Carroll College

**IRB GUIDANCE FOR CLASS PROJECTS**

Federal regulations and Carroll College policies require Institutional Review Board (IRB) approval for research involving **information about** **living human subjects**. These regulations and policies serve to protect the rights and welfare of human participants and apply to human subjects research conducted individually or collectively (i.e. as a class or in groups) by Carroll College faculty, staff, or students. **Approval for projects requiring IRB approval must be obtained prior to involving human subjects in the project.** Failure to obtain proper approval in advance of a project’s initiation may jeopardize your data, prevent you from publishing the results, and place you and the college in violation of federal regulations.

**Independent student research projects** **in which human subjects are involved, either directly or through use of data about them, always require IRB approval**. Examples of such projects include research projects conducted by Carroll College honors students in conjunction with honors requirements; projects by students individually enrolled in an independent study or research practicum with a professor; and projects by students planning to present their findings at a state, regional, or national conference.

**Some class projects that involve human subjects will require IRB approval**. However, many such class projects are conducted solely for educational purposes, do not qualify as research, and will not require IRB approval. This document was created specifically to help faculty determine **before** conducting a given activity whether IRB approval is required. It is the hope of the IRB that the information provided within will allow faculty to modify future class projects, when possible, to avoid the need for IRB approval.

**Class instructors and departments are responsible for providing the necessary training in respecting the privacy of participants and** **the confidentiality of data.** To help students better understand issues relating to human subjects research, the instructor might require that students complete [the Moodle Protecting Human Research Participants Training course](https://moodle.carroll.edu/course/view.php?id=1151). Class instructors and departments are encouraged to contact the IRB for guidance about ways to handle topics such as privacy, confidentiality, informed consent, and professional ethics when class projects are part of the course syllabus. The IRB can provide guidance on managing risks of deductive disclosure, coercion-free recruiting, informed consent, and special considerations for projects that include potentially vulnerable individuals. These issues may exist even when IRB approval is not required, in which case instructors and departments play an even greater role in providing the appropriate guidance and oversight.

**If this guidance directs you to seek IRB Review of your project,** go to the Carroll College [Institutional Review Board page](https://www.carroll.edu/academic-services/institutional-review-board) and follow the instructions given there.

**To** **determine if your particular project will require IRB approval**, please answer the questions in Part A. If you answer “yes” to any question (including subparts) within Part A, your project will require IRB review. If you answer “no” to all the questions (including subparts) in Part A, please proceed to the questions in Part B.

**PART A.**

1. Is the proposed project a **systematic investigation,** the findings of which you or your students expect, ultimately, **to present to a wider audience,** through presentation and/or publication? *Systematic investigations begin with specific questions or hypotheses and are conducted with the intent of drawing scientific conclusions*.
2. Do you or your students plan to enroll participants from **vulnerable** **populations:**

* Institutionalized persons, including prisoners, others involuntarily detained or incarcerated, or parolees?
* Minors (less than 18 years)?
* Pregnant women?
* Mentally disabled or decisionally impaired?
* Economically or educationally disadvantaged?
* Non-English-speaking?
* Patients?
* Persons who are HIV+ or have AIDS?
* Other?

1. Do you or your students plan to enroll subjects from **select populations,** e.g. people of a specific ethnicity, race, religion, etc?
2. Is **deception** required for the validity of this study? *Deception in research involves lying to or intentionally misleading subjects. Withholding information may or may not be deception, depending upon whether subjects have sufficient information to make an informed choice about whether or not to participate in the research.*
3. Will the study involve **videotaping, audiotaping, or filming** of subjects (newly collected or existing)?
4. Will you or your students be collecting **sensitive information,** e.g. about

* Sexual behavior?
* Criminal behavior?
* Juvenile delinquent behavior?
* Alcohol or drug use?
* Recreational drug use?
* Child abuse?
* Physical abuse?
* Immigration status?
* Medical or psychological history?
* Other potentially sensitive information?

1. Will the project involve **secondary data** that include **Protected Health Information** (PHI) that is subject to HIPAA regulation? *Access to PHI requires a waiver of HIPAA authorization, which requires an IRB application and IRB approval.*
2. Will you or your students obtain **individually identifiable information** about the individuals in the study? *Individually identifiable information is that which can be linked to specific individuals by the investigator(s) either directly or indirectly (e.g. by name, code number, or pattern of answers). Individually identifiable information may be created as a result of the researcher’s* ***direct interaction/intervention*** *with the human participants or may be obtained as* ***existing******data*** *(e.g. research records, patient records, and/or human biological specimens).* *Interaction includes communication or interpersonal contact between the investigator and subject (e.g. surveying, interviewing, focus groups). Intervention includes both physical procedures by which data are gathered (e.g. measurement of heart rate) and manipulations of participants’ environment that are performed for research purposes.*

**\* Exception:** **When the purpose of direct interaction/intervention is training, an educational exercise, or professional development, and not research, the response to Question 8 (Part A) should not be considered in determining the need for an IRB review.** The project or practicum is not “research” even ifstudents ask people questions as part of learning how to conduct interviews or surveys, take histories, administer assessments, or perform “in-house” evaluations as requested by the practicum site.

**→ If you answered “YES” to ANY of the questions (including subparts) in PART A,**

**your project REQUIRES an IRB REVIEW.**

***Complete PART B only if you answered “NO” to ALL of the questions in PART A.***

**PART B.**

1. Is the proposed study a student research project that is a **normal part of the student's course work** (e.g. a project required of all students in a research methods class), supervised by the class instructor, with the purpose of the project the being development of the student's research skills?
2. Is the project of **minimal risk to participants?** *Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.*
3. For projects involving **direct interaction** with subjects (e.g., in person, via mail, email, web surveys,or telephone): Will the project involve direct interactionwhere the purpose is training, aneducational exercise or professional development, and **not** research? *The project or practicum is not “research” even if**students ask people questions as part of learning how to conduct interviews or surveys, take histories, administer assessments, or perform “in-house” evaluations as requested by the practicum site.*
4. For projects involving use of **secondary data**: Will the project be limited to secondary data analysesthat are assigned and conducted as educational exercises,and that use only **publicly available data**, **anonymous data** (where there are no identifiers in anyone’s possession) and/or **de-identified datasets** (datasets include private information andcodes that link to identifiers, but the investigators lackaccess to the identifiers)?*Data or records cannot contain Protected Health Information (PHI) that is subject to HIPAA.*

**→ If you answered “NO” to ANY of the questions in PART B, your project REQUIRES an IRB REVIEW.**

**→ If you answered “NO” to ALL of the questions in PART A**

**→ AND answered “YES” or “Not Applicable” to ALL of the questions in PART B,**

**Your project DOES NOT require IRB review.**