1. POLICY

There are six categories of research activities involving human subjects that may be exempt from the requirements of the Federal Policy for the Protection of Human Subjects (45 CFR 46). Individual investigators do not have the authority to determine that their own research qualifies for exempt status; this determination must be made by the Office for Protection of Human Subjects (OPHS) staff, upon review of an application for Exempt Status submitted by the investigator. The research may not begin until the investigator has received notification that the research qualified for exempt status. In order to be eligible for exempt status, all of the proposed research activities of a study must fit in one or more of the six exemption categories listed in section 1.2 of this policy.

Although research that qualifies for exempt status is not governed by federal requirements for research involving human subjects, investigators of exempted studies still have a responsibility to protect the rights and welfare of their subjects, and are expected to conduct their research in accordance with the ethical principles of Justice, Beneficence and Respect for Persons as described in the Belmont Report.

Specific Policies

1.1 Research That Is Not Exempt

The exemption categories listed in section 1.2 do not apply to the following research:

- Research that involves greater than minimal risk
- Survey or interview of children vis-à-vis category 2
- Observation of the public behavior of children when investigators interact with the children vis-à-vis category 2
- Research involving prisoners
- Research involving use of protected health information from the UC Berkeley Tang Health Center, Human Resources Health Plan, Intercollegiate Athletics, Optometry Clinic, or Psychology Clinic.
- Research regulated by the Food and Drug Administration (FDA). With the exception of Category 6, FDA-regulated research does not qualify for exempt status. Research will not qualify for exempt status under Category 6 if there have been food and color additives incorporated into the food product and these additives are used in research with the intent to apply to the FDA for marketing of the additive.

1.2 Exempt Research Activities

1. Educational Practices: 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.
2. Educational Tests (Cognitive, Diagnostic, Aptitude, Achievement), Survey Procedures, Interview Procedures, or Observation of Public Behavior: Research involving these procedures is exempt, if:
   i. the information obtained is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects; or
   ii. any disclosure of the subject’s responses outside of the research could not reasonably place the subject at risk of criminal or civil liability or be damaging to the subject’s financial standing, employability, or reputation.

3. Educational Tests, Survey Procedures, Interview Procedures, or Observation of Public Behavior: Research NOT exempt under Category B: Research involving these procedures is exempt, only if:
   i. subjects are elected or appointed public officials or candidates for public office; or
   ii. federal statute(s) require(s) without exception that confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Existing Data: Research involving collection or study of existing data, documents, records, or specimens, if:
   i. these sources are publicly available; or
   ii. the information is recorded by the researcher in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and Demonstration Projects Conducted by or Subject to the Approval of Department or Agency Heads: This research is exempt if it is designed to study, evaluate, or otherwise examine:
   i. public benefit or service programs; or
   ii. procedures for obtaining benefits or services under those programs; or
   iii. possible changes in methods or alternatives to those programs or procedures; or
   iv. possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and Food Quality Evaluation and Consumer Acceptance Studies: This research is exempt, if:
   i. wholesome foods without additives are consumed; or
   ii. a food is consumed that contains a food ingredient at or below the level and for a use found to be safe by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service (FSIS) of the US Department of Agriculture (USDA); or
   iii. a food is consumed that contains an agricultural chemical or environmental contaminant at or below the level found to be safe by the FDA or approved by the EPA or the FSIS of the USDA.
1.3 Action Taken If Proposed Research Does Not Meet Criteria for Exemption

If the IRB Chair or OPHS staff determines that the proposed research does not meet the criteria for exempt status, the investigator will be notified in writing and asked to submit the appropriate application materials for either expedited or full committee review.

1.4 Modifications to an Exempt Protocol

All modifications to a project previously deemed exempt from IRB review must be submitted to the IRB for prospective review and certification of exemption prior to implementation. In some circumstances, proposed changes to the protocol may disqualify the project from exempt status in which case either expedited or full committee review would be required, as appropriate.

2. SCOPE

These policies and procedures apply to investigator claims for Exemption from 45 CFR 46 requirements.

3. RESPONSIBILITY

OPHS staff are responsible for reviewing and making a determination regarding research applications that claim exemption from 45 CFR 46.

The OPHS Director, IRB Manager and/or IRB Chair/Designee are responsible for providing consultation in the review of claims of exemption. The IRB Chair or OPHS Director has final authority to determine a finding of exempt status, or to revoke determinations granted by OPHS staff.

4. PROCESS OVERVIEW

The investigator submits to the IRB an application for determination of exempt status and any additional required information/documentation (e.g., copy of survey instrument).

An IRB administrative staff member reviews the application to determine if the investigator has submitted all of the necessary documentation and supporting materials for exempt review and ensures that all required elements are complete and in proper format. The staff member, in consultation with the OPHS Director, OPHS Assistant Director, or IRB Chair as appropriate, evaluates the exemption request for (1) level of risk; (2) category of activity; and (3) other relevant considerations.

If the research qualifies as exempt, the staff member provides the investigator with a letter of exempt status.

If the research does not qualify for exemption, the staff member contacts the investigator to request a non-exempt application for expedited or full committee review.

Investigators are not permitted to make the determination of exempt status on their own. Exemption can only be granted by the OPHS staff or IRB Chair.
5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.101
21 CFR 56.104
21 CFR 56.105