***Protecting Human Subjects in Student Inquiry Projects:
Addressing the Educational, Ethical, and Legal Obligations of Liberal Arts Institutions***

**Determining Whether IRB Review is Required: Policy for Evaluating a Proposed Investigation**

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The purpose of this policy document is to help institutions determine whether a proposed investigation requires advance IRB review and approval. This policy is derived from federal regulations at 45 CFR Part 46, informally known as the Common Rule (because it is “common” to many different federal agencies and departments that conduct, or provide funding for, research involving human subjects). The policy is accompanied by a checklist an institution can use to summarize its analysis of a proposed project in relation to federal requirements and record its final determination as to whether IRB review is required.

Determining whether a project requires IRB reviewrequires answers to the following three questions, in this order:

1. Is the project “research” as federally-defined?
2. If so, does the research involve “human subjects” as federally-defined?
3. If so, is the human subjects research subject to the Common Rule?

**For a project to require IRB review, the answer to all three questions must be “yes.”**

Answering each of these questions correctly in relation to a specific project requires an understanding of numerous terms and concepts in the Common Rule. The principles and provisions below identify and explain the key issues involved in determining whether a project is “research,” involves “human subjects,” and is subject to the Common Rule. This policy is intended to summarize and “operationalize” the relevant regulatory provisions at 45 CFR 46; it is not intended to substitute for it.

***1. Is the project “research” as federally-defined in the Common Rule?***

*Research* is federally-defined as “a systematic investigation…designed to develop or contribute to generalizable knowledge” [45 CFR 46.102(d)]. Projects are generally considered “research” as federally-defined when they have **all** of the following characteristics:

a. **The project is a systematic investigation.** Systematic investigationsthat may yieldgeneralizable knowledge arecharacterized by a careful and clearly-stated research design that includes a clear and significant research question, a theoretical framework, a review of previous research, and clear procedures for collecting, analyzing, and reporting data about the subjects.[[1]](#footnote-1)

b. **The project design is intended, or is otherwise likely, to yield results that are generalizable beyond the group from which the sample was selected*.*** Indicators of the potential generalizability of results include, but are not limited to, the following:

* The project has a significant theoretical component; it is designed to test a novel hypothesis, use empirical evidence to critique or develop a theory, investigate causation, or establish explanations.
* The project investigator identifies the project results as intended to contribute to generalizable knowledge.
* The project investigator states an intent togeneralize or apply the findings to a population other than, or in addition to, the study population from which a sample was drawn. For example, if the investigator studies a sample of students from her own university, but draws conclusions about university students in general (not just those at her own university), then the investigator is generalizing beyond the group from which the sample was selected.
* The project investigator specifies a larger population to which the findings will be generalized or applied.
* The project investigator indicates that the project is a pilot study [or a case study], the results of which are intended to be used to develop a generalizable research project in the future.
* The project design would support generalization beyond the study population, even if the investigator doesn’t specify an intent to do so.
1. **Project design and results are intended, or otherwise suitable, for dissemination to a scholarly or professional audience beyond the institution*.*** The question here is whether the design of the project would support dissemination. In some cases this can be established by a stated intent to disseminate; in other cases, a project may be suitable for dissemination by virtue of the quality of the research design, even if the investigator does not intend to disseminate. Professional or scholarly dissemination typically requires a sufficiently detailed description of the methods of investigation and the prior research that gave rise to the project, such that other investigators could critique, replicate or build upon it.

Examples of venues for dissemination to scholarly or professional audiences include, but are not limited to:

* Articles, books, and monographs in peer-reviewed scholarly venues, both paper and electronic
* Presentations to conferences or annual meetings of scholarly or professional associations, including undergraduate research conferences
* Websites of scholarly or professional organizations
* Reports, exhibits, presentations, or other materials for public or private institutions (government agencies, not-for-profit institutions, companies, etc.)

***2. Does the research study “human subjects” as federally-defined in the Common Rule?***

A *human subject* is federally-defined as “a living individual about whom an investigator…conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information” [45 CFR 46.102(f)].

Such projects have the following characteristics:

1. **The project involves obtaining information about** **living individuals**. In order to be a “project with human subjects,” the researcher must be seeking data *about the subjects*, not about something else. For example, if a researcher is investigating a community organization and asks employees in the organization about its policies, its sources of funding, or its history, then the employees are not the subjects of the investigation – the community organization is. (In this example, the employees are the human equivalent of a reference list in a review of the scholarly literature.) On the other hand, if the investigator asks the employees about their opinions of the organization’s policies, their experience in fund-raising, or the length of time they have worked in the organization, then the employees *are* the subjects of the investigation.
2. **The investigator obtains the information through intervention or interaction with the individuals OR through procedures that result in individually-identifiable private information**. ***Either*** of these types of procedures, in combination with 2a above, can define a research project as “research with human subjects.”
3. **Procedures involving intervention or interaction:** According to the federal regulations, “*Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject” [45 CFR 46.102(f)]. Data-collection procedures involving interventions or interactions may occur face-to-face, on paper, electronically, or by telephone. Common examples of such procedures include, but are not limited to:
	* *Written surveys*
	* *Interviews*
	* *Focus groups*
	* *Experiments*
	* *Written or physical tests*
	* *Observation of human behavior or interactions in non-public settings*
	* *Measurement of physical characteristics (heart rate, height, weight, etc.)*
	* *Collection of physical samples (blood, saliva, hair, etc.)*
4. **Procedures that yield individually-identifiable private information.** A project may also constitute “research with human subjects” if the investigator uses “individually-identifiable private information” at some point in the project. An investigator may obtain individually-identifiable private information even if there are no procedures involving direct contact with the subjects (for example, by analyzing a data set with identifiers provided by someone else). Such information is defined as follows:
5. **Individually-identifiable:** “[T]he identity of the subject is or may readily be ascertained by the investigator or associated with the information” [45 CFR 46.102(f)]. In other words, if the investigator or someone reading the investigator’s work can determine whose “data” belongs to whom – who said what, who did what, who scored how much, who is characterized by what – then the study involves individually-identifiable private information.
6. **Private:** “Private information includes 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 (for example, a medical record)” [45 CFR 46.102(f)].

The information the investigator obtains must be **both** private **and** identifiable in order for this type of project to be considered “research with human subjects.” Project procedures that may involve the use of individually-identifiable private information include, but are not limited to, the following:

* *Analysis of existing data, documents, or specimens that include identifying information.* Examples of existing data sources include transcripts, course enrollment information, organizational membership records, medical records, artifacts, applications, etc. Federal data-privacy regulations provide the following list of types of identifying information [45 CFR 164.514b]:
* *Names*
* *Geographic locations smaller than a State (e.g., street address, city, county, ZIP code)*
* *Specific dates (other than year alone) associated with an individual (e.g., date of birth, date of enrollment, date of marriage, etc.)*
* *Telephone numbers*
* *FAX numbers*
* *Electronic mail (email) addresses*
* *Social Security numbers*
* *Medical record or health plan beneficiary numbers*
* *Account numbers*
* *Certificate/license numbers*
* *Vehicle identifiers and serial numbers*
* *Device identifiers*
* *Web Universal Resource Locators (URLs)*
* *Internet Protocol (IP) address numbers*
* *Biometric identifiers (e.g., finger and voice prints)*
* *Full face photographic or other comparable images*
* *Any other unique identifying number (e.g., a student ID number)*
* *Use of private information about individuals to identify a sample or recruit subjects.* Examples include a list of students in a course, or names and contact information for members of an organization.
* *Gathering private information through any of the data-collection methods listed in 2.b(1) above (surveys, interviews, tests, etc.).* In fact, with the exception of surveys where respondents are anonymous, any of the “interventions or interactions” listed above could potentially yield “individually-identifiable private information.” Interviews, for example, are rarely conducted in such a way that the interviewer obtains no identifying information (such as a name) about the interviewees. Even if the investigator “anonymizes” a subject’s information by removing all identifiers in reporting results, the information was still individually-identifiable to the investigator in the process of collecting it, so the project still involves “individually-identifiable private information.”

Note that a project involving individually-identifiable private information may be considered “research with human subjects” even if the private information is not specifically reported in the findings of the project. If an investigator obtains identifiable private information in order to select a sample, to recruit project participants, or to draw inferences about the subjects, and the topic of the investigation focuses on the subjects’ characteristics, attitudes, or behaviors, then the investigator may be conducting research with human subjects.

***3. Is the human subjects research project subject to the Common Rule?***

Some projects may constitute “research with human subjects” as federally defined, but fall outside the provisions of the Common Rule. Such projects do *not* require review and approval by an IRB (though an institution may have established different procedures for ensuring that such projects are conducted ethically). A project is subject to the Common Rule, and therefore requires IRB review, when **both** of the following conditions are met:

1. **The project is conducted or supported by a federal agency that has adopted the Common Rule, or is covered by an institutional commitment to broaden the application of the Common Rule.**

Unless exempt from the provisions of the Common Rule (see 3b below), a human subjects research project is subject to review by an IRB and to the provisions of the Common Rule if **either** of the following is true:

* + 1. **The project is conducted or supported by a federal agency that has adopted the Common Rule.** Fifteen federal agencies require compliance with the federal regulations known as the “Common Rule” for research with human subjects that is conducted by, or with funding from, these agencies. These agencies include:
* The Department of Health and Human Services (HHS) (which houses the federal Office for Human Research Protections, or OHRP)
* The Department of Agriculture (USDA)
* The Department of Energy (DOE)
* The National Aeronautics and Space Commission (NASA)
* The Department of Commerce
* The Consumer Product Safety Commission (CPSC)
* The Agency for International Development (USAID)
* The Department of Housing and Urban Development (HUD)
* The Department of Justice (DOJ)
* The Department of Defense (DOD)
* The Department of Education (ED)
* The Department of Veterans Affairs (VA)
* The Environmental Protection Agency (EPA)
* The National Science Foundation (NSF)
* The Department of Transportation

(2) **The project is covered by an OHRP-approved Federalwide Assurance that commits the institution to applying the Common Rule to all non-exempt human subjects research regardless of the source of support**. Institutions with Institutional Review Boards (IRBs) complete and periodically renew a legal document known as a “Federalwide Assurance” (FWA), by which the institution “assures” the federal government of its compliance with federal regulations for the protection of human subjects in research, including IRB review as appropriate. That assurance is “federalwide” because the institution’s “assurance” extends to all fifteen US departments and agencies that subscribe to the Common Rule (listed in 3a(1) above). An institution’s FWA must be approved by the Office for Human Research Protections (OHRP) in order for the institution to be eligible for research funding from any of these federal departments and agencies.

One of the decisions an institution must make in completing its Federalwide Assurance is whether it will voluntarily elect to apply the Common Rule to *all* human subjects research that is not federally-designated as exempt (see below), even if the research is not supported by one of the fifteen US departments or agencies that have adopted the Common Rule. In other words, an institution’s Federalwide Assurance indicates clearly whether the institution has committed to applying the provisions of the Common Rule only to human subjects research activities supported by one of the Common Rule-bound agencies, or whether it will apply those provisions more broadly. If an institution’s Federalwide Assurance indicates that the institution applies the Common Rule more broadly, then IRB review is required for all research with human subjects that is not otherwise exempt as described below, irrespective of whether the research is federally-funded.

1. **The project is not exempt from the provisions of the Common Rule** [45 CFR 46.101(b)]. The federal regulations on protecting human subjects identify several conditions under which a research activity may be “exempt” from the provisions of the Common Rule. Projects that don’t meet one or more of these conditions are not exempt. To put it in positive terms – if a human subjects research project that is otherwise subject to the Common Rule as described in 3a above meets any of the three conditions below, it must be reviewed by the IRB.

Research projects are not exempt from the Common Rule if **any** of the following conditions are met.

(1) **The subjects are prisoners**. [45 CFR 46.101(i), footnote 1] – The Common Rule prohibits exemption for research in which the subjects are prisoners; such research must be reviewed by an IRB and is subject to the provisions of the Common Rule.

(2) **The subjects are minors and the data are being gathered through survey, interview, or participant-observation procedures.** [45 CFR 46.101(i), footnote 1] – The Common Rule also prohibits exemption (i.e., requires IRB review and compliance with the provisions of the Common Rule) for federally-defined research that uses survey, interview, or participant-observation procedures for gathering data from and about minors (children and adolescents under the age of 18). These types of research activities with minors must be reviewed by an IRB.

(3) **The research activities are not specified as “exempt” in the Common Rule.** The Common Rule includes a list of human subjects research activities which are exempt from the provisions of the Rule. Projects that are “exempt” must still be conducted ethically in accordance with the policies of the investigator’s institution, but they are not federally-required to follow the specific steps for protecting human subjects as outlined in the Common Rule, nor is IRB review federally-required for these projects.[[2]](#footnote-2)

**Research activities that *are* federally-designated as “exempt”:** “…[R]esearch activities in which the **only** involvement of human subjects will be in one or more of the following categories are exempt from [the Common Rule]” [45 CFR 46.101.b]:

* + - 1. **Educational research in schools and colleges.** “Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods” [45 CFR 46.101.b(1)]. “Established or commonly-accepted educational settings” include schools, colleges, and universities; some other types of environments might also be considered established educational settings.
			2. **Research involving the anonymized collection of non-incriminating data.** “Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation” [45 CFR 46.101.b(2)]. incrimination

In other words, research in which information about human subjects is gathered through surveys, interviews, educational tests, or observations of public behavior may be exempt from the Common Rule if the information is:

* Made anonymous (stripped of identifiers) by the investigator AND
* Unlikely to be harmful or incriminating to the subjects in any of the ways described in the regulatory language above.
	+ - 1. **Research with public officials or candidates, or research subject to other federal confidentiality requirements: “**Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph [(b)(2)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101%28b%29) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter” [45 CFR 46.101.b(3)].
			2. **Research that uses publicly-available or anonymized existing data: “**Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects” [45 CFR 46.101.b(4)].
			3. **Research on public programs: “**Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs” [45 CFR 46.101.b(5)].
			4. **Research involving safe foods: “**Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture” [45 CFR 46.101.b(6)].

Any research activity with human subjects that is *not* on the list above must be reviewed by an IRB if the activity is supported by one of the federal agencies that subscribes to the Common Rule or if the institution’s Federalwide Assurance commits the institution to broader application of the Rule.[[3]](#footnote-3) Common examples of “non-exempt” human subjects research activities include, but are not limited to:

* *Research involving surveys, interviews, observations of public behavior, or tests in which the investigator records identifying information about the subjects* (names, student ID numbers, social security numbers, addresses, detailed demographic information, or other types of identifying information from the list in 2b)(2) above).
* *Research involving surveys, interviews, observations of public behavior, or tests in which information is gathered that could harm a subject’s reputation, employability, financial well-being, or legal status* if the information were to be disclosed.
* *Research analyzing existing data that is not publicly-available and that includes individual identifiers* (even if the identifiers are separated from the main data set through a “crosswalk” or other technique).
* *Research involving the collection of data from voice, video, digital, or image recordings* made for research purposes [65 FR 60364-60367].
* *Research involving the collection of various kinds of physical data or biological specimens from healthy, non-pregnant adults through interventions or interactions posing no greater than minimum risk,* such as moderate physical strength or endurance testing, sensory testing, body composition assessment, collection of hair or nail clippings, or collection of blood samples by finger or heel stick [65 FR 60364-60367].

A “Determining Whether IRB Review is Required” form accompanies this policy document, and serves as the record of an institution’s analysis of a specific project in relation to IRB review requirements.

1. *As noted in the Belmont Report: “The term ‘research’ designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.”* [↑](#footnote-ref-1)
2. Please note, however, that “exempt” projects *do* have to abide by the *institution’s* policies for protecting subjects and securing advance ethics review and approval, and some institutions require exempt projects with human subjects to apply the Common Rule and secure IRB review and approval just like non-exempt projects. [↑](#footnote-ref-2)
3. Note that an exempt project must have the characteristics set forth in the federal language cited for each category of exemption. The summary labels for each category are provided as a convenience; what governs the determination of exemption is the specific regulatory language, not the labels for each category. [↑](#footnote-ref-3)