CLASSROOM PROTOCOLS

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 (OASH) in the Office of the Secretary (OS), 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 classroom protocol application and student IRB application have been formed based on the regulations required by OHRP.

All student research with human subjects must be reviewed by the Institutional Review Board. When students conduct research with human subjects as a part of a classroom assignment, the instructor may wish to apply for approval for all the students rather than asking each student to apply individually for IRB approval. Research for classroom projects may not qualify for full or expedited review, only exempt. If a student wants to propose a project that qualifies for full or expedited review, an individual IRB application must be submitted for full board review. This process can take 6-8 weeks to obtain final approval. Therefore, the students must avoid projects that qualify for full or expedited review.

Classroom protocols cover three “types” of classroom projects:
- The entire class does the same research project
- Students conduct their own individual research project
- Students conduct research projects in groups

Once the classroom protocol has been approved, students do not need to submit any additional applications for their research to the IRB. However, the students must submit an IRB application to the instructor for their projects. Given that classroom projects must qualify for exempt review, much of the information requested in the regular IRB application is not relevant nor would it be allowed. Therefore, a simplified IRB application (classroom project student IRB application) has been created for classroom projects. This document is located on the IRB website. Instructions to help students complete the application also have been created and those instructions are also located on the IRB website. The Augsburg IRB is allowing the instructor to serve as its proxy to review the student IRB applications. The proxy powers only allow instructors to approve studies that fall within the parameters provided in the classroom protocol application. If a proposed project involves a component that goes beyond the parameters, two options are possible: (1) the student could submit an IRB application for review by the board (not recommended); or (2) a request to modify the parameters could be sent to IRB@augsburg.edu (not case sensitive). In that request, be sure to address all issues on the classroom protocol application that would be affected by the modification. The next time the course is taught, a new classroom protocol IRB application should be submitted that incorporates the changes. If a student research project extends beyond the end of the course, a regular IRB application must be submitted for review by the IRB. Research may not continue after the course ends, until regular IRB approval is obtained.

What do I need to do?

The instructor will need to submit an electronic copy of the Classroom Protocol Application and supporting documents (only needed in rare cases) to IRB@augsburg.edu. Please label each document: Course prefix and number, followed by the name of the document (for example, Psy 215 IRB application). Be sure the name of the document is an accurate reflection of the contents. If supporting documents are not submitted and/or the documents are not titled as instructed above, the application WILL NOT BE REVIEWED. If multiple instructors teach the course, one instructor may submit the form for all instructors but each instructor must be cc'd when the application is submitted. Once the instructors receive the e-mail they should reply to all confirming that they have read the application and agree to adhere to everything specified in it and that they have read the information on this page. The department chair also must be cc'd. When the department chair receives the cc'd submission, they will need to reply to all indicating that they have approved the proposal for submission. Your application will not be reviewed until the chair’s approval e-mail and instructor's confirmation e-mails have been received. THE IRB ONLY WILL COMMUNICATE WITH INSTRUCTORS AND CHAIRS USING THEIR AUGSBURG E-MAIL ADDRESS.

Each year after initial approval, the instructor should send an e-mail to IRB@augsburg.edu (following the procedures listed above), indicating any changes to the original application. If changes are substantive, a new application should be submitted.
Receipt of an application from the instructor’s and department chair’s Augsburg e-mail address serves as an electronic signature verifying that:

- The information provided in the application form is correct and the instructor(s) agrees to adhere to all aspects of the research included in the application.
- The instructor will obtain prior written approval from the IRB for any substantive modifications in the application.
- The research will not commence until the official IRB approval letter is received. The letter will be sent electronically from the chair using the IRB@augsburg.edu e-mail address to the department chair and all instructors will be cc’d.
- The student researcher is responsible for keeping all materials (e.g., raw data, consent documents) during the term and the instructor is responsible for doing so after the term ends for three years (this includes copies of the final reports). Both parties will provide these documents in a prompt manner to the IRB, if requested. Such requests will randomly be done to ensure that the classroom projects adhere to the parameters outlined in the classroom protocol application. If these conditions are not met, approval to conduct classroom research projects will be suspended.

INSTRUCTIONS FOR COMPLETING THE CLASSROOM PROTOCOL APPLICATION

1. COURSE INFORMATION

Provide the course number and title.

Provide the name of the department chair and the course instructor and provide their contact information. If there are multiple instructors, list each name and each piece of contact information separated by a comma. Be sure the order is the same for each piece of requested information.

The next question asks you to describe why conducting a research project needs to be a component of the class.

Check the appropriate statement that describes the nature of the classroom assignment. There three two options: All students will complete the same research project, students will conduct individual research projects, or students will conduct group projects.

Check the statement indicating that you have submitted a copy of the classroom assignment.

The next question asks you to indicate the level of review for the possible projects. Check all that apply. To determine if the possible projects qualify for exempt review 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.

2. RESEARCH QUESTIONS/HYPOTHESES

Provide the general type of research questions your students will be addressing.

3. METHODOLOGY

This section asks you to check the methodologies that might be used in the classroom projects. Check all that apply and provide an example study for each that you check. The options are: analysis of existing data, records, or specimens, observation of public behavior, interviews/focus groups, surveys, or experimental.
If you check the analysis of existing sources, explain the potential sources and their locations. Check the statement indicating that you have submitted the approval letter granting the class access to the data. Note: changes to this would be considered a substantive change. If this is the sole method used for the classroom project(s), skip to question #9.

If you check the observation of public behavior and it is the sole method used in the classroom projects, skip to question #9.

If you check interviews/focus groups provide an example of a possible study.

If you checked surveys, provide an example of a possible study. Indicate if the students will be creating their own survey(s). Check yes or no. If no, indicate if permission to use the survey has been obtained. Check yes or no. If no, explain why approval is not needed (e.g. open-source, provided in a journal article, etc.). Note: This reason needs to be about why approval is not needed rather than an explanation of why you have not obtained approval to use the survey.

If you checked experimental, provide an example of a possible study.

If needed, the next question allows you to provide any additional information relevant to methodology.

4. Subject Identification

The first question asks you to describe the subject population, in general, that will be targeted for the research projects.

The next question asks if there is a relationship between potential subjects and the instructor or student researchers. 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 yes, describe the relationship for the instructor and the student researchers. The next question asks if the relationship(s) could be considered close. Note: close is defined as a relationship that is personal, involves frequent contact, or involves a power differential. Check yes or no. If no, explain why it is not a close relationship (be sure to explain for both the instructor and student researchers). If yes, explain why the relationship is close and describe the steps taken to mitigate the possible coercion involved in such situations.

If needed, the next question allows you to provide any additional information relevant to the identification of subjects.

5. Recruitment

The first question asks how the student researchers will be recruiting potential subjects. There are 2 options — in-person recruitment or recruitment via some type of posting. Check all recruitment methods that apply. For each recruitment method that you check, you should describe how subjects would be recruited with that method.

Check the statement indicating that you swear that you will tell students not to recruit subjects by any other method than those listed.

If needed, the next question allows you to provide additional information relevant to recruitment. Note: other recruitment methods may not violate a potential subject’s privacy in order to gain access to them for research (e-mail are considered private and while students have access to them, they do not have access to them for the purpose of research). Access to student e-mails for purposes of research requires college approval.

6. Risk/Benefit Ratio

The first set of questions is about the direct benefits.

The first question asks if subjects will receive a reward/incentive for participating in the research projects. Check yes or no. If yes, indicate if at least one of the direct benefits is course credit or extra credit. Check yes or no. If yes, identify the
course(s). Note: If course credit or extra credit is given, there must be IRB-approved documentation from the department, on file, indicating that they have agreed to give course credit (or allow extra credit) for research in the course. 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. Check the statement indicating that this documentation is on file with the IRB. If not on file, course credit or extra credit will not be allowed. If no, describe the proposed incentive/reward and justify why it is not coercive. Check the statement indicating that you swear you will tell students not to provide any direct benefit beyond those listed.

The second question is about the indirect benefits. Indicate the potential benefits to science or society (in general) as a result of participating in the research projects (e.g., adding to existing knowledge). 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.

The next question is about risks. Exempt studies must have no risk. So if the possible research projects qualify for exempt review, be sure that the potential studies involve no risk and check that statement. Be sure to explain why the potential research projects will not involve any risk and provide an example.

Check the statement indicating that you swear the student research projects will not involve any risk beyond those listed, unless they meet the criteria listed above.

The next question asks you to explain how the potential risks are reasonable in relation to the anticipated benefits.

If needed, the next question allows you to provide additional information relevant to the risk/benefit ratio.

7. Protection Procedures

This section relates to the precautions you will take to minimize the risks indicated in the last section.

The first question is about required precautions. Check each one.

The next question asks if direct quotes may be used in the students’ final report. Check yes or no, If yes, check the statement indicating that you swear students will be told to use pseudonyms (e.g., fake names) when discussing the person being quoted.

Check the statement indicating that students will adhere to the listed protection procedures.

If needed, the next question allows you to provide additional information relevant to the protection procedures.

8. Informed Consent Process

Check the statement indicating that students will be told to obtain consent, using a subject consent form, before collecting data.

Check the statement indicating that students will be told to adhere to the guidelines outlined by the IRB for creating a subject consent form for student classroom projects.

Check the statement indicating that students will be told to read the consent form to subjects to ensure they received the consent information.

The next question is about the questions students will ask subjects to assess their understanding of the risks associated with the possible studies and the tasks they will be asked to do. Check all required questions. Note: these questions should be asked after reading the consent form to subjects.

Check the statement indicating that students will be told to ask the required questions.
If needed, the next question allows you to provide additional information relevant to the informed content process.

**9. Confidentiality**

Check the statement indicating that you will have access to the raw data and swear that the students will be told not to share the raw data with anyone other than you, students in the class (if the class is all doing the same project), or members of their group (if group projects are used). *Note: the definition of raw data is the actual data obtained from a subject in its complete form.*

The next question asks if the raw data (including existing sources) may contain identifying information (i.e., information that may allow the subject to be identified). Check yes or no. If yes, you will need to answer several questions.

Check the statement indicating that students will be told to hold the identity of subjects in complete confidence.

Check the statement indicating that students will be told to keep the data in a locked file or password protected computer, database, or digital storage system.

The next question asks if the raw data may include audio or video recordings. Check yes or no. If yes, check the statement indicating that students will be told that the recordings should only be transcribed by the student researchers.*Note: only student researchers working on the project in which the recordings were made may do the transcribing.*

The next question asks you to describe how the final report will be disseminated in the class room setting. Check all that apply. The options are: paper, oral presentation, and other means of dissemination. If you check other, please describe it.

Check the statement indicating that students will told not to disseminate the final report in any manner beyond what is listed.