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. Augsburg’s Student IRB application has been formed based on the regulations required by OHRP.

IRB Application Instructions

The information below provides guidelines to help students complete the Student Classroom project IRB application. This application should only be used for projects conducted as an assignment in a class which has been approved through the classroom protocol.

1. Project Title

   This title should accurately reflect the purpose of the study. This title should be used on the consent form unless you are using an experimental design in which your methodology requires you to hide the true purpose of the study.

2. Review Category

   Exempt is the only type of research that can be done in a classroom setting.

   To determine if your study qualifies for exempt review you should go to: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101%28b%29

   For additional help in determining the level of review OHRP also 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 meet the requirement for expedited or exempt review, it may not be conducted in a classroom project without approval by the full board.

3. Research Investigator Information

   A. This major subsection asks you to provide the contact information of the principal investigator. If you are filling out the IRB application, you are the principal investigator. Provide your contact information. You must list an Augsburg e-mail address.

   B. This major subsection asks if there is a co-investigator. Co-investigators in the context of a class are the members of your group working on the research project with you or every student in the class if the whole class is conducting the same research project. If using a group project,
provide the names of your group members. If the entire class is conducting the same study, write “all students.” If you are doing an individual project, check not applicable.

C. This major subsection asks you to provide the prefix, number, and title of the course and the contact information for your instructor.

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

4. **Research Question/Hypothesis, Purpose, and Methodology**

A. This major subsection asks you to 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).

B. This major subsection is about the methodology you will be using in your study. Respond to the questions in the four minor subsections.

   I. This minor subsection asks you to identify the methodology you will be using in your study (check all that apply)

   □ Analyzing existing data, records, or specimens. If you check this box 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.

   If this is the sole method used in your study, skip to question #8. Respond to that question and the application is complete. If other methods will be used, continue to answer questions (i.e., do not skip any questions).

   □ Observation of public behavior (i.e., behavior that occurs in a situation in which the person being observed has no expectation of privacy and their behavior is unaffected by the researcher). If you check this box, respond to the questions in the three subsections.

   a. This subsection asks you to indicate who will be observed.

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

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

   If this is the sole method used in your study, skip to question #8. Respond to that question and the application is complete. If other methods will be used, continue to answer questions (i.e., do not skip any questions).

   □ Qualitative Research; Indicate if the research method involves:

   □ Interviews; indicate where the interviews will take place
Focus Groups; indicate where the focus groups will take place

Survey Research (not surveys used in an experimental methodology); Check the delivery method for the surveys

Hard copy, indicate where the surveys will be completed
On-line, indicate the survey tool used to deliver and create the survey (e.g., survey monkey)

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 multiple types of subjects will be included in your study (e.g. baseball and football player). Check yes or no.

If no, indicate the maximum number of subjects who may participate in your study. **Note:** This number will not necessarily reflect the actual number of subjects who eventually participate but represents the number you will attempt to obtain, even if it does not happen. The number you list is the maximum number of subjects who may participate in your study, so it is better to err on the high side than the low side.

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 who may participate in your study. **Note:** This number will not necessarily reflect the actual number of subjects who eventually participate but represents the number you will attempt to obtain, even if it does not happen. The number you list is the maximum number of subjects who may participate in your study, so it is better to err on the high side than the low side.

IV. This minor subsection asks you to indicate if the study has more than one phase (e.g. subjects will complete a survey and based on responses may be asked to participate in an interview. Check yes or no.

If no, respond to the questions in the two subsections

a. This subsection asks you to describe the one phase

b. This subsection asks you to identify the criteria for selecting someone to be in your study (e.g., students in a Psy 105 class)

If yes, respond to the questions in the two subsections

a. This subsection asks you to explain each phase of the study

b. This subsection asks you to indicate the criteria for selecting someone to be a subject in EACH phase of the study

C. If needed, this major subsection allows you to provide additional information relevant to the research question/hypothesis, purpose, and methodology

5. MATERIALS
A. This major subsection asks you identify the types of data you will be collecting in your study. Check all that apply.

- Audio recordings
- Video recordings
- Written notes
- Photographs
- Drawings
- Interview/focus groups; if you check this box, respond to the question in the one subsection

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

- Surveys; if you check this box, respond to the question in the one subsection

I. This subsection asks you to provide the survey. If not possible to cut and paste, indicate that it is attached in a separate document. The submission box is even with the left-hand margin below the subsection.

- Other, please identify.

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

6. **RISK/BENEFIT RATIO**

A. This major subsection is about benefits. Answer the questions in the two minor subsections.

I. This minor subsection asks about the direct benefits. Respond to the questions in the two subsections.

   a. This subsection asks if subjects will receive a reward/incentive for participating in your study. Check yes or no. If no, skip to minor subsection II. If yes, describe the proposed incentive/reward.

   b. Check the box indicating that you swear not to provide subjects with any other rewards/incentives than those listed.

II. This minor subsection is about the indirect benefits. Answer the question in the one subsection.

   a. This subsection asks you to indicate the potential benefits to science or society (in general) as a result of participating in this research (e.g., adding to existing knowledge). If one of the direct benefits is course 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.**

B. This major subsection relates to the risks of participating in your study. Respond to the questions in the one subsection

   I. This subsection asks if your study involves any risks to subjects. **Note: Please read all risks before indicating no. In exempt, your study should have no risks.**
a. This subsection asks you to explain how the potential risks to subjects are reasonable in relation to the anticipated benefits.

C. This major subsection relates to the precautions you will take to minimize the risks indicated in the previous major subsection. Respond to the questions in the two minor subsections.

I. This subsection is about the required precautions you MUST have in your study. Check each one.

II. This subsection relates to the precautions that will be taken when reporting the data in the final report. Respond to the questions in the one subsection.

   a. This subsection asks if you will be using direct quotes in the final report. Check yes or no.

D. If needed, this major subsection allows you to provide additional information relevant to risk/benefit ratio.

7. SUBJECT DESCRIPTION AND IDENTIFICATION

A. This major subsection is about your subject population. Respond to the questions in the two minor subsections.

   I. This minor subsection asks you to identify the specific subject populations you are targeting in your study.

   II. This minor subsection asks you to provide the rationale for purposely targeting the populations checked.

B. This major subsection asks you to indicate if there is a relationship between potential subjects and the primary investigator, co-investigator (if relevant), or instructor. 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 and skip to major subsection C.

   If yes, respond to the questions in the two minor subsection.

      I. This minor subsection asks you to describe the relationship(s). Note: Be sure to describe the relationship for the primary investigator, co-investigator (if relevant), and instructor.

      II. This minor subsection asks if the relationship(s) could be considered particularly close. Note: particularly close is defined by a relationship that is personal, involves frequent contact, or one that involves a power differential. Check yes or no.

      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 considered close

         b. This subsection asks you to describe the steps taken to mitigate the possible coercion involved in such situations.
C. If needed, this subsection allows you to provide additional information relevant to subject description and identification.

8. CONFIDENTIALITY

A. Check the box by this major subsection indicating that you swear not to show the raw data to anyone other than the instructor and co-investigator (if relevant).

B. This major subsection asks if the raw data (including existing sources) contains identifying information (i.e., information that may allow the subject to be identified). Check yes or no. **Note: If you check yes, you are swearing that you will keep the raw data in a locked file or a password protected computer, database, or digital storage system.**

C. This major subsection asks if raw data include audio or video recordings. Check yes or no. **Note: if you check yes, you are swearing that you will be the only one who will transcribe the recordings.**

D. This major subsection asks how the final report will be disseminated. Check all that apply. **Note: These options are for the classroom only. If you plan to disseminate the results in a format or place other than the classroom, Check other and describe the format and/or location.**

Check box indicating that you swear you will not disseminate the results in any other manner than listed.

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

9. RECRUITMENT

A. This major subsection asks you to identify the ways in which potential subjects will be recruited (check all that apply)

- Potential subjects will be recruited in person; If this box is checked respond to the questions in the two minor subsections
  
  I. This minor subsection asks you to identify the exact location and describe the context in which the recruitment will be made, and who will be doing the recruitment.
  
  II. This minor subsection asks you to provide an exact copy of the verbal script that will be used to recruit subjects. The submission box is even with the left-hand margin below the subsection.

- Potential subjects will be recruited via some type of posting (e.g. subject pool posting); If this box is checked respond to the questions in the two minor subsections.
  
  I. This minor subsection asks to describe the specific type of posting
  
  II. This minor subsection asks you to provide the exact copy of the recruitment posting. The submission box is even with the left-hand margin below the subsection.
B. Check the box by this subsection indicating that you swear that you will not recruit subjects by any other ways than those listed.

C. If needed, this major subsection to provide additional information relevant to recruitment. Note: if you intend to use another method of recruitment, it may not violate a potential subject’s privacy in order to gain access to them for recruitment. This includes obtaining e-mail addresses from the student directory. Access to e-mails for the purposes of research needs college approval.

10. INFORMED CONSENT PROCESS

A. This major 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 is about the questions you will ask subjects to assess their understanding of the issues related to consent and the tasks they will be asked to do; Respond to the questions in one minor subsections.

   I. This minor subsection asks you to check each of the required questions you will ask subjects. Note: These questions should be asked after reading the consent form to subjects.

C. Check the box by this major subsection indicating that you swear that you will read the consent form to subjects

D. Check the box by this major subsection indicating that you swear that consent will be obtained with a subject consent form immediately prior to the collection of data.

E. If needed, this major subsection allows you to provide additional information relevant to the informed consent process

GUIDELINES FOR CREATING A SUBJECT CONSENT FORM

Depending on the types of subjects and your specific methodology, you may need to provide separate subject consent form for each type of subject. You should think about your design to determine if you can cover all types of subjects in one consent form. If this is not possible or it would be cumbersome/confusing to do so, you should use multiple consent forms.

The following pages contain information about creating a consent form. The information for each type contains examples for each paragraph of the document. These examples DO NOT contain every possible variation that may be needed. Be sure to follow the guidelines of what should be included in each paragraph rather than cutting and pasting the example paragraph.

The top of the consent form should have the title of the project (centered). The title should be the same as the one listed in section 1 of the Student IRB application. The only exception is when an experimental method necessitates the true nature of the study not be revealed before participation. In this situation, create a title that is plausible given your methodology.
The first paragraph should state that they have been invited to participate in a study about the research question you described in section 4, major sub section A of the Student IRB application. This should be very brief and general. The only exception is when an experimental method necessitates the true nature of the study not be revealed before participation. In this case, create a research question that is plausible given your title and methodology. The next sentence should state why they were selected as a possible subject by listing the selection criteria provided in section 4, major subsection B, minor subsection IV of the Student IRB application. The last sentence should inform them that they should read the form and ask any questions they have before agreeing to participate in the study.

Example: You are invited to participate in a research study about reading stories. You were selected as a possible subject because you are a student in Psy 105 and signed up to participate in the study. Please read this form and ask any questions you may have before agreeing to participate in the study.

The second paragraph should state who is conducting the study, their major, year in school, and the course for which they are doing the research. The name of the course instructor also should be listed. Include the instructor’s degree (e.g., Ph.D., Ed.D.), and title (Adjunct Professor, Assistant Professor, Associate Professor, or Professor). If the instructor and/or the student researcher have a close relationship to potential subjects, it will need to be disclosed here.

Example: This study is being conducted by Jane Doe as part of the requirements in my Soc 263 course. I am a senior sociology major. The instructor of the course is John Smith, Ph.D. an Associate Professor in the Sociology department.

The third paragraph should be titled PROCEDURES (left justified and in a line by itself) followed by a paragraph that describes what subjects will be asked to do. This information was provided in section 4, major subsection B, minor subsections II and IV of the student IRB application. If you plan to record an interview, you will need to include that and be sure to indicate that the recording only will occur if granted permission.

Example: If you agree to be in this study, you will complete a 20 item multiple-choice survey about your views on the food options at Augsburg. The survey should take about 8 minutes to complete.

The fourth paragraph should be titled RISKS AND BENEFITS OF PARTICIPATING IN THIS STUDY (left justified and in a line by itself) followed by a paragraph that describes the risk and benefits associated with participation in the study listed in section 6 of the Student IRB application. Be sure to list the direct (section 6, major subsection A, minor subsection I, subsection a), and the indirect benefits (section 6, major subsection A, minor subsection II, subsection a). If there are no direct benefits, state that. Be sure to include all the checked risks on the Student IRB application (section 6, major subsection B, minor subsection I, subsection a). Do not include the risk of deception.

Example: The risks to participation are the following: possible invasion of privacy of subject or family. The direct benefit is course credit in your Business 160 course. Indirect benefits are learning about how consumer research is conducted.
The fifth paragraph should be titled **CONFIDENTIALITY** (left justified and in a line by itself) followed by a paragraph describing the ways in which you will maintain confidentiality. This includes information from section 8 including major subsections A, B (if checked yes), C (if checked yes), and major subsection D. Information from section 6, major subsection C, minor subsection II, subsection a (if checked yes). The paragraph you should begin with a sentence indicating that the records of the study will be kept confidential, unless required by law.

*Example: The records of this study will be kept confidential, unless required by law. Only the researcher and her advisor, Dr. Smith, will have access to the data. The results will be disseminated in a final paper and oral presentation in my Psy 315 class. The results also may be presented at Zyzoggeton or Minnesota Undergraduate Psychology Conference.*

The sixth paragraph should be titled **VOLUNTARY NATURE OF THE STUDY** (left justified and in a line by itself) followed by a paragraph indicating that the subjects’ decision about whether or not to participate will not affect their future or current relations with Augsburg College, the researcher, or the instructor of the course in which they are enrolled (if relevant). Include the information about the required precautions to minimize risk provided in section 6, major subsection C, minor subsection I.

*Example: Your decision about whether or not to participate in this study will not affect your current or future relations with Augsburg College, the researcher, or the instructor of your Psy 105 course. If you decide to participate, you are free to skip questions in the interview or withdraw at any time without affecting those relationships.*

The seventh paragraph should be titled **CONTACTS AND QUESTIONS** (left justified and in a line by itself) followed by a paragraph that begins by informing subjects that may ask any questions they have now. Provide the e-mail contact information of the course instructor. Also, provide your Augsburg e-mail contact information. Include information about contacting the IRB if they have concerns/questions about their rights as a research subject or you want to report problems/complaints about the research study. On a separate line, include a sentence indicating they will be given a copy of the form for their records.

*Example: You may ask any questions you have now. If you have questions later, you may contact me, Jane Doe, at doe@augsburg.edu. You may also contact my advisor, John Smith, at smith@augsburg.edu. If you have questions about your rights as a research subject or you want to report problems/complaints about the research study, send an e-mail to IRB@augsburg.edu. You will be given a copy of this form to keep for your records.*

The eighth paragraph should be titled **STATEMENT OF CONSENT** (left justified and in a line by itself) followed by consent statements to (1) participate in the study, (2) be audio or video taped (if relevant), and (3) use direct quotes (if relevant). Each consent statement should include a signature line for the subject. For the consent statement to participate in the study, you will need to include a line for the subject to print their name, a line for the date after the subject signature line, a line for the student researcher to print their name, and a signature and data line for the student researcher.

*Example: I have read the above information or have had it read to me. I have received answers to questions asked. I consent to participate in the study.*
Guidelines for Creating RECRUITMENT DOCUMENTS

Recruitment documents are used when you are recruiting subjects to participate in a study but the data collection will occur at a later point in time. There are two basic recruitment documents: verbal scripts for in-person recruitment, and postings. Samples are not provided but recruitment documents contain some of the same information as a consent form so you should look at the guidelines for creating the subject consent form for guidance.

Recruitment documents should include the following information (not necessarily in the order listed below):

• your name
• name of co-investigator’s, if relevant
• the title of the project (on postings)
• your affiliation with Augsburg College (e.g., senior sociology major)
• any close relationships with potential subjects, if relevant (section 7, major subsection B, minor subsection I of Student IRB application)
• the selection criteria for participation in the study (section 4, major subsection B, minor subsection IV of Student IRB application)
• an invitation to be in a study about your research question—brief and general (section 4, major subsection A of Student IRB application). The only exception is when the experimental methodology necessitates the true nature of the study not be revealed before participation. In this case, create a research question that is plausible given your methodology.
• what subjects will be asked to do if they choose to participate (section 5 of Student IRB application) including anticipated recordings (section 4, major subsection, minor subsections II and IV of Student IRB application)
• the risks (section 6, major subsection B, minor subsection I) as well as the direct benefits (section 6, major subsection A, minor subsection I) and indirect benefits (section 6, major subsection A, minor subsection II)
• what to do if they are interested in participating in the study (i.e., how they should contact you)