

Chapman University IRB Guidelines for Student Classroom Projects and Research Involving Human Subjects

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

- Failure to obtain IRB approval when required may jeopardize a student's ability to publish or present their results and will place the faculty member and the University in violation of federal regulations.
- 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 (irb@chapman.edu) for guidance in handling topics such as privacy, confidentiality, informed consent, and professional ethics when IRB approval is considered unnecessary [or necessary] and for guidance in modifying future class projects, when possible, to avoid the need for IRB approval.

It is the Instructor's ethical responsibility to assume the role of Principal Investigator and to ensure that IRB approval is obtained if a classroom project is deemed to be research as defined below.

It is the Student's ethical responsibility to agree that, without IRB approval, course assignment projects and student research day presentations will NOT be disseminated in any format, including any and all social media portals or outlets.

Key Definitions in Human Subjects Research

Research

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

Generalizable Knowledge

A key component of the definition of research is whether the results will be used to contribute to generalizable knowledge. If the intent is to disseminate the results of the research *beyond the classroom assignment or student research day* then IRB approval is required.

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:

- 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 (whether faculty or student) 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 digital commons, Facebook, blogs, or any other electronic portal or media
- 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 faculty or student) conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information. [45 CFR 46.102(f)].

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

Differences between Classroom 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. *Classroom Research practica* – the supervised practical application of the theory of research methods in the classroom. These projects **do not require IRB approval IF**:
 - a. The project involves secondary data analysis of extant data [data that have already been collected] such as publicly available de-identified [which means a person cannot be identified in any manner] data **AND** the project will not be disseminated or shared beyond the course [i.e., the project is for a course assignment only]
 - b. The project involves direct or indirect interaction [e.g., practice assessments, in person interview, or via email, telephone, or survey] **BUT** the purpose is training and professional development **AND** the project will not be disseminated [i.e., the project results are for a course assignment only]
2. *Directed or independent research* – research conducted with the *intent* of contributing to generalizable knowledge. This may include, but is not limited to, independent undergraduate and graduate research projects [if the intent is dissemination], honors theses, masters' theses and dissertations. Please note that theses and dissertations are part of public dissemination because the results are made available through the library. These projects **DO require IRB approval**.

Classroom Research Practica

Classroom 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 6).

1. **No minors or vulnerable populations**

This criterion includes pregnant women, neonates, prisoners, children, and individuals who lack the capacity to consent, such as persons with mental retardation. *Exception:* Projects conducted in established or commonly accepted educational settings involving normal educational practices such as practice assessments, 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**

This criterion includes participants who will not encounter risks greater than they would normally encounter in their daily lives or during the performance of routine physical, psychological, or educational 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 that **present more than minimal risk to participants and require IRB approval**. The following examples are topics that involve more than minimal risk but 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 apply but do not comprise a complete list:

- Children
- Any ethnic group
- Individuals with alcohol or drug addiction
- Gay/lesbian/bisexual/transgender individuals
- Migrant workers
- Prisoners

2C. Any project in which the participants can be identified by their responses.

3. **No potential for publication or sharing of the 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 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 project, its risks and given the opportunity to voluntarily consent to participate.
5. **No identifiable video or audio recording.** Video and audio recording are allowed only if the recording is masked [i.e., all faces, names and identifying information are blocked] and the recordings are erased no later than the end of the current term.
6. **No 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 not meet all the above criteria of a research practica must be reviewed and approved by the IRB prior to the initiation of the project. This includes theses and dissertations because these products are part of the public sphere and can be accessed beyond the classroom.

Instructor Responsibilities

As instructors and trainers it is incumbent upon all of us to ensure, to the largest extent under our control, that our students adhere to the ethical and legal guidelines put forth in this document. 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, the research must be halted and IRB approval must be obtained immediately before the research continues.
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 IRB website. Although CITI training is not required for classroom projects, the IRB strongly suggests that all students participate in the training regarding research in their prospective field. *CITI training is required for all research that requires IRB approval at the undergraduate and graduate levels.* Note: NIH training is no longer accepted for undergraduate, graduate, nor faculty training levels.
3. *Ensuring* that the rights and welfare of human subjects involved in a research practica project are adhered to as if the project were approved by the IRB because 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 when applicable to human subjects. The consent form model is found on the IRB website. The IRB recommends the consent forms for

research practica projects state the following if including human participants: “*This classroom research practica project is being conducted for educational, not research purposes.*”

5. *Reporting* any adverse incidents to the IRB immediately upon occurrence. This is essential because unintended consequences may occur even with the most seemingly benign project.
6. *Advising* students that any human participant data collected or analyzed should not contain personal identifying information. And that students are responsible to maintain confidentiality and agree that they will not disseminate the findings of their project in any format, written or electronic.

The IRB Chair is available for consultation regarding human subject research issues. Please remember that data collected under a classroom 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, the student must 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 does not require IRB review and approval. The IRB strongly suggests that faculty/instructors and students complete the form and maintain it in their respective records for a period of three years.

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 Chapman University. The completion of this classroom 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 understand that without Institutional Review Board approval I am not allowed to present the findings of my research beyond the classroom or student research day. This includes ***never*** sharing the findings of the research or dissemination to any and all types of social media (e.g. Facebook, blogs, YouTube, email, digital commons). Doing so may have consequences that harm the individual[s] I have studied only for class purposes. I have no intent to and will not produce generalizable knowledge or disseminate the findings beyond presentation to instructors or peers in a Chapman University 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 without any coercion or pressure being placed upon them. I have discussed whether a consent document is needed.
- The participants cannot be identified by their responses or participation.

I am a student at Chapman University and I agree to the above:

Student _____ Date: _____
Signature /Printed Name

I am the instructor for this student and I agree to the above.

Instructor _____ Date: _____
Signature /Printed Name