ Yes ☐ No | Photographs |

1. If you answered YES to any of the above questions in Question 6, then please provide the following information:

Where will the recordings or photographs be stored?

|  |
| --- |
|        |

If your materials will be destroyed, when (approximate date) will the materials be destroyed? *This should also be included in the consent form. If you are not destroying materials, be sure to state how they will be stored.*

|  |
| --- |
|        |

How will confidentiality be maintained?

|  |
| --- |
|        |

**PART IV: Description of the Population**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Approximate number of subjects:
 |       | Approximate age range: |       |

1. How will subjects be selected or recruited, and how will subjects be approached (or contacted)?

|  |
| --- |
|       |

1. Will subjects be compensated (including extra credit\*)? ☐ Yes ☐ No

|  |
| --- |
| *If yes, then please explain how much, when, and how they will be compensated, and explain whether they must complete the project in order to be paid.* |
|      *\*If extra credit is to be given, please explain how students who do not participate may earn extra credit through alternative means.*       |

1. Are any subjects under 18 years of age? ☐ Yes ☐ No

If yes, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. Please provide a copy of the parental consent form with the IRB application.

If yes, does the proposed research include children between the ages of 8 and 17 years old? An assent form should be used for subjects who are 8 to 17 years old. Please provide a copy of the minor assent form with the IRB application.

1. Are any subjects not legally competent to give consent? ☐ Yes ☐ No

|  |
| --- |
| *If yes, then please explain how consent will be obtained. Who will give consent on their behalf? What procedures will be followed? Please attach consent form.* |
|       |

1. Will any minority groups be excluded from the study pool? ☐ Yes ☐ No

|  |
| --- |
| *If yes, then please justify the exclusion.* |

     .

1. Will any minority groups be targeted in this study? ☐ Yes ☐ No

*If yes, please provide justification for targeting minority groups.*

*Specify how risks are minimized for this population.*

1. Is this study likely to involve any subjects who are not fluent in English? ☐ Yes ☐ No

**If yes, please submit both English and translated versions of consent forms, surveys, interview questions, etc. Please ensure that the translations are accurate.**

1. Does this study involve subjects located outside of the United States? ☐ Yes ☐ No

*If yes, please explain on an attached page exactly who the subjects are or who the populations you are recruiting from are and the identities (if possible) and responsibilities of any additional investigators.*

1. Does this study target economically or educationally disadvantaged populations? ☐ Yes ☐ No

*If yes, please provide justification for including/targeting* *economically or educationally disadvantaged populations.*

*Specify how risks are minimized for this population.*

**PART V: Use of Deception**

If any deception is required for the validity of this activity, explain why this is necessary. *Please also include a description of when and how subjects will be debriefed regarding the deception, and* ***attach a debriefing script.***

|  |
| --- |
|       |

**PART VI: Risks and Benefits – Questions 1-4 are REQUIRED information for all applicants**

1. **Describe any potential risks to the subjects,** ***and describe how you will minimize these risks***. These include stress, discomfort, social risks (e.g., embarrassment), legal risks, invasion of privacy, and side effects.

|  |
| --- |
|       |

1. In the event that any of these potential risks occur, how will the situation be handled (e.g., compensation, counseling, etc.)? Even if risks are minimal, you must have a plan (e.g. comfort them, remind them they can withdraw from the study, etc.).

|  |
| --- |
|       |

1. Will this study interfere with any subjects’ normal routine? ☐ Yes ☐ No
2. Describe the expected benefits to both the individual research subjects and those for society. *This is required information.*

|  |
| --- |
|       |

1. If blood or other biological specimens will be collected, then please address the following:

|  |  |
| --- | --- |
| 1. Brief description of sampled tissues:
 |       |
| 1. Describe the personnel involved and procedure(s) for obtaining the specimen(s). *Please note that IRB requires that only trained certified or licensed persons may draw blood. Contact IRB for more information.*
 |
|       |

**PART VII: Use of Collected Data**

Please check all that apply:

|  |
| --- |
| ☐ Thesis / Dissertation |
| ☐ Journal Article / Publication |
| ☐ Grant Activities |
| ☐ Other *(briefly describe)*: |       |

**PART VIII: Drug or Alcohol Consumption**

*Note: If your project is exempt from expedited or full board review, then you may skip this section and proceed to Part IX on the next page.*

1. Will any *Investigational New Drug* (IND) or any other substance regulated by the
Food and Drug Administration (FDA) be used? ☐ Yes ☐ No

*If yes, then please note that the Eastern University IRB is not able to provide approval
or oversight for your project. In order to conduct research involving Investigational
New Drugs (INDs) or other substances subject to FDA regulation, you will need to work
with a collaborator affiliated with another institution whose IRB is able to provide the
review and oversight required by federal regulations.*

1. Will alcohol be ingested by the subjects? ☐ Yes ☐ No

|  |
| --- |
| *If yes, then please describe what type and how it will be administered.* |
|  |

**PART X: Assurances – *signatures not required if submitting through Brightspace***

This investigation involves the use of human subjects. I understand Eastern University’s policy concerning research involving human subjects and I agree to:

1. Obtain voluntary and informed consent of persons who will participate in this study, as a required by the Eastern University Institutional Review Board (IRB).
2. Report to the Eastern University IRB any adverse effects on subjects which become apparent during the course of, or as a result of, the activities of the investigators.
3. Cooperate with members of the IRB who are responsible to review this project, and to give project reports as required by the IRB.
4. Obtain prior approval from the IRB before amending or altering the project or before implementing changes to the approved consent form.
5. Maintain documentation of IRB approval, consent forms and/or procedures, together with the data, for at least three years after the project has been completed.
6. Treat human subjects in the manner specified on this form.

|  |
| --- |
| **Principal Investigator:** *The information provided in this form is accurate, and the project will be conducted in accordance with the above assurances.* |
| Signature |  | Print Name |       | Date |       |
| Signature | Principal Investigator | Print Name |       | Date |       |
| Signature | Principal Investigator | Print Name |       | Date |       |
|  Principal Investigator |
| **Faculty Sponsor** (if PI is a student):*The information provided in this form is accurate, and the project will be conducted in accordance with the above assurances.* |
| Signature |  | Print Name |       | Date |       |
|  Faculty Sponsor (if P.I. is a student) |
| **Chair, Director, or Dean:** *This project will be conducted in accordance with the above assurances.* |
| Signature |  | Print Name |       | Date |       |
|  Chair, Director, or Dean |

**Please Note: *The IRB approval is effective for only one year*. After that, an extension request must be submitted before you can continue your project.**

**Institutional Review Board Approval:**  *These assurances are acceptable, and this project has adequate protections for the subjects. This project has been properly documented and reviewed and is in compliance with federal, state, and university regulations.*

**Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Print Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Print Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_**

Eastern University IRB use ONLY:

Review Status of Protocol: ☐ Exempt ☐ Expedited ☐ Full Board