

UC Davis Policy and Procedure Manual

Chapter 240, Research Integrity

Section 54, Activities that Require Departmental Review but are Exempt from Review by Human Subjects Review Committee

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Supersedes: New

Responsible Department: Office of Research

Source Document: Code of Federal Regulations Title 45, Part 46

Exhibit A, Statement of Exemption

I. Policy for Review of Exempt Categories

Research that involves human subjects may fall within one or more exempt categories as defined by the Department of Health and Human Services (HHS) [45 CFR 46.101(b)]. University policy requires a review procedure to determine that the research does, in fact, qualify for exemption so that the necessary certification of exemption can be made. Therefore, although categories of research are exempted from full committee review by the Human Subjects Review Committee (HSRC), they must be reviewed at the departmental level and the HSRC Chair or Coordinator must concur that the study is indeed exempt.

II. Exempt Categories

The exempt categories are as follows (for complete definitions, see Exhibit A):

- A. Education research--normal educational practices.
- B. Educational tests, survey procedures, interview recording procedures, or observation of public behavior unless certain conditions apply.
- C. Educational test, survey or interview procedures, or observation of public behavior not exempt in above category if certain conditions apply.
- D. Collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if publicly available and unidentifiable in recording.
- E. Research or demonstration projects regarding certain public benefit or service programs.
- F. Taste and food quality evaluation and consumer acceptance studies if certain conditions apply.

III. Vulnerable Populations

Any research involving certain vulnerable populations as subjects cannot be considered for exemption and will require HSRC review even though the study may meet all other requirements for exemption.

- A. Research involving children, the mentally or physically disabled, prisoners, parolees, addicts, pregnant women, fetuses, and others in conditions of dependency must undergo HSRC review.
- B. Research involving University students when participation is in connection with or as part of a course of study must undergo HSRC review.
- C. Research involving subjects from any population when coercion or deception is used must undergo HSRC review.

IV. Exemption Procedure

Any investigator who wishes to undertake research involving human subjects that she or he considers to be exempt from review by the HSRC must complete a Statement of Exemption (Exhibit A).

- A. Nonsponsored research

For nonsponsored research, a copy of the statement is kept in the departmental or unit files as

long as the research is ongoing. The original statement is forwarded to the Office of Research for inclusion in the permanent records of the HSRC.

B. Sponsored research certification of exemption

For sponsored research, the original statement is forwarded to the HSRC or with the grant application to the Office of Research. The Office of Research will prepare a certification of exemption to the sponsoring agency as long as the sponsor's name and address are indicated on the exemption form.

V. Departmental Review of Exempt Categories

Departments and other academic units are encouraged to establish internal review committees or other procedures to review such research. A statement of these procedures should be sent to the Office of Research.

VI. Questions

Questions regarding the exemption procedure may be referred to the Coordinator of the Human Subjects Review Committee, Office of Research, (530) 752-6931.