

## IRB Guidelines for Student Research Involving Human Subjects

The following guidelines are presented to assist faculty in determining whether course-related research activities require IRB review and approval. Please remember

1. Failure to obtain IRB approval may jeopardize a student's ability to publish or present the results and place you and the University in violation of federal regulations.
2. The IRB cannot grant "retroactive" approval once the research is underway.

Faculty are encouraged to contact the IRB through the Office of Research and Sponsored Programs (Sandy Terranova at 590-7522 or [sterranova@fgcu.edu](mailto:sterranova@fgcu.edu)) for guidance in handling topics such as privacy, confidentiality, informed consent, and professional ethics when a class project is considered exempt from IRB approval and for guidance in modifying future class projects, when possible, to avoid the need for IRB approval. Tools are available on the ORGS' Regulatory Compliance [Updated Policies/Guidelines](#) and [Form Library](#) pages.

### Key Definitions in Human Subjects Research

#### Research

A systematic investigation including research development, testing and evaluation designed to develop or contribute to generalizable knowledge. [Title 45 Code of Federal regulations (CFR) part 46.102(d)]

#### Generalizable Knowledge

Title 45 CFR 46 does not provide a definition of generalizable knowledge. However, generalizable knowledge applies to research projects in which the investigator intends to:

- Identify a project design that is replicable
- Draw conclusions that will contribute to general knowledge in the field
- Generalize or apply the findings to a population other than, or in addition to, the population from which a sample was drawn
- Specify a larger population to which the findings will be generalized or applied

Additionally, generalizable knowledge occurs when the researcher intends or anticipates sharing the results with an audience outside the University. Potential means of dissemination include, but are not limited to:

- Articles and books in professional, peer-reviewed scholarly venues, both paper and electronic
- Presentations at conferences or annual meetings of professional associations
- Publication on websites, Facebook, blogs, etc.
- Reports, exhibits, or presentations for public or private institutions (government agencies, not-for-profit institutions, companies, etc.)
- Exhibits or presentations for members of the general public

### Human Subject

A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. [45 CFR 46.102(f)].

The following section will help you determine if the research activity requires IRB approval.

### **Differences between Research Practica and Directed or Independent Research Projects**

Generally, student research involving human subjects falls into one of the following categories. If the research activity does not fall into one of the categories, please contact the IRB for guidance.

1. Research practica – the supervised practical application of the theory of research methods in the classroom. These projects **do not require IRB approval**.
2. Directed or independent research – research conducted with the intent of contributing to generalizable knowledge. This includes, but is not limited to, independent undergraduate and graduate research projects, and honors theses, masters' theses and dissertations. These projects **do require IRB approval**.

### Research Practica

Research practica are class projects designed to provide students an opportunity to practice research methods including interviewing, surveying, observation techniques, and data analysis. Typically limited in scope, these projects do not lead to generalizable knowledge and are not undertaken with that goal in mind. Research practica **projects do not require IRB review if the project meets ALL of the following criteria** (1 through 7).

1. **No minors or vulnerable populations**, such as pregnant women, neonates, prisoners, children, students outside of the course, individuals who lack the capacity to consent, non-English speaking individuals or individuals with English as a second language, etc., are included in the project.

*Exception:* Projects conducted in established or commonly accepted educational settings involving normal educational practices such as education instructional strategies or the effectiveness of or comparison among instructional techniques, curricula, or classroom management methods.

2. **No more than minimal risk to the participants** i.e., participants will not encounter risks greater than they would normally encounter in their daily lives or during the performance of routine physical or psychological examinations or tests.
  - 2A. Projects involving the collection of information or asking questions that are personal or sensitive, and/or involve socially stigmatized behaviors and attitudes present more than minimal risk to participants. The following examples are topics that involve more than minimal risk and do not comprise a complete list.
    - Illegal activity or incriminating topics; topics that could lead to civil or criminal liability
    - Health related information, eating disorders and behaviors, contraceptive practices
    - Sex or sexuality, rape, incest

- Death including suicide
- Violence or violent acts
- Failure and inadequacy, depression
- Substance use and/or abuse including, but not limited to alcohol, marijuana, steroids, amphetamines, narcotics (cocaine, heroin etc.) and prescription medication legally or illegally obtained
- Traumatic experiences including war or combat experiences of veterans
- Identifying personal data such as names, social security numbers or other codes that can be identified or be linked to participants
- Private information that could put participants at risk through a breach of confidentiality

2B. Projects that systematically select participants from specific groups and ask questions about one's opinion, behavior or beliefs on a topic considered more than minimal risk. The following examples do not comprise a complete list:

- Children
- Any ethnic group
- Addicts
- Gay/lesbian/bisexual/transgender individuals
- Migrant workers
- Prisoners

2C. Any project in which the participants will be able to be identified by their responses.

3. **No potential for publication or sharing of project outside of the classroom, including with one's service learning agency.** Data generated may be used only for the course in the classroom. Research Day presentations required by the course, are considered research practica if they meet all of the other conditions in this section. Presentation or reports of classroom projects to the class must be restricted in detail so that identities, locations and other pertinent data are blinded. Data from the project cannot be used for any type of publication, presentation, thesis, or dissertation.
4. **No use of deception (withholding information about the real purpose of the research).** The class project cannot include any deception. Participants must be fully informed about the research, its risks and given the opportunity to voluntarily consent to participate.
5. **No videotaping.** Audio taping is allowed only if the recording is erased upon transcription or no later than the end of the current term. The tapes must be placed in a locked and secure site, and the instructor must exercise extra caution in advising students of this practice.
6. **No interviewing participants outside of research practica courses.**
7. No immediate potential or intention to submit a proposal for funding for the project (grants, awards, etc.).

**If a class project does not meet ALL of the above parameters, the student or instructor must submit an application to the IRB and have it approved *prior* to the initiation of the data collection.**

#### Directed or Independent Research Project

Any research conducted by undergraduate or graduate students that uses human beings as subjects that does meet all the above criteria of a research practica must be reviewed and approved by the IRB prior to the initiation of the project.

## Instructor Responsibilities

The responsibilities of instructors include:

1. Determining, prior to assigning a research practica project, if the project requires review by the IRB. If a student research project begins as a research practica project and develops into generalized research, IRB approval must be obtained immediately.
2. Educating and training students in human subjects research ethics. The University offers training in human subject research for biomedical and social and behavioral investigators through the Collaborative Institutional Training Initiative, [CITI](#). Registration and logon instructions are found on the ORGS' Regulatory Compliance [Training Program](#) page under 'Human Subjects in Research'.
3. Ensuring that the rights and welfare of human subjects involved in a research practica project are adhered to as if the project was approved by the IRB as these projects are not reviewed by the IRB.
4. Reviewing and approving the research practica project's informed consent form and procedures, survey instruments, and scientific methods and procedures prior to use by students. The IRB recommends students follow the Informed Consent Form Model to write their informed consent. The model is found on the [ORGS Form Library](#). The IRB recommends the consent forms for research practica projects state the following: "*This research practica project is being conducted for educational, not research purposes.*"
5. Ensuring that students obtain authorization for access to other institutions and organizations. The IRB offers *Guidelines for Letters from Agencies Cooperating with the Research* found on the ORGS [Updated Policies/Guidelines](#) page.
6. Retaining the paperwork (data, informed consents, surveys, etc.) for the period prescribed by University policy.
7. Reporting any adverse incidents to the IRB within 48 hours of occurrence.
8. Advising students that any human participant data collected or analyzed should not contain personal identifying information if the information is not required for the assignment.

The IRB Chair is available for consultation regarding human subject research issues. Please remember that data collected under a research practica project may not be used at a later date for presentation at conferences or in publications, theses, or doctoral dissertations. Many publications ask for proof of IRB approval before accepting a manuscript and the IRB cannot provide retroactive approval. If there is any possibility the student will disseminate the results of the project, it is recommended the student obtain IRB approval prior to conducting the project.

*The checklist on the following page may be useful for both faculty and students to document that their classroom research practica project can be exempt from IRB review and approval.*

## Classroom Research Checklist

*ALL items below must be satisfied for practica projects to proceed outside of IRB review.*

Course \_\_\_\_\_

Project Title \_\_\_\_\_

Student Assurances:

I am enrolled in a graduate or undergraduate course at FGCU. The completion of this research practica project is a requirement to complete the course.

The primary purpose of the research project is as a learning experience in the methods and procedures of research.

My instructor is fully aware of all aspects of the research practica project.

I have no intent to produce generalizable knowledge or disseminate the findings beyond presentation to instructors or peers in a FGCU educational setting.

The project involves no more than minimal risk to participants (as defined in the *University's IRB Guidelines for Student Research Involving Human Subjects*).

The project **does not involve** questions or opinions about **sensitive topics, socially stigmatized behaviors or beliefs, illegal activity, health-related information, substance abuse, traumatic experiences or confidential information, etc.** which could place a participant at risk if disclosed.

The project **does not involve** minors or persons from **vulnerable populations** as participants (as defined in the *University's IRB Guidelines for Student Research Involving Human Subjects*).

The project involves the **voluntary participation** of individuals in other research practica classes without any coercion or pressure being placed upon them. I have discussed whether a consent document is needed.

The participants will not be able to be identified by their responses.

Student \_\_\_\_\_ Date: \_\_\_\_\_  
Signature /Printed Name

Instructor \_\_\_\_\_ Date: \_\_\_\_\_  
Signature /Printed Name