

Policy on Classroom and Student Research Institutional Review Board

Barry University, in compliance with Federal Law (45CFR46.101], is required to be formally aware and subsequently approve by means of an Institutional Review Board (IRB), all research involving human subjects conducted at the University or under the direction of University faculty, staff, and students.

Research is defined as “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”[45 CDR 46.102(d)] Hence, research (resulting from the observance or interaction with human subjects) for the purpose of creating or producing material to augment the body of knowledge in one’s academic discipline merits IRB review.

Human subjects “means a living individual about whom an investigator (whether professional or student) conducting research obtains

- (1) Data through intervention (direct physical contact or manipulation of subject’s environment) or interaction (communication or interpersonal contact) with the individual, OR
- (2) Identifiable private information (information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.” [45 CFR 46.102(f)

Therefore, IRB approval is necessary if human subjects are involved, either directly or the use of data about them which is derived for the purpose of research. However, an educational experience and a research project are not coterminous. The key determining factor is whether the student’s activity is purely within the parameters of an educational exercise whose intent is not to produce or contribute to “generalized knowledge” but rather for exposure and assimilation into the mind-set of the canons of inquiry particular to one’s academic discipline. If the purpose is purely educational then IRB approval is not required (see next page). In addition, if the student is doing any research classified below that merits IRB Review /Approval then it is imperative the student to complete the tutorial, *Protecting Human Research Participants (PHRP)* located on line at:

<http://phrp.nihtraining.com/users/login.php>

Activity	Requires On-Line Tutorial	Does not Require On-line Tutorial but signed third party confidentiality agreement should be submitted.
Student initiated research where the student is the principal investigator or co-investigator	T	
Research where student directly assists in the distribution of surveys, questionnaires, interviews, etc., and addresses participant’s questions concerning any aspects of the particular study	T	
Research where the student is merely preparing the room, distributing or gathering the data instruments, typing data into a data base, or transcribing notes, audio-tapes, etc.		T

The following examples/scenarios in the format of questions and answers are given with the intention of clarifying what is considered educational (not requiring IRB approval) and what is research (requiring IRB approval)

Student Research (research where the individual student chooses to do research where human subjects are directly involved through personal interaction or through the use of data derived from such activity)	Needs IRB review	Does not need IRB review
Student is currently preparing to do research that involves direct interaction with other human beings (either by direct encounters, US mail, or email) thereby deriving the subject's data for the purpose of completing an independent research project, undergraduate honors thesis/master thesis (project)/doctoral dissertation, or comparable activity where the data findings will be presented or shared in a public forum	T	
Student is doing a research project involving the employment of data derived from human interaction that is publically available with no identifying linkages or codes (secondary analysis) and has no intent to publish or present such results in a public forum.		T
Student is using departmental subject pools (e.g., psychology, sociology, business,) for purposes of deriving data from fellow students even when such activity is considered a class requirement.	T	
Student is doing research on data derived from an previously approved IRB project (e.g., survey) where there is no identifying linkages or codes but wishes to report such new application of the data in a public forum.	T	
Student is doing research involving information that has been published, such as editorials, newspaper articles, movies, or commentary on historical documents or personages and may wish to publish such results in a public forum		T
Class Projects (classes where the intent of the instructor is to <u>introduce the entire class to the methodology of research</u> pertinent to the discipline. This goal is clearly stated in the course syllabus and the learning process is purely for educational purposes and not for any intent to publish or present publically.		
Class projects that involve direct intervention and are done <u>both for educational experience as well as research</u> so that the results of such activity may be presented in a public forum or the data may be stored or employed for use by other students for purposes of research	T	
Class projects or professional <i>practica</i> that involves direct interaction (by person, US mail, telephone, or email etc.) but where the <u>sole purpose</u> is for training, educational assimilation, or professional development and <u>not</u> for research even if the format involves what is traditionally recognized as direct research, e.g. student interviewing techniques, reliable survey construction, taking histories, etc. Understandably, the students need to adhere strictly to the principles of confidentiality in this educational setting which is the responsibility of the instructor to ensure.		T