

Policy for the Protection of Human Subjects Application and Exemptions

1. Application of Federal Requirements
 - 1.1. Research in Foreign Country
2. Exemptions
 - 2.1 Educational Setting
 - 2.2 Educational Tests
 - 2.3 Non-exempt
 - 2.4 Public or Anonymous Data
 - 2.5 Specific Research and Demonstration Projects
 - 2.6 Taste and Food Quality
3. IRB Determination of Exempt Projects
4. Modified Review of Exempted Projects
 - 4.1. No IRB Review
 - 4.2. Human Subjects Committee (HSC) Review
 - 4.2.1. Projects Not Covered by Federal Regulations
 - 4.2.2. No Review for Class Surveys
5. Federal Override Authority

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1. Application of Federal Requirements

Research supported by federal funds and involving human subjects must comply with regulations that are found at **Title 45 Code of Federal Regulations (CFR) Part 46, Protection of Human Subjects**, also referred to as the "Common Rule." These projects must be reviewed and approved by an Institutional Review Board (IRB). Whittier College has established an IRB per the policy titled "Institutional Review Board."

1.1. Research in Foreign Country

A Whittier College research project may include participation of an entity that will perform a portion of the work in some other country. If the work will be performed under some standard other than the Common Rule, prior to performance of the work, the funding federal Department or Agency head must rule on whether the foreign standard, such as the Declaration of Helsinki amended in 1989, is at least equivalent, and therefore may be substituted for the U.S. standard.

2. Exemptions

Exemptions from the Common Rule are listed in **45 CFR 46.101(b)**. Research involving human subjects that only fall under one or more of the listed activities is exempt from the requirements of the Common Rule, unless specifically required by funding Department or Agency heads. Exempted items will not require review according to the Common Rule. The following exemption descriptions are summarized from **45 CFR 46.101(b)**. However, any dispute over what is exempted based upon procedure language and federal regulations shall ultimately be based upon the actual language of the regulations and not this procedure.

2.1 Educational Setting

Research is exempted from the Common Rule if it involves routine educational practices that are performed in acknowledged educational settings, such as the following.

2.1.1 Research on regular and special education instructional strategies

2.1.2 Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

2.2 Educational Tests

Research is exempted if it involves the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior.

2.2.1 Unless when recording data, human subjects can be identified, directly or through identifiers linked to the subjects, **AND**

2.2.2 If there would be any criminal or civil liability risk to the human subjects or potential damage to the subjects' financial standing, employability, or reputation by any disclosure of the research responses.

2.3 Non-exempt

Research is not exempt under section 2.2 involving the use of

- Educational tests (cognitive, diagnostic, aptitude, achievement),
- Survey procedures,
- Interview procedures, or
- Observation of public behavior

for the following categories of information.

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2.3.1 Data regarding human subjects who are elected or appointed public officials or candidates for public office.

2.3.2 Where federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and after.

2.4 Public or Anonymous Data

Research is exempt when it involves the following,

- The collection or study of existing data,
- Documents,
- Records,
- Pathological specimens, or
- Diagnostic specimens,

if the sources are publicly available or if the information is recorded by the investigator so that subjects are totally anonymous, both directly and indirectly.

2.5 Specific Research and Demonstration Projects

Research and demonstration projects approved by federal funding Department or Agency heads are exempt when they are designed to study, evaluate, or otherwise examine public benefits, as in the following items.

2.5.1 Public benefit or service programs

2.5.2 Procedures for obtaining benefits or services under those programs

2.5.3 Possible changes in or alternatives to those programs or procedures

2.5.4 Possible changes in methods or levels of payment for benefits or services under those programs

2.6 Taste and Food Quality

Taste and food quality evaluation and consumer acceptance studies in the following categories are exempted.

2.6.1 Consumption of wholesome foods without additives

2.6.2 Consumption of food that is deemed safe according to standards established by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA) when it contains the following.

- A food ingredient at or below the level and for a use found to be safe
- An agricultural chemical or environmental contaminant at or below the level found to be safe

3. IRB Determination of Exempt Projects

The first action of the IRB, when reviewing a proposed research project having (a) human subject(s), is to determine whether or not the research is exempted according to this procedure and 45 CFR 46.101(b).

4. Modified Review of Exempted Projects

Research projects determined to be exempted from Common Rule review according to Section 2 will be addressed in the following fashion.

4.1 No IRB Review

No IRB review is required, once that it is determined that the research project is exempt per the following exempted categories.

- Projects that utilize only existing public data or anonymous information.
- Research and demonstration projects that have been approved for funding by the head(s) of a federal funding department or agency, and when project's focus is one or more of the categories listed in sections 2.5.1 – 2.5.4 of this procedure.
- Exempted taste and food quality research that uses ingredients that are present at levels that FDA, EPA, or USDA consider to be safe.

4.2 Human Subjects Committee (HSC) Review

Whittier College will continue to have a Faculty Human Subjects Committee (HSC) to review human subject projects that are not covered by the federal regulations.

4.2.1 Projects Not Covered by Federal Regulations

Research projects involving human subjects, which are either not funded through a federal agency or are exempted from the federally required IRB review (per 45 CFR 46.101(b)), shall undergo review by the Faculty Human Subjects Committee (HSC).

The following categories of projects that are exempted from the Common Rule must undergo HSC approval and annual review after approval.

- Educational setting projects regarding regular or special education instructional strategies and comparison of instructional techniques, curricula, or classroom management methods.
- Educational tests, surveys, interviews, or observations of public behavior where data is collected with not both identifiers of the subjects and criminal/civil liability incurred by the subjects.

The main purpose of this HSC review is to assure that proper precautions are taken to protect subjects and to guarantee their anonymity.

4.2.2 No Review for Class Surveys

Instructors may survey students within their classes about the topics/themes of the courses, related issues, or the pedagogy of teaching the subjects without requesting IRB or HSC approval.

5. Federal Override Authority

Final interpretation about what is regulated under the Common Rule and what is exempted is accorded to applicable federal funding Department or Agency heads.