

Chaminade University IRB
Summary of Exempt Research Categories
Updated June 2015
Updated in Light of new Common Rule
January 2018

OHRP EXEMPT CATEGORIES 45 CFR 46.101(B)

☐ Exempt Category 1: Educational Exemption.

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

- research on regular and special education instructional strategies, or
- research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Unless there are perceived adverse effects on the ability of students to learn or educators to instruct.

☐ Exempt Category 2: Surveys, Interviews, Educational Tests and Observational of Public Behavior.

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures interview procedures, or observation of public behavior.

Note: This exemption does not apply to the following types of research; 1) research involving children that includes surveys, in interviews, and observations of public behavior when the investigator is a participant in the activities being observed; and 2) research in which information is recorded in such a manner that participants can be identified and disclosure of the information could reasonably place the participants at risk. It also does not include studies with interventions, the collection of biospecimens, those where there is a link to additional personally-identifiable data or research with children (except for educational tests or some public observation, these do fall under this exemption).

☐ Exempt Category 3: Benign Behavioral Interventions.

Research involving the collection of data via an interaction (e.g. survey, interview, audio/visual recording) from adult subjects with prospective agreement. Note – this is not applicable to research with children, if there is deception (unless prior consent to this is obtained), studies where physiological data are collected (e.g. EEG, wearable devices, such as FitBit™, blood pressure monitors) and studies linking to personally-identifiable data.

☐ Exempt Category 4: Secondary Research (Identifiable private information or biospecimens).

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 participants cannot be identified, directly or through identifiers linked to the participants.

This includes prospective data review, the maintenance of identifiers (if ALL study data is protected health information PHI), research that is conducted by, or on the behalf of, a Federal department/agency or using government-generated or government-collected information obtained for non-research activities.

Note: All of the data or materials must exist prior to proposing the research.

☐ Exempt Category 5: Public Benefit/Service Program Research (Federal Demonstration Projects).

Research and demonstration projects that are conducted by or subject to the approval of department or agency heads and that are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

Note: In order to be eligible for this exemption, all of the following must apply:

- The research is conducted pursuant to specific federal statutory authority.
- The research has no statutory requirements for IRB review.
- The research involves no significant physical invasions or intrusions upon the privacy interests of the participant.
- The research has authorization or concurrence by the funding agency (if funded).

Note – the project must also be published on a federal website.

☐ Exempt Category 6: Taste/Food Quality Evaluation and Consumer Acceptance

Taste and food quality evaluation and consumer acceptance studies:

- if wholesome foods without additives are consumed; or
- 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 (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service of the US Department of Agriculture(USDA).

☐ Exempt Category 7: Storage/Maintenance of Identifiable Data/Biospecimens Obtained with 'Broad Consent'.

Research that will store data and/or specimens in a repository, with identifiers maintained, that were collected under an approved IRB protocol with 'Broad Consent' for future secondary research use.

☐ Exempt Category 8: Use of Identifiable Data/Biospecimens Obtained with ‘Broad Consent’.

Secondary Research with the use/analysis of identifiable data/biospecimens that were collected under an approved IRB protocol with ‘Broad Consent’.

Certain studies may be eligible for a Limited IRB Process in which only the IRB Chair or a designated expert reviewer provides review. Its purpose is to ensure privacy/confidentiality protections are in place with exempt research that involves the collection or use of sensitive, identifiable data (exemptions 2, 3 and 8) and, for exemption 7, that "broad consent" was obtained and (if appropriate) documented according to an approved protocol. For exempt studies involving access to PHI (e.g., from medical records), the required Privacy Board review may be integrated with Limited IRB Review by the same assigned reviewer. Eligibility for this fast track review will be determined administratively after the Form II is received by the IRB.