

The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of subjects. OHRP is part of the Office of the Assistant Secretary for Health in the Office of the Secretary, U.S. Department of Health and Human Services. OHRP provides clarification and guidance, develops educational programs and materials, maintains regulatory oversight, and provides advice on ethical and regulatory issues in biomedical and behavioral research. The creation of Augsburg's IRB application was based on the regulations required by OHRP.

In creating the IRB application and the instructions for completing the application (presented below), we have tried to anticipate all possible variations in research projects. However, it is impossible to anticipate everything. Therefore, use the general principles you are able to derive from the instructions to make the needed adaptations for your specific project. Each section of the application provides space for you to provide additional information.

You will need to submit an electronic copy of the IRB application and all supporting documents to [IRB@augsborg.edu](mailto:IRB@augsborg.edu) (not case sensitive). **The IRB only will communicate with applicants and advisors using their Augsburg e-mail address.** Please label each document: last name, first initial, followed by the name of the document (e.g., Smith A. IRB application). Be sure the name of the document is an accurate reflection of the content. If supporting documents are not submitted and/or the documents are not properly titled, the application WILL NOT BE REVIEWED.

If you are a student, you will need to cc your advisor when you submit your application. The advisor must then reply to all indicating that they approve the application for review by the IRB. The application will not be reviewed until the approval e-mail is received from the advisor. Receipt of an application from the principal investigator's Augsburg e-mail address and the advisor's approval from their Augsburg e-mail address serves as an electronic signature verifying that:

- The information provided in the application form is correct and the Principal Investigator (PI) agrees to adhere to all aspects of the research included in the application.
- The PI will obtain prior written approval from the IRB for any substantive modifications in the proposal, including, but not limited to changes in cooperating investigators, agencies, recruiters, research assistants, as well as changes in procedures and the number and types of subjects.
- Any significant new findings that develop during the course of this study, which may affect the risks and benefits to participation, will be reported in writing to the IRB and to the subjects.
- The research will not commence until the official IRB approval letter is received. The letter will be sent electronically to the PI using the [IRB@augsborg.edu](mailto:IRB@augsborg.edu) e-mail address.
- The researcher is responsible for keeping all materials (e.g., raw data, consent documents) and will provide them to the IRB in a timely manner, if requested

If these conditions are not met, approval of this research could be suspended.

**DATA COLLECTION MAY NOT BEGIN UNTIL THE PRINCIPAL INVESTIGATOR RECEIVES THE IRB APPROVAL LETTER.**

Consult the instructions below when completing the IRB application. These instructions provide valuable help to complete the application. The information below and the instructions for creating consent and recruitment documents are appropriate for the 2019-2020 academic year.

The number on the application has a series of major subheadings (labeled with capital letters). These headings represent areas to which you need to respond. Under each major subheading are minor subheadings (labeled with roman numerals). At times, you will need to respond to these minor subheadings; at other times, the need to respond depends on responses to a question in the major subheading. Further subheadings (below major headings and minor subheadings) are labeled with small letters, then small roman numerals, then ●, then ❖. These latter four subheadings will require a response depending on your answer to a question in the previous subsection. Therefore, you will not necessarily respond to questions with those subheadings.

All questions/statements in **red** require the submission of information that **MUST** be submitted. They are in red to alert you to the fact that an additional document must be submitted. If the required information is not submitted, it will delay approval of your projects. So it is important to include all required materials.

## INSTRUCTIONS FOR COMPLETING THE IRB APPLICATION

### 1. PROJECT TITLE

In general, the title should accurately reflect the purpose of the study. The title listed here should be used on the consent form. One exception to this general rule is when an experimental method necessitates the true nature of the study not be revealed before participation.

### 2. REVIEW CATEGORY

Check the level of review required for your study. There are three options: full, expedited, or exempt.

To determine if your study qualifies for expedited review go to: <http://www.hhs.gov/ohrp/policy/expedited98.html>

To determine if your study qualifies for exempt review go to:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101%28b%29>

*NOTE: when minors are subjects and interview/survey procedures are used, exempt review does apply.*

For additional help in determining the level of review, OHRP provides decision trees to assist you in making the decision. Go to: <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>

If your study does not qualify for expedited or exempt review, full review is required.

*Note: It is within the purview of the chair to change the level of review.*

### 3. RESEARCH INVESTIGATOR INFORMATION

This number requests contact information for the researchers and research assistants on this project. If an employee or student of Augsburg College, Augsburg e-mail address must be provided.

- A. This major subsection asks about the principal investigator. If you are filling out the IRB application, you are the principal investigator. Indicate if you are faculty, staff, or a student. Check the appropriate boxes and provide the requested information.
- B. This major subsection asks If there is a co-investigator on the project. Check yes or no. If no, skip to major subsection C. If yes, respond to the questions in the two minor subsections.
  - I. This minor subsection asks you to provide the contact information for the co-investigator. If you have multiple co-investigators, list each name and each piece of contact information separated by a comma. Be sure the order is always the same for each piece of requested information.
  - II. This minor subsection ask you to indicate if any of the co-investigators are affiliated with a non-academic institution. Check yes or no. If no, skip to major subsection C. If yes, identify the co-investigator. If there is only one co-investigator, write "see above" (the person has already been identified so there is no need to include the name twice). **Check the statement indicating that you submitted a signed Non-Academic Institution Affiliated Co-Investigator Confidentiality Agreement from this person.** This document is located on the IRB website in the Supplementary Resources section. You will need to scan a copy of the signed document in order to submit it electronically. *Note: a signed confidentiality agreement is not needed from a co-investigator at an academic institution because all academic institutions require IRB review in order to conduct research. This process negates the need for a confidentiality agreement.*
- C. This major subsection asks about the use of research assistant(s). Indicate whether you plan to use research assistants to collect or analyze data. Check yes or no. If no, skip to major subsection D. If yes, provide the research assistant's contact information. If you plan to use multiple research assistants, list each name and each piece of contact information separated by a comma (or on a different line). Be sure the order is always the same for each piece of requested information. **Check the statement indicating that you have submitted a signed Research Assistant Confidentiality Agreement.** This document is located on the IRB website in the Supplementary Resources section. You will need to scan the signed document in order to submit it electronically. *Note: If you do not know the identity of the research assistants at the time the application is submitted, you will need to submit the contact information and the confidentiality agreement before the research assistant may do anything related to the research project. The same must be done if new research assistants are added to the project.*

D. If needed, this major subsection allows you to provide additional information relevant to the research investigators.

#### 4. FEDERAL GRANT FUNDING

A. This major subsection asks if Federal grant funding will be sought/has been obtained for this project. Check yes or no. If no, skip to major subsection B. If yes, respond questions in the two minor subsections.

I. This minor subsection asks you indicate the federal funding agency (e.g., NSF grant).

*Note: If an IRB approved project receives federal funding, it is subject to continuing review and approval by the IRB. When the project is completed, a research project close-out form must be submitted to the IRB. These required documents are available in the Supplementary Resources section of the IRB website.*

B. If needed, this major subsection allows you to provide additional information relevant to Federal grant funding.

#### 5. Cooperating Agency/Organization and OTHER NEEDED REVIEWS

A. This major subsection asks if the research is being conducted in cooperation with and agency/organization. *Note: A cooperating agency/organization is not a co-investigator or a funding agency; a cooperating agency is an agency/organization through/from which you are recruiting subjects for your study. Typically, a cooperating agency/organization will ask for a copy of the final report but this is not always so. Therefore, a request for a final report is a sufficient criterion to count as a cooperating agency/organization but not necessary.* Indicate yes or no. If no, skip to major subsection B. If yes, respond to the questions in the two minor subsections.

I. This minor subsection asks you to identify the cooperating agency/organization.

II. This minor subsection asks you describe the nature of relationship(s) (e.g., previous or current employer, intern, etc.) between the cooperating agency/organization and the principal investigator and co-investigator and research assistant (if relevant). *Note: these relationships need to be disclosed at the time of consent.*

*Check the box indicating that you have submitted an approval letter from the proper authority at the agency/organization to conduct this research.* You will need to scan the signed letter in order to submit it electronically.

B. This major subsection asks if your research project needs to be reviewed by another internal committee of the college. Check yes or no. If no, skip to major subsection C. If yes, respond to the questions in the three minor subsections.

I. This minor subsection asks you to indicate the committee.

II. This minor subsection asks you to provide the reason for the review.

III. This minor subsection asks you to provide the status of the review. There are three options:  submission is pending,  under review, or  approved. Check the appropriate box. If the submission is pending or under review explain why you needed to submit the Augsburg IRB application before approval was obtained. *Note: In general, the IRB requires approval letters to be submitted before an application will be reviewed. However, we are aware that there may be extenuating circumstances that prevent the submission of the approval letters required in this section. Once approval is obtained, the principal investigator must submit a copy of the approval letter.* Final approval will not be granted until the approval letter is received. *If approved, check that you have submitted an approval letter from the committee.* You will need to scan the signed letter in order to submit it electronically.

C. This major subsection asks if your research project needs to be reviewed by another IRB. Check yes or no. If no, skip to major subsection D. If yes, respond to the questions in the three minor subsections.

I. This minor subsection asks you to indicate the location of the other IRB.

II. This minor subsection asks you to indicate the status of the review. There are three options:  submission is pending,  under review, or  approved. Check the appropriate box. If the submission is pending or under review explain why you needed to submit the Augsburg IRB application before approval was obtained. *Note: In general, the IRB requires approval letters to be submitted before an application will be reviewed. However, we are aware that there may be extenuating circumstances that prevent the*

submission of the approval letters required in this section. Once approval is obtained, the principal investigator must submit a copy of the approval letter. Final approval will not be granted until the approval letter is received. If approved, check that you have submitted an approval letter from the committee. You will need to scan the signed letter in order to submit it electronically.

- D. If needed, this major subsection allows you to provide additional information relevant to the cooperating agency or other needed reviews.

## 6. RESEARCH QUESTION/HYPOTHESIS, PURPOSE, AND METHODOLOGY

A. This major subsection asks you describe your research question/hypothesis in lay language (language understood by a person unfamiliar with the area of research), provide the justification for the research--what is the need or problem being addressed by the study (i.e., the purpose for conducting the study), and how it fits with previous research in the field, if relevant.

B. This major subsection asks about the methodology that will be used in your study. There are three minor subsections that need to be addressed.

I. This minor subsection asks you to identify the methodology(ies) you will be using. There are five options (check all that apply):

Analyzing existing data, records, or specimens. If you check this methodology, answer the questions in the two subsections.

a. This subsection asks you to identify the source of the existing data, records or specimens.

b. This subsection asks you to identify the location of the existing data, records or specimens

Check the box that you have submitted an approval letter granting you access to the source. You will need to scan the signed letter in order to submit it electronically.

If this is the sole method used in your study, skip to question #10. You only need to answer the questions in that section. Once those questions are answered, the application is complete and may be submitted. If other methodologies will be used, continue with the application.

Observation of public behavior. Public behavior is defined as behavior that occurs in a situation in which the person being observed has no expectation of privacy and their behavior is "natural" (i.e., unaffected by the researcher). If this methodology is checked respond to the questions in the three subsections.

a. This subsection asks you to identify who will be observed. *Note: This is not specific (e.g., names) but general (e.g., people shopping at X)*

b. This subsection asks you to describe the behavior that is being observed.

c. This subsection asks you to identify where the observations will occur.

If this is the sole method used in your study, skip to question #10. You only need to answer the questions in that section. Once those questions are answered, the application is complete and may be submitted. If other methodologies will be used, continue with the application.

Qualitative research. Indicate if you will be using interviews or focus groups and indicate where they will take place.

Survey research. *Note: This does not include the use of surveys in an experimental design.* Indicate whether the delivery of the survey will be on-line or in hard-copy. If on-line provide, the survey tool used to deliver and create the survey (e.g., survey monkey). If hard-copy, indicate where the surveys will be completed.

Experimental research. Indicate where the experiment will be conducted.

Normal educational setting. *Note: This means that the research focuses on teaching with subjects who are enrolled in a specific class(es).* Check yes or no. If no, skip to major subsection C. If yes, respond to the questions in the three subsections.

a. This subsection asks you to identify the "grade-level" of the subjects. There are two options:  
 pre-school to high school,  post-secondary or beyond. Check the appropriate box.

- b. This subsection asks if the research is conducted during class time. Check yes or no.

If no, respond to questions in the two subsections.

- i. This subsection asks you to indicate where the research will be conducted.
- ii. This subsection asks you to indicate when the research will be conducted.

If yes, respond to the questions in the two subsections.

- i. This subsection asks you to describe in detail the activity for non-subjects
- ii. This subsection asks to indicate who will be supervising the non-subjects if they are minors. If the potential subjects are not minors, check not applicable

- c. This subsection asks if there is any part of the study that all students will need to do even if they choose not participate in the study (e.g., all students will participate in the lab session but only lab reports from those participating will be used in the study). Check yes or no. If no, skip to major subsection C. If yes, respond to the questions in the two subsections

- i. This subsection asks you to explain what all students must do and why
- ii. This subsection asks you to explain the accommodations for the students who choose not to participate.

- II. This minor subsection asks you to indicate how long it will take to complete the survey, interview, focus group, or experiment.

- III. This minor subsection asks you to indicate if you plan to recruit multiple types of subjects (e.g., parents and students) for the study. Check yes or no.

If no, indicate the maximum number of subjects who may participate in the study.

If yes, respond to the questions in the two subsections.

- a. This subsection asks you to identify the types of subjects
- b. This subsection asks you to indicate the maximum number of each type of subject who may participate in the study

- IV. This minor subsection asks you to indicate if there is more than one phase in your study. Check yes or no.

If no, respond to the questions in the two subsections.

- a. This subsection asks you to describe the one phase of the study.
- b. This subsection asks you to identify the criteria for selecting someone to be a subject in the study (e.g., client in your case load, 5 years management experience, student in a Psy 105 class)

If yes, respond to the questions in the two subsections

- a. This subsection asks to explain each phase of the study.
- b. This subsection asks you to indicate if you “expect” subjects to participate in each phase of the study. *Note: expect does not mean that a subject must participate in every phase but that the study was designed for subjects to participate in every phase.* Check yes or no. If yes, skip to minor subsection V. If no, indicate the criteria for selecting someone to be a subject in EACH phase of the study (e.g., students in my 8<sup>th</sup> grade class will respond to a survey and based on the answers to the survey, subjects may be asked to participate in an interview).

## 7. MATERIALS

- A. This major subsection asks you to identify the types of data you are collecting. There are eight options provided and one option to identify another type of data not included in the provided options. Check all that apply. The options are:

- audio recordings
- video recordings,
- written notes
- photographs
- drawings
- Interview focus group questions. If this method is checked, respond to the question in the one minor subsection.

I. This minor subsection asks you to provide the initial interview/focus group questions with the understanding that additional questions may be asked based on subject responses the initial questions.

- Surveys. If this method is checked, respond to the questions in the two minor subsections:

I. This minor subsection asks you to provide the survey(s). If not possible to cut and paste it, submit it in a separate document and indicate “the survey is attached in a separate document.”

II. This minor subsection asks you to indicate if you created the survey. Check yes or no. If no, indicate whether you have permission to use the survey. Check yes or no. If yes, skip to major subsection B. If no, do you have permission to use the survey?

**If yes, you must submit the approval letter granting you permission to use the survey.** You will need to scan the signed letter in order to submit it electronically.

If no, explain why approval is not needed (e.g. open-source, provided in a journal article, etc.).  
*Note: this reason needs to focus on why approval is not needed rather than an explanation of why you have not obtained approval to use the survey.*

- Another methodology that is not covered by the above methods and identify what it is.

B. If needed, this major subsection allows you to provide additional information relevant to your materials.

## 8. RISK/BENEFIT RATIO

A. This major subsection asks to identify if you are providing monetary compensation to the subjects for participating in your study. If no, skip to major subsection B. If yes, respond to the questions in the two minor subsections.

I. This minor subsection asks you to describe the type (e.g., cash, gift card) and the amount of compensation.

B. This major subsection is about benefits. Respond to the questions in the two minor subsections.

I. This minor subsection asks about direct benefits. Please indicate if subjects will receive a reward/incentive (other than monetary compensation) for participating in your study. Check yes or no. If no, skip to minor subsection II. If yes, indicate if one of the direct benefits is course credit/extra credit. Check yes or no.

If yes, respond to the questions in the two subsections.

a. This subsection asks you to identify the course(s) from which subjects will receive course credit/extra credit.

b. This subsection asks if there is approval allowing course credit/extra credit for this course(s) on file with the IRB? If yes, skip to minor subsection II. *Note: This documentation should include the equivalent alternatives for students who choose not to participate, and why course credit or extra credit is not considered coercive.* If no, **you must submit an approval letter (or e-mail from an Augsburg e-mail address if an Augsburg classroom) granting approval for course credit credit/extra credit.** You will need to scan the signed letter in order to submit it electronically.

If no, respond to the questions in the two subsections

a. This subsection asks you to describe the proposed reward/incentive

b. This subsection asks you to justify how the proposed incentive/reward is not coercive

II. This minor subsection asks about indirect benefits. Indicate the potential benefits to science/your discipline or society (in general) as a result of participating in this research (e.g., adding to existing knowledge, assisting a school/agency/company). If the one of the direct benefits is course credit or extra credit, at least

one of the indirect benefits should relate to how participation in the research helps meet the objectives of the course. *Note: all studies must have at least one indirect benefit.*

C. This major subsection is about risks. Respond to the questions in the one minor subsection.

I. This minor subsection asks you to indicate whether your study involves any risks to subjects. Check yes or no. If no, justify why your study does not involve any risks. *Note: be sure to review all the listed risks before answering this question.* If yes, respond to the questions in the two subsections. *Note: When you consider each risk, there is a continuum ranging from minimal to extensive. In your answer, describe where the risk falls on this continuum and why you made that assessment. For example, consider the risk of invasion of privacy of subject or family. Asking about gender or TV show preferences would be on the low end of the risk continuum but asking about participation in criminal activities would be on the high end of the continuum. Expedited studies must have no more than minimal risk so if expedited review was checked, be sure the risk is at the low end of the continuum.*

a. This subsection asks you to check all of the risks associated with your study. *Note: the board may feel that another risk is appropriate or that a risk listed is not appropriate* The options are:

Inability to guarantee anonymity; respond to the question in the one subsection.

i. This subsection asks you to provide the reason why anonymity cannot be guaranteed.

Use of private records (medical, agency, or educational); respond to the question in the one subsection

i. This subsection asks you to describe how the risk is involved in the study.

Possible invasion of privacy of subject or family; respond to the question in the one subsection

i. This subsection asks you to describe how the risk is involved in your study

Discussion of/questions about sensitive topics; respond to the question in the one subsection

i. This subsection asks you to describe how the risk is involved in your study

Social or economic risk (participation in your study could lead to social or economic harm); respond to the question in the one subsection

i. This subsection asks you to describe how the risk is involved in your study.

Probing for personal information; respond to the question in the one subsection

i. This subsection asks you to describe how the risk is involved in your study.

Physical injury; respond to the question in the two subsections

i. This subsection asks you to describe how the risk is involved in your study

ii. This subsection asks you to provide a referral if physical injury occurs. *Note: even if you feel that your study will not cause physical injury and therefore a referral is not needed, the board may disagree with your assessment and require a referral.*

Psychological stress; respond to the questions in the two subsections

i. This subsection asks you to describe how the risk is involved in your study

ii. This subsections asks you to provide a referral if subjects feel that they need assistance dealing with the stress caused by the study. *Note: even if you feel that your study will not cause psychological distress and therefore a referral is not needed, the board may disagree with your assessment and require a referral.*

Use of deception (including the inability to reveal the true purpose of the research as part of the experimental method); respond to the question in the two subsections

i. This subsection asks you to describe how the risk is involved in the study

- ii. This subsection asks you to describe the “debriefing procedure” that will be followed at completion of or withdrawal from the study.
    - Other potential risks to your study; respond to the question in the two subsections
      - i. This subsection asks you to specify the risk
      - ii. This subsection asks you to describe how the risk is involved in your study.
  - b. This subsection asks you to explain how the potential risks to subjects are reasonable in relation to the anticipated benefits.
- D. This major subsection asks you to identify the procedures you will implement to protect subjects from the risks involved in your study. Respond to the questions in the two minor subsections.
  - a. This subsection asks you if you will be using direct quotes. Check yes or no. If no, skip to major subsection E. If yes, respond to the question in the one subsection.
    - i. This subsection asks you to indicate if you plan to identify subjects by name. Check yes or no. *Note: if you want to identify the subjects you must specifically reveal this at the time of consent and ask the subject’s permission to do so by providing a separate consent line on the consent form. If not granted permission you must use a pseudonym (e.g., fake names, subject 1) when quoting subjects.*
      - If yes, respond to the question in the one subsection
        - This subsection asks you to explain the reason for wanting to identify the subjects. *Note: you must request permission from the subject to identify them by name on the consent form and if not granted permission, you will need to use pseudonyms (e.g., fake names, subject 1, etc.) when discussing the subject being quoted.*
      - If no, you will use pseudonyms when discussing the subject being quoted.
- E. This major subsection asks you describe any other precautions that you will use to protect subjects from specific risks associated with your study (other than those listed above). If there are no additional precautions check, not applicable.
- F. If needed, this major subsection allows you to provide additional information relevant to the risk/benefit ratio.

## 9. SUBJECT DESCRIPTION AND IDENTIFICATION

- A. This major subsection asks you identify the populations you will be targeting in your study. Respond to the questions in the two minor subsections.
  - I. This minor subsection asks you to check all the populations you are targeting in the study. If your target population is not included in the list, identify the specific population you are targeting under “other.”
  - II. This minor subsection asks you to provide the rationale for targeting the populations you checked.
- B. This major subsection asks if you are anticipating a sample of gender, race, or ethnicity that is proportionate to the general population. Check yes or no. If yes, skip to major subsection C. If no, explain why not.
- C. This major subsection asks if you are identifying potential subjects based on private records “owned” by the cooperating agency/organization(s). Check yes or no. If no, skip to major subsection D. **If yes, you must submit an approval letter(s) specifically granting you access to the private records.** You will need to scan the signed letter in order to submit it electronically. *Note: If the agency/organization needs to provide permission for multiple things (see other questions that require an agency/organization approval letter), you only need to submit one letter that addresses all issues, but be sure it addresses all aspects that require approval.*
- D. This major subsection asks if there is a relationship between potential subjects and the principal investigator, and if relevant the co-investigator, and research assistant. Check yes or no. *Note: Be conservative in answering this question. Think deeply about any connection there might be between the potential subjects and these people.*
  - If no, explain why there is no relationship.
  - If yes, respond to the questions in the two minor subsections.

- I. This minor subsection asks you to describe the relationships(s)
- II. This minor subsection asks you to indicate if the relationship could be considered close. Check yes or no. *Note: close is defined by a relationship that is personal, involves frequent contact or one that involves a power differential. If the relationship is close, it needs to be disclosed at the time of consent.*  
If no, explain why the relationship is not considered close.  
If yes, respond to the questions in the two subsections.
  - a. This subsection asks you to explain why the relationship is close.
  - b. This subsection asks you to describe the steps taken to mitigate the possible coercion involved when the relationship is close.
- E. If needed, this major subsection allows you to provide additional information relevant to subject description and identification.

## 10. CONFIDENTIALITY

- A. This major subsection asks you to identify who will have access to the raw data in addition to the principal investigator, and if relevant the co-investigator, research assistants, transcriptionist(s) and/or translator(s). *Note: The definition of raw data is the actual data obtained from a subject in its complete form.* If you are a student, you should check academic advisor. If you plan to show the raw data to anyone else, check other and identify the individual(s) including title and agency/organization. *Note: you may not show the raw data to anyone you do not indicate in this section.*
- B. This major subsection asks you if the raw data contain identifying information (i.e., information that may allow the subject to be identified). Check yes or no. If no, skip to major subsection C. If yes, respond to the questions in the three minor subsections.
  - I. **This minor subsection asks you to indicate where the raw data will be kept. Check all that apply. You must check at least one. The options are:  a locked file or  password protected computer, database, or digital storage system.** If checking the latter option, respond to the questions in the one subsection.
    - a. This subsection asks you to indicate if the computer/database/digital storage system is located at the cooperating agency/organization(s). Check yes or no and then skip to minor subsection II. *Note: if yes, this information must be disclosed at the time of consent.*
  - II. This minor subsection asks if the data will be part of a subjects' chart, student file, or other permanent record. Check yes or no. If no, skip to minor subsection III. If yes, explain.
  - III. This minor subsection asks if the raw data will include audio or video recordings. Check yes or no. If no, skip to major subsection C. If yes, answer the question in the one subsection.
    - a. This subsection asks if the recordings will be transcribed. Check yes or no. *Note: transcriptions are considered raw data.*  
If no, skip to major subsection C.  
If yes, indicate who will be doing the transcription. The options are:  principal/co-investigator,  research assistant, or  other. Check all that apply. If other is checked, identify the person **and check the box that you have submitted a signed Transcriptionist Confidentiality Agreement.** This document is located on the IRB website in the Supplemental Resources section. You will need to scan the signed document in order to submit it electronically. *Note: If a research assistant is doing the transcribing, there is no need to submit a transcriptionist confidentiality agreement as the research assistant confidentiality agreement covers transcription activities.*
- C. This major subsection is about how and to whom the final report will be disseminated. Check all that apply. There are six provided options:
  - Possible publication in scholarly journals
  - Possible publication in a book

- Possible presentation at local, regional, national or international conferences via poster or oral presentation
- Subjects; if this is checked you must guarantee that each subject will receive a copy of the final report
- External funding agency
- Cooperating agency/organization(s); if this option is checked, provide the name with title and agency/organization affiliation to whom the report will be given and in what form (e.g. paper, oral presentation). If multiple agencies/organizations, be sure to identify the agency/organization when providing the name of the person receiving the report.
- Other means of dissemination; check this box if you plan to disseminate the results in a format or place not listed and describe the format and/or location.

If the principal investigator is a graduate student, check all the ways in which the final report will be disseminated. There are three options:  paper to Faculty for completion of degree requirements,  oral presentation to Faculty for completion of degree requirements, and  the Lindell Library.

If the principal investigator is an undergraduate student, check all the ways in which the final report will be disseminated. There are five options:  URGO presentation and paper,  McNair presentation and paper,  LSAMP presentation,  paper to Faculty for Departmental Honors, and  presentation to Faculty for Departmental honors.

D. If needed, this major subsection allows you to provide additional information relevant to confidentiality.

## 11. RECRUITMENT

**IMPORTANT:** In this section, you will be required to provide recruitment documents. There are various types of recruitment documents. Therefore, a helpful guideline for creating recruitment documents is available. It is located on the IRB website in the Supplemental Resources section. Keep in mind that a separate recruitment document may be required for each type of subject, unless the wording addresses all types of subjects and all subjects are doing the same tasks. If you respond no to the first question, the guideline for creating recruitment documents is not relevant to your study. See the next section for the appropriate type of document.

A. This major subsection asks you to indicate if the researcher will have contact with the subjects during data collection. Check yes or no.

If no and it is true for all methodologies employed in the study skip to major subsection C. *Note: If you check no, this means that there is no contact with the subjects at any time (e.g., on-line survey). Therefore, recruitment and consent are occurring at the same time and the recruitment information will be included in the section on the consenting process (#12).*

If yes, this means that there will be direct contact between the researcher and the subject. *Note: In these situations, data collection typically occurs at a later point in time after recruitment.*

B. This major subsection asks you to identify the methods by which you will recruit subjects. Check a box by each of the minor subsections that apply (I-III) that apply and/or provide another method of recruitment (IV) that is not listed.

I. You will check the box by this minor subsection if you plan to recruit potential subjects via  e-mail,  postal mail letter, or  telephone. Check all that apply and then respond to the questions in the one subsection.

a. This subsection asks you to identify who will be doing the recruitment. There are two options—the researchers or someone else. Check the appropriate box and then respond to the questions in the respective subsections.

The principal/co-investigator and/or research assistant will be recruiting subjects via the checked methods. Then respond to the questions in the two subsections.

i. This subsection asks you to indicate how the contact information (telephone number, e-mail address, postal address) for potential subjects will be obtained. There are five options and you should check all that apply.

- Principal/co-investigator personally possesses the contact information. *Note: the definition of “personally possess” is that the potential subject personally gave you their contact information or you have interacted with them on a personal level (not just work related) using that contact information, even if they did not personally give it to you.* If you check this option, answer the question in the one subsection:
- This subsection asks you to describe how/why the principal/co-investigator have access to the contact information:
- Contact information for potential subjects is publically available. *Note: publically available is defined as a source that is available to anyone (e.g. website in which contact information is available without the need for a password).* If check this option, respond to the question in the one subsection.
- This subsection asks you to identify the public venue from which you will obtain the contact information.
- The cooperating agency/organization will be asked to provide the contact information for potential subjects. *Note: This includes an agency/organization at which you currently are employed or interning. Access to employee contact information for your job/internship does not mean you may access it for your research.* If you check this option, respond to the questions in the two subsections.
- This subsection asks you to identify the names (including title and agency/organization) of the contacts
  - This subsection asks you to describe how/why they have access to the contact information for potential subjects
- Check the box indicating that you have submitted a signed approval letter from the proper authority at the cooperating agency/organization specifically granting access to the contact information.** You will need to scan the signed letter in order to submit it electronically. *Note: If the agency/organization needs to provide permission for multiple things (see other questions that require an agency/organization approval letter), you only need to submit one letter that addresses all issues, but be sure it addresses all aspects that require approval. Note: If you are using this contact method, you will need to have contacted the agency/organization(s) before submitting the IRB application, as you need to obtain an approval letter from the agency/organization granting you access to the private contact information when submitting the application.*
- People who the principal/co-investigator personally know will be asked to provide the contact information. If you check this option, respond to the questions in the two subsections.
- This subsection asks you to identify the type of people who will be asked to recruit subjects. *Note: the type of people is general (e.g., friends, colleagues) and not specific names of people.*
  - This subsection asks you to describe how/why they have access to the contact information.
- A snowball method of recruitment will be used—subjects will be asked for the contact information of other potential subjects. If you check this box, respond to the questions in the one subsection.

- This subsection asks you to describe how/why the subjects have access to the contact information.
- ii. This subsection asks you to provide the recruitment e-mail, postal mail letter, or script for the telephone recruitment. Be sure this is worded from the perspective of the researcher. The submission box is even with the left-hand margin below the subsection.
- Other people (i.e., recruiters) than the principal/co-investigator or research assistant will be recruiting potential subjects with the checked recruitment methods. Then respond to the questions in the two subsections.

- i. This subsection asks you to indicate the ways in which the recruiters will be identified. There are three options and you should check all that apply.

- Recruiters are employed at/work for the cooperating agency. *Note: this should be interpreted broadly—the person could be an intern or a volunteer, not just a paid employee. This is a good option if you feel that the cooperating agency/organization would not allow you to contact employees directly or you know they will not allow you to do this. You only would check this option if you personally do not possess the contact information for those you wish to contact at the agency/organization(s). Remember that access to these potential recruiters at the agency/organization(s) should be obtained without invading the person's privacy. If you choose this method, you do not need to contact potential recruiters before submitting the IRB application. Knowing the names of the contacts (i.e., potential recruiters) is not necessary because you do not need an approval letter from the agency/organization(s). Approval letters only are needed when obtaining private contact information for potential subjects.*

If you check this option, respond to the questions in the two subsections.

- This subsection asks you to describe how the recruiters will be identified.
- This subsection asks you to describe how/why the recruiters have access to potential subjects

- Principal/co-investigator personally know the recruiters. *Note: This is a good option if you feel that your personal contacts would not want you to contact the people they know directly or you know they would not want you to do this. If you choose this method, you do not have to contact potential recruiters before submitting the IRB application.*

If you check this option, respond to the questions in the two subsections.

- This subsection asks you to describe how the principal/co-investigator personally know the recruiters
- This subsection asks you to describe how/why the recruiters have access to potential subjects

- A snowball method of recruitment will be used—subjects will be asked to be recruiters. If you check this option, respond to the question in the one subsection

- This subsection asks you describe how/why subjects have access to other potential subjects.

- ii. This subsection asks you to provide the recruitment e-mail, postal mail letter, or script for the telephone recruitment. Be sure this is worded from the perspective

of the recruiter and NOT the researcher. The submission box is even with the left-hand margin below the subsection.

II. You will check the box by this minor subsection if you plan to recruit subjects in person. If this method is checked, respond to the questions in the four subsections.

- a. This subsection asks you to identify the location (e.g., St. Helena's Church) and the specific context (e.g., after Sunday masses in the social hall) at which the recruitment will take place.
- b. This subsection asks you to identify who will be doing the recruitment. *Note: the agency/organization may require that someone other than you do the recruiting or you may choose this option. Consider issues related to coercion in the recruitment situation, when making this decision. If potentially coercive, someone else should do the recruiting.*
- c. This subsection asks you to indicate who is providing approval to do the recruitment at this location. There are two options:

Check the box that you have submitted a signed approval letter(s) from the cooperating agency/organizations(s) specifically giving you permission to recruit subjects in the context listed. You will need to scan the signed letter in order to submit it electronically. *Note: If the agency/organization needs to provide permission for multiple things (see other questions that require an agency/organization approval letter), you only need to submit one letter that addresses all issues, but be sure it addresses all aspects that require approval. If you are using this recruitment method, you will need to have contacted the agency/organization(s) before submitting the IRB application, as you need to obtain an approval letter.*

You are the proper authority who would grant permission to recruit in this location. *Note: This means that you are "in charge" of what happens in this context and the potential subjects are not minors. For example—professor in your college classroom or you are conducting a workshop. This cannot be a situation involving minors. Even if you feel that you are the proper authority, the board may disagree and require approval from a higher authority.*

- d. This subsection asks you to provide the exact wording of the verbal script that will be used to recruit subjects and the handout given to potential subjects (if relevant). If the person doing the recruitment is not the researcher be sure the recruitment script is worded from the recruiter's perspective and not the researcher's perspective. The submission box is even with the left-hand margin below the subsection.

III. You will check the box by this minor subsection if you plan to recruit potential subjects via some type of posting. If this method is checked, respond to the questions in the one subsection.

- a. This subsection asks you to indicate if the posting is in virtual space (e.g., facebook). Check yes or no.

If yes, respond to the questions in the two subsections and then skip to minor subsection IV.

- i. This subsection asks you to identify the specific venue
- ii. This subsection asks you to provide the exact wording that will be used in the posting. The submission box is even with the left-hand margin below the subsection.

If no, this means that the posting will be placed in a physical location. Respond to the questions in the three subsections.

- i. This subsection asks you to describe the specific type of posting.
- ii. This subsection asks you to provide the exact wording that will be used in the posting. The submission is box is even with the left-hand margin right below the subsection.
- iii. This subsection asks if the physical location is private property. Check yes or no.

If no (i.e., a public space), respond to the questions in the two subsections.

- This subsection asks you to describe the public place at which the posting will be placed
- This subsection asks you to justify why the location is public

If yes (i.e., private property), respond to the questions in the one subsection.

- This subsection asks you to describe the private property at which the posting will be placed

Check the box indicating that you have submitted a signed approval letter granting permission to post at the private location. You will need to scan the signed letter in order to submit it electronically.

IV. Check the box by this minor subsection if you plan to recruit potential subjects by another method of recruitment that is not listed above. If this method is chosen, respond to the question in the one subsection.

a. Explain the recruitment method.

C. If needed, this major subsection allows you to provide additional information about recruitment.

## .12. INFORMED CONSENT PROCESS

**IMPORTANT:** In this section, you will be required to provide consent documents. There are various types of consent documents and depending on your methodology some will include recruitment information. Therefore, a helpful guideline for creating consent documents is available. It is located on the IRB website in the Supplemental Resources section on the IRB website. Keep in mind that a separate consent document may be required for each type of subject, unless the wording addresses all types of subjects and all subjects are doing the same tasks.

A. This major subsection concerns issues related to the level of cognitive impairment and age of the subjects.

I. This major subsection asks you to indicate if the subjects are cognitively impaired. Answer yes or no.

If yes (subjects are cognitively impaired), respond to the questions in the two subsections and then skip to major subsection B.

- This subsection asks you to indicate the type AND level of cognitive impairment.
- This subsection asks you to indicate the “status” of the subjects. There are three options. Check the one that applies.

Subjects are over 18 with no legal guardian. If you check this box, respond to the questions in the two subsections

- This subsection asks you to explain why subjects do not have a legal guardian despite being cognitively impaired
- This subsection asks you to provide a subject consent form with modified language, if appropriate given the level of cognitive impairment. The submission box is even with the left-hand margin below the subsection.

Subjects are over 18 with a legal guardian. If you check this box, respond to the questions in the two subsections.

- This subsection asks you to explain why a legal guardian is needed.
- This subsection asks if a parent/guardian consent form with subject assent statements is appropriate for subjects with this level of cognitive impairment (i.e., subjects are capable of understanding the language on a parent/guardian consent form). Check yes or no.

If yes, respond to the questions in the two subsections

- This subsection asks you to explain why subjects are capable of understanding the language on a parent/guardian consent form with subject assent statements. *Note: there is no definitive level of cognitive*

*ability needed to understand the language in a consent form. Use your judgment.*

- This subsection asks you to provide a parent/guardian consent form with subject assent statements. The submission box is even with the left hand margin below the subsection.

If no, respond to the questions in the three subsections

- This subsection asks you to explain why subjects are not capable of understanding the language on a parent/guardian consent form with subject assent statements. *Note: there is no definitive level of cognitive ability needed to understand the language in a consent form. Use your judgment.*
- This subsection asks you to provide a parent/guardian consent form. The submission box is even with the left-hand margin below the subsection.
- This subsection asks you to provide a subject assent form. The submission box is even with the left-hand margin below the subsection.

Subjects are minors. If you check this box, respond to the questions in the one subsection

- i. This subsection asks you to indicate if a parent/guardian consent form with subject assent statements is appropriate for subjects with this level of cognitive impairment (i.e., subjects are capable of understanding the language on a parent/guardian consent form). Check yes or no.

If yes, respond to the questions in the two subsections

- This subsection asks you to explain why subjects are capable of understanding the language on a parent/guardian consent form.
- This subsection asks you to provide a parent/guardian consent form with subject assent statements. The submission box is even with the left-hand margin below the subsection.

If no, respond to the questions in the three subsections

- This subsection asks you to explain why subjects are not capable of understanding language on a parent/guardian consent form
- This subsection asks you to provide a parent/guardian consent form. The submission box is even with the left-hand margin below the subsection.
- This subsection asks if an assent form is appropriate for subjects at this age and with this level of cognitive impairment. Check yes or no. If no, skip to major subsection B. If yes, provide the subject assent form. The submission box is even with the left-hand margin below the subsection.

If no (subjects are not cognitively impaired), respond to the questions in the one minor subsection.

- a. This subsection asks you to indicate the age range of the subjects. There are four options. Check the one that applies.

0-7 years of age. Respond to questions in the three subsections and then if this is the sole age range of your subjects, skip to major subsection B

- i. This subsection asks you to provide a parent/guardian consent form. The submission box is even with the left-hand margin below the subsection

ii. This subsection asks you to describe when and where parent/guardian consent will be obtained

iii. This subsection asks you to indicate who will be obtaining consent.

8-17 years of age. Respond to questions in the four subsections and then if this is the sole age range of your subjects, skip to major subsection B

i. This subsection asks you to provide a parent/guardian consent form. The submission box is even with the left-hand margin below the subsection.

ii. This subsection asks you provide a subject assent form (wording may vary depending on the subjects' age. The submission box is even with the left-hand margin below the subsection.

iii. This section asks you to describe when and where parent/guardian consent and subject assent will be obtained

iv. This subsection asks you to indicate who will be obtaining parent/guardian consent and subject assent. *Note: the person who obtains assent could be the parent/guardian if the both the parent/guardian consent form and assent form is brought home OR you could choose to obtain assent before data collection begins (and after parent/guardian consent has been obtained). The latter is preferred as the researcher can go over it with the minor subject.*

18+ years of age. Respond to the questions in the one subsection.

i. This subsection asks if there is contact with the subject. Check yes or no.

If no, (e.g., on-line survey, customer service survey located in a public space) in at least one phase of the study or at least one type of subject, respond to the questions in the one subsection

- This subsection asks if you are using an on line survey. Check yes or no.

If yes, provide the recruitment/consent e-mail. The submission box is even with the left-hand margin below the subsection.

If no, provide the recruitment/consent letter. The submission box is even with the left-hand margin below the subsection.

If yes, respond to the questions in the two subsections

- This subsection asks you to indicate all the "types of contact" there will be with subjects. There are two options. Check all that apply.

Subjects will be physically present

Subjects will be present via  phone or a  skype-like technology. Check all that apply. Then respond to the questions in the two subsections.

- ❖ This subsection asks you to describe the process for obtaining and tracking consent. *Note: in these situations, a signed consent form cannot be obtained easily so you need to develop a process to accomplish this. Some suggestions for this include recording the consenting process or sending the subject consent form via e-mail and having the subjects mail the signed form back to you before the skype or phone interview.*

- ❖ This subsection asks you to describe the process for getting subjects a copy of the consent form. *Note: subjects must be given a copy of the consent form for*

*their records. Given that you will be unable to personally hand them the consent form, you must determine a method for doing this. One option is to e-mail or mail them the consent form*

- This subsection asks you to provide a copy of the subject consent form. The submission box is even with the left-hand margin below the subsection.

B. This major subsection asks you provide the questions you will ask subjects to assess their understanding of the study and consent.

First, you will check one of two boxes

- There is no contact with subjects so no questions will be asked. If this is the sole method, skip to C
- There is contact with subjects. Respond to the questions in the four minor subsections.

I. This minor subsection asks you to check the required questions that you must ask subjects. Check each box.

- Do you understand that that you are free to withdraw from the study at any time?
- Do you understand that you may skip any questions or tasks?
- Do you have any questions about what you are being asked to do?

II. This minor subsection asks you to indicate if age-appropriate or ability-appropriate versions of the above questions is needed. Indicate yes or no. If no, skip to minor subsection III. If yes, provide the appropriate version of each question.

C. If needed, this major subsection allows you to provide additional information about informed consent.y

### 13. STUDIES INVOLVING NON-ENGLISH SPEAKING SUBJECTS

**IMPORTANT:** If this section is relevant to your study, you will be required to submit at least one translator confidentiality agreements. This document is located on the IRB website in the Supplemental Resources section. You will need to scan the signed document(s) in order to submit it electronically.

A. This major subsection asks you to indicate if the study involves non-English speakers. Check yes or no. If no, the application is complete. If yes, respond to the questions in the one subsection.

I. This minor subsection asks you to indicate which types of translation will be needed in your study. There are three options. Check all that apply.

- Written materials (e.g., recruitment/consent forms). If checked, respond to the question in the one subsection.

a. This subsection asks you to indicate if the principal/co-investigator will be doing the translation. Check yes or no.

If yes, describe the principal/co-investigator's qualifications to do the translation.

If no, respond to the questions in the two subsections.

i. This subsection asks you to identify the person doing the translation

ii. This subsection asks you to describe the person's qualifications to do the translation.

- Information verbally delivered during the study by the researcher (e.g., interview questions) or provided by the subject (e.g., subject responses). Respond to the questions in the two subsections.

a. This subsection asks you to indicate if the principal/co-investigator will be doing the translation. Check yes or no.

If yes, describe the principal/co-investigator's qualifications to do the translation.

If no, respond to the questions in the two subsections.

- i. This subsection asks you to identify the person doing the translation
- ii. This subsection asks you to describe the person's qualifications to do the translation.

Check the box indicating that you have submitted a signed translator confidentiality agreement. *Note: If a research assistant is doing translation, the translator confidentiality agreement must be submitted as the research assistant confidentiality agreement does not cover translation activities.*

Raw data that must be translated into English. Respond to the questions in the one subsection.

- a. This subsection asks you to indicate if the principal/co-investigator will be doing the translation. Check yes or no.

If yes, describe the principal/co-investigator's qualifications to do the translation.

If no, respond to the questions in the two subsections.

- i. This subsection asks you to identify the person doing the translation
- ii. This subsection asks you to describe the person's qualifications to do the translation.

Check the box indicating that you have submitted a signed translator confidentiality agreement. *Note: If a research assistant is doing translation, the translator confidentiality agreement must be submitted as the research assistant confidentiality agreement does not cover translation activities*

*Note: It is likely that if you need a translator to translate information verbally during the study you also will need someone to translate the materials into that language, and translate the raw data into English for data analysis. We ask about each of these separately, as different people may be doing each type of translation task. If the same person is ever repeated, write "same as above." The Translator Confidentiality Agreement covers both verbal and written translation activities. So if the same person is doing both, only one confidentiality agreement needs to be submitted.*

- B. If needed, this major subsection allows you to provide additional information related to studies involving non-English speaking subjects.