



**The UNIVERSITY OF NORTH FLORIDA  
Office for Research and Sponsored Programs (ORSP)**

**Waiving IRB Review of Class Projects in Research Methods and Similar Courses**

- I. Overview
- II. Definitions
- III. Who is Affected by This Procedure
- IV. Procedures
- V. Forms
- VI. Appendix – N/A

**I. Overview**

The purpose of these guidelines is to assist instructors and students in courses designed to help students develop the knowledge and research skills necessary to conduct research involving human participants. The Institutional Review Board at UNF recognizes that obtaining such knowledge and skills through hands-on research applications, called *class projects* in this document, is a valuable and essential educational experience. Nonetheless, it is the responsibility of this board and the Research Integrity Unit of the Office of Research and Sponsored Programs to ensure that human participants are protected in all research activity conducted at UNF or by UNF faculty, staff, and students. To facilitate the expeditious review of class projects, the Institutional Review Board has approved the following procedures for waiver of IRB review for specific kinds of class projects.

Note: IRB approval of research protocols cannot be made retroactively. Therefore, if instructors or their students may want in the future to use data collected as part of a class project for presentation or publication, then instructors or their students must submit an IRB protocol for review along with any other appropriate information, as required for approval of research projects.

**II. Definitions**

Class Projects: Class projects at UNF are those in which students' involvement is limited to developing the knowledge and skills needed for conducting research with human participants. Class projects might involve interviews in person or by telephone, observations, written or electronic surveys, or analysis of archival data. Given the pedagogical nature of class projects and the inexperience of students conducting class projects, the subject matter of such projects cannot involve more than minimal risk or include vulnerable participants, as defined and described below. This designation as a class project does not apply to courses labeled (a) directed independent study, (b) supervised research, (c) honors theses, (d) masters theses, or (e)

dissertations *if* these courses involve collecting data from human participants (as defined in 45 CFR 46).

**Student Research:** Student research includes, but is not limited to, (a) directed independent study, (b) supervised research, (c) honors theses, (d) masters theses, or (e) dissertations that involve collecting data from human participants (as defined in 45 CFR 46). These forms of student research are subject to oversight and review by the Research Integrity Unit of the Office of Research and Sponsored Programs and the Institutional Review Board, and all appropriate documentation should be submitted well before a student research project is scheduled to begin.

### **III. Who is Affected by This Procedure**

Professors and students in research methods and similar classes who plan to utilize human subjects or human subjects' data.

### **IV. Procedures**

#### **Requirements for Classification as a Class Project.**

In order to obtain a determination from the Research Integrity Unit that student activity in classrooms qualifies as a class project rather than research, class projects must meet the following criteria.

1. *Description of Activity as a Class Project Rather than as Research.* In order for projects to be considered class projects rather than research, instructors and students cannot describe their class projects as *research*. For example, neither instructors nor students can describe their class projects as research to prospective participants, other students, university faculty, and university staff. We ask that you do not refer to the class projects as research in descriptions or documents (e.g., syllabus) relating to your class projects. To the extent that these projects involve practicing and honing skills (e.g., data analysis, interview techniques, observational methods), projects should be described as exercises in developing and practicing such skills or as class projects.
2. *No Dissemination in Ways that Contribute to Generalizable Knowledge.* As described in federal regulations concerning research with human participants, research is any systematic investigation (including but not limited to research development, testing, or evaluation) designed and intended to contribute to generalizable knowledge (45 CFR 46.102). Two of the ways (but not the only ways) in which research knowledge is disseminated and therefore is made generalizable is through (a) presentation of research findings at symposia, colloquia, or similar meetings conducted for the purpose of generalizing knowledge and (b) scholarly publications whose mission is the dissemination of knowledge in academic disciplines. These symposia, colloquia, and publications could be internal (e.g., UNF's Annual Research Symposium, the *Osprey Journal of Ideas and Inquiry*) or external (e.g., journals, Internet sites). Data collected by instructors and students in class projects cannot be used by them or anyone else for publication or presentation outside of the course for which the projects were conducted.

The only exception to this provision involves community-based projects (e.g., program evaluation). For community-based projects, dissemination of project information is limited to reports to community agencies for which project information was collected. If you have questions about whether your project may be generalizable, please contact an IRB administrator by emailing [irb@unf.edu](mailto:irb@unf.edu) or calling (904) 620-2455.

3. *Participants from Vulnerable Groups Cannot Be Included.* Class projects cannot involve the use of vulnerable populations, as defined in federal regulations. Members of such vulnerable populations include but are not limited to minors (i.e., individuals less than 18 years of age), prisoners, and persons lacking the capacity to give informed consent. Additionally, individuals potentially vulnerable to coercion or undue influence (e.g., individuals with whom students in a research methods course have a supervisory relationship) should not be included. Additionally, projects may not specifically target pregnant women. However, pregnant women may be included in class project activities if pregnancy is coincidental to their involvement and not a variable of interest.
4. *No More than Minimal Risk.* Some potential research topics (e.g., illegal activity, sexual behavior and attitudes, history of sexual/physical abuse, mental health) involve more than minimal risk. Therefore, class projects cannot involve topics that involve physical, social, psychological, and/or legal harm to the participants. Specifically, the following topics and procedures should be avoided in order to minimize risk.
  - a. Use of deception.
  - b. Invasive data collection methods.
  - c. Administration of licit or illicit drugs.
  - d. Administration of shock or other forms of punishment.
  - e. Sexually explicit materials or questions.
  - f. Taking samples of blood, saliva, and other bodily fluids.
  - g. Questions about drug use.
  - h. Questions about illegal behavior.
  - i. Questions about sexual orientation, sexual experience, or sexual abuse.
  - j. Purposeful creation of anxiety or stress.
  - k. Procedures that involve the invasion of privacy.
  - l. Physical exercise or physical stressors.
  - m. Questions about suicidal thoughts or ideas.
5. *Provision for Informed Consent.* Participants in a class project must be fully informed about the nature of the project (including but not limited to its risks and benefits) and must voluntarily consent to participate in the class project. The only exceptions to this requirement for informed consent are projects that only involve (a) the observation of public behavior or (b) the use of archival data (i.e., existing data, records, or documents), provided these data are recorded by students in such a way that the participants cannot be identified. Class projects are not research and must be of minimal risk. Students may document that subjects have been informed about a class project without requiring those participants to sign an informed consent document. Potential participants should receive

an informed consent document to read and use to decide if they would like to participate; however, participants would not be required to sign and/or return this document. Students will initial the “Informed Consent Verification Form” to attest that each participant has received an informed consent document to keep and has verbally agreed to participate.

6. *Adequate Provision for Data Monitoring and Storage.* Any data collected as part of class projects must be collected and stored in such a way that the identity of participants cannot be compromised. Surveys, for example, cannot contain any identifiers by which the identity of the participants could be determined. Such identifiers include but are not limited to names, social security numbers, university ID numbers, driver’s license numbers, and addresses.

The use of video recordings to record participants’ behavior is prohibited. The use of audio recordings is restricted to cases in which (a) hand-written notes could not practically be used to collect information from interviews and (b) the identity of the participants cannot be determined from the responses being recorded. If audio recording occurs, participants must be reminded that they should not identify themselves in any way. Use of audio recordings must be restricted (e.g., audio recordings cannot be played for anyone except the students in the course and the instructor of the course) and must be destroyed immediately after the information on the recordings has been transcribed (and no later than the end of the semester in which the course occurs).

**All information collected from participants in class projects (e.g., surveys, observation notes, and interview transcriptions) must be destroyed at the end of the semester.** This requirement does not apply to course-related products such as student papers that may need to be retained by instructors as part of the course records.

7. *Instructor Responsibility for Student Training.* Given that students in research methods classes are inexperienced with respect to ethical issues in conducting research with human participants, it is essential that these students be well informed and prepared. Therefore, instructors must agree to train their students with respect to ethical principles and issues that may arise in interactions with human participants. Although not required, it is recommended that instructors suggest that their students complete the core module (and any additional modules relevant to the specific issues of the class projects) of the CITI training program. For more information about CITI training, please refer to the Guidelines and Instructions for Completing the Required CITI Training.

### **Responsibilities of Instructors and Students.**

*Instructor Responsibility.* If class projects do not qualify as research (see the criteria outlined above), then instructors must agree to the following:

1. Inform individuals (e.g., other faculty whose students may participate in these class projects) that the activity in these class projects is not research but is instead activity designed to give students an opportunity to develop their knowledge and skills about conducting research.

2. Guarantee that the results and data from class projects will neither be presented nor published outside the class for which the project was conducted.
3. Verify that the activities conducted as part of these class projects do not involve vulnerable groups and more than minimal risk as defined in the criteria outlined above in these instructions.
4. Ensure that students have dually informed participants about class project activities and provided participants with a copy of the informed consent document for their records. Students are to attest that they have obtained informed consent from participants by initialing the Informed Consent Verification Form.
5. Ensure that no deception of any kind will be used in these projects.
6. Confirm that data from participants in class projects will be collected and stored in a way that meets the criteria outlined above in these instructions.
7. Ensure that the rights and welfare of participants are protected, and accept full responsibility for approving and monitoring class projects from start to finish in order to assess the impact of these projects on participants.
8. Report to the IRB unanticipated adverse events, unexpected problems, and complaints from participants.
9. Complete the CITI training required of all PIs and research assistants at UNF. Please note that this training must be completed prior to recruitment and/or data collection.
10. Recommend that students in their research methods courses complete the CITI training.
11. Complete the "Instructor Checklist for Class Projects" and initiate data collection for the class projects only after having received approval for waiver of IRB review for the class projects from the Research Integrity Unit of the Office of Research and Sponsored Programs at UNF. Please note that it will be necessary for instructors to forward their completed Instructor Checklists to UNF's IRB before a waiver of IRB review can be generated for your class project.
12. Require students to receive approval for their projects and complete the student checklist prior to initiating data collection.

**Documentation to submit:**

*In order to receive a waiver, please submit copies of the following documents no less than two weeks prior to recruitment and data collection to ensure sufficient processing time:*

- a) Syllabus for all courses in which class projects will be utilized. If the section numbers are not included on this document please supply that information in an additional document or correspondence (e.g., email, independent document).
- b) Detailed description of class project including but not limited to topics of interest, recruitment method, data collection method, location of data collection, description of measures/assessments that will be utilized.
- c) Detailed description of provisions for data monitoring and storage (e.g., data stored in instructor's locked office at UNF, data stored on UNF's secure server).

*Student Responsibility.* Students conducting the class projects must agree to the following:

1. Inform individuals (e.g., other students, participants, and faculty whose students may participate in these class projects) that the activity in the class project is not research but is instead activity designed to develop their knowledge and skills about conducting research.
2. Guarantee that the results and data from the class project will neither be presented nor published outside the class for which the project was conducted.
3. Verify that the activities conducted as part of the class project do not involve vulnerable groups or more than minimal risk as defined in the criteria outlined above in these instructions.
4. Ensure that participants have been dually informed about class project activities and provided with a copy of the informed consent document for their records. You are to attest that informed consent has been obtained from participants by initialing the Informed Consent Verification Form.
5. Ensure that no deception of any kind will be used in these projects.
6. Confirm that data from participants in the class project will be collected and stored in a way that meets the criteria outlined above in these instructions.
7. Ensure that the rights and welfare of participants are protected.
8. Report to the class instructor unanticipated adverse events, unexpected problems, and complaints from participants
9. Complete the “Student Checklist for Class Projects” and initiate recruitment and data collection only after the instructor has indicated that you may begin the class project.

### **Timeline for Review**

Please submit the “Instructor Checklist for Class Projects,” with attachments the Research Integrity Unit of the Office of Research and Sponsored Programs (irb@unf.edu) no less than two weeks prior to desired date for recruitment and data collection. As is the case with all research conducted by UNF faculty, staff, and students, determination of the student activity as a class project rather than research must be made by the Research Integrity Unit of ORSP.

Although the Research Integrity Unit of the OSRP has requested that documents are submitted no less than two weeks prior to the desired date of recruitment and data collection, the staff is committed to review instructor requests in a timely manner. Determination of a waiver should be made within 5 business days after receipt of the complete “Instructor Checklist for Class Projects,” with all required attachments.

### **Waiver Duration and Document Resubmission**

Previously, class project waivers were only valid for one semester. However, the UNF IRB has approved a revised class project procedure for resubmissions. In this new procedure, once a class project has received a waiver, that waiver is valid for three academic years rather than one semester as long as the following stipulations are met:

1. The required class project documentation has been submitted and received a waiver from the UNF IRB.
2. Class project procedures will not change from term to term and will remain as outlined in the original class project submission. Although the procedure must not change, if applicable, individual student topics may differ from semester to semester as long as those topics continue to meet the requirements outlined in the class project guidelines

(e.g., no vulnerable subjects, no sensitive topics, project not described as research, results will not contribute to generalizable knowledge). If you have a question about whether a topic is appropriate, please contact an IRB administrator by emailing [irb@unf.edu](mailto:irb@unf.edu) or calling (904) 620-2455.

3. Risk to participants is not increased beyond the level of risk outlined in the original submission. If you have a question about whether risk to participants may be increased, please contact an IRB administrator by emailing [irb@unf.edu](mailto:irb@unf.edu) or calling (904) 620-2455.
4. If the faculty overseeing the class project will change, it will be necessary to resubmit the class project documentation for that project in order to receive a new waiver.
5. If the class to which a project is associated will change (e.g., class project reviewed and waived for an introduction course and now same instructor wants to implement class project in an advanced course), it will be necessary to resubmit the class project documentation for that project in order to receive a new waiver.
6. After three years the waiver will expire and it will be necessary to resubmit the class project documentation for that project in order to receive a new waiver.
7. Instructor CITI certification remains up to date. As you may know, CITI Course Completion

Reports are valid for 3 years. If you have not completed CITI training or if your completion report expires within the next 60 days, please complete the initial or refresher training course by following this link: <http://www.citiprogram.org/>.

#### **IV. Forms**

See next page

## **Instructor Checklist for Class Projects**

Instructor Name and Title: \_\_\_\_\_.

Department: \_\_\_\_\_. Office Phone: \_\_\_\_\_. UNF email: \_\_\_\_\_.

Course Prefix and Number: \_\_\_\_\_. Semester and Year for Course: \_\_\_\_\_.

Protocol Title: \_\_\_\_\_.

Describe the class projects included in this course in an attachment to this document. Please attach a syllabus or course handouts, highlighting the relevant information. Make sure you describe the procedures for maintaining confidentiality, minimizing risk, and monitoring results.

As the instructor for class and project identified above, I agree to

1. Inform individuals (e.g., other faculty whose students may participate in these class projects) that the activity in these class projects is not research but is instead activity designed to give students an opportunity to develop their knowledge and skills about conducting research.
2. Guarantee that the results and data from class projects will neither be presented nor published outside the class for which the project was conducted.
3. Verify that the activities conducted as part of these class projects do not involve vulnerable groups and more than minimal risk as defined in the criteria outlined in the document "Procedures for Waving IRB Review of Class Projects."
4. Ensure that students have dually informed participants about class project activities and provided participants with a copy of the informed consent document for their records. Students are to attest that they have obtained informed consent from participants by initialing the Informed Consent Verification Form.
5. Ensure that no deception of any kind will be used in these projects.
6. Confirm that data from participants in class projects will be collected and stored in a way that meets the criteria outlined in the document "Procedures for Waving IRB Review of Class Projects."
7. Ensure that the rights and welfare of participants are protected, and accept full responsibility for approving and monitoring class projects from start to finish in order to assess the impact of these projects on participants.
8. Report to the IRB unanticipated adverse events, unexpected problems, and complaints from participants.
9. Complete the CITI training required of all PIs and research assistants at UNF. Please note that this training must be completed prior to recruitment and/or data collection.
10. Recommend that students in my research methods courses complete the CITI training.
11. Complete the "Instructor Checklist for Class Projects" and initiate data collection for the class projects only after having received approval for waiver of IRB review for the class projects from the Research Integrity Unit of the Office of Research and Sponsored Programs at UNF. Please note that it will be necessary for you to forward your completed

Instructor Checklists to UNF's IRB before a waiver can be generated for your class project.

12. Require students to receive my approval for their class projects and complete the student checklist prior to initiating data collection.

Instructor Signature and Date: \_\_\_\_\_  
CITI Course completion date: \_\_\_\_\_

**Submit the "Instructor Checklist for Class Projects" and attachments to Kayla Champaigne ([k.champaigne@unf.edu](mailto:k.champaigne@unf.edu)) in the Research Integrity Unit, Office of Research and Sponsored Programs.**

## Student Checklist for Class Projects

Student Name: \_\_\_\_\_ UNF email: \_\_\_\_\_.

Course Prefix and Number: \_\_\_\_\_. Semester and Year for Course: \_\_\_\_\_.

Project Title: \_\_\_\_\_.

Note: Attach a description of the class project as required by the course instructor.

As a student involved in the class and project identified above, I agree to

1. Inform individuals (e.g., other students, participants, and faculty whose students may participate in these class projects) that the activity in the class project is not research but is instead activity designed to develop knowledge and skills about conducting research.
2. Guarantee that the results and data from the class project will neither be presented nor published outside the class for which the project was conducted.
3. Verify that the activities conducted as part of the class project do not involve vulnerable groups or more than minimal risk as defined in the document "Procedures for Waiving IRB Review of Class Projects."
4. Ensure that participants have been dually informed about class project activities and provided with a copy of the informed consent document for their records. You are to attest that informed consent has been obtained from participants by initialing the Informed Consent Verification Form.
5. Ensure that no deception of any kind will be used in these projects.
6. Confirm that data from participants in the class project will be collected and stored in a way that meets the criteria outlined in the document "Procedures for Waving IRB Review of Class Projects."
7. Ensure that the rights and welfare of participants are protected.
8. Report to the class instructor unanticipated adverse events, unexpected problems, and complaints from participants.
9. Complete the "Student Checklist for Class Projects" and initiate recruitment and data collection only after the instructor has indicated that you may begin the class project.

Student Signature and Date: \_\_\_\_\_

