Policy Number: 12
Title: IRB Review of Human Subjects Research - Exempt
Date of Last Revision: 10/12/07, 08/21/10, 11/09/10, 01/24/11, 06/05/13, 05/01/16, 06/01/16, 10/19/17, 02/28/18

Policy:
It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) that all human subjects research activities under its jurisdiction be reviewed to determine whether the research meets one or more of the exemption categories described in the Federal regulations and complies with UC Irvine’s ethical standards.

I. Exempt Eligibility
   A. Research activities involving human subjects that are exempt from the requirement that they receive IRB full or expedited review are identified in 45 CFR 46.101(b)(1)-(6), 45 CFR 406.301(a), 45 CFR 46.401(b) and 21 CFR 56.104(d).
   B. With the exception of undergraduate exempt research, only experienced HRP Staff Reviewers or the IRB may confirm which activities qualify for an exempt review.
      a) Undergraduate exempt research is submitted for exempt review and confirmation through the Undergraduate Research Opportunities Program (UROP).
         a. There may be some exceptions where the IRB will retain confirmation of exemption for undergraduate exempt research, such as the inclusion of children or use of protected health information (PHI).
   C. Investigators do not have the authority to make an independent determination that research involving human subjects is exempt from federal regulations. An Investigator may suggest a particular category of exemption, but the final determination of applicability will be made by experienced HRP Staff Reviewers, the IRB Chair or designate.
   D. Investigators must submit a completed IRB application to conduct Exempt human subjects research. IRB Applications for Exempt Research are accepted on a rolling basis.
   E. Exempt confirmation may be granted for no more than three (3) years. A Continuing Protocol Application (CPA) may be submitted to continue the research.
   F. Research may be granted exempt status if all research activities involve procedures listed in one or more of the specific categories under 45 CFR 46.101(b):
      1. 45 CFR 46.101(b)(1): Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
         a. Research on regular and special education instructional strategies; or
         b. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
         c. Educational settings are not limited to classrooms. It includes settings where other educational activities are taking place such as a conference, meeting, or other.
         d. The study procedures should not:
            1. Entail a significant deviation in time or effort from those educational practices already existent in the study site; or
            2. Involve an increase in the level of risk or discomfort beyond normal, routine educational practices.
e. The school or other institution grants written approval for the research to be conducted.

2. 45 CFR 46.101(b)(2): Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   a. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   b. Any disclosure of the human subjects’ responses outside of 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.
   c. If the research involves children as participants, the research must be limited to educational tests (cognitive, diagnostic, aptitude, achievement), and observation of public behavior when the investigator(s) do not participate in the activities being observed. Research that uses survey procedures, interview procedures, or observation of public behavior when the investigator(s) participate in the activities being observed cannot be granted an exemption.
   d. Audio/video recordings and photographs may be permissible in this category.

3. 45 CFR 46.101(b)(3): 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 45 CFR 46.101(b)(2) if:
   a. The human subjects are elected or appointed public officials or candidates for public office; or
   b. Federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. 45 CFR 46.101(b)(4): Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
   a. To qualify for this exemption, data, documents, records, or specimens must have been collected before submission of the IRB application.
   b. Under this exemption, an investigator (with proper institutional authorization) may inspect private, identifiable records, but may only record information in a non-identifiable manner. The data must be permanently and completely de-linked at the time of extraction. A code may be used to organize data as it is collected. However, the code may not be a means of re-linking the data set to the original data source. Investigators are required to provide a data abstraction sheet to the IRB.

5. 45 CFR 46.101(b)(5): Research and demonstration projects, which are conducted by or subject to the approval of Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
   a. Public benefit or service programs; this exemption is for federally supported projects and is most appropriately invoked with authorization or concurrence by the funding agency. The following criteria must be satisfied to invoke the exemption for research and demonstration projects examining "public benefit or service programs:"


(1) The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services under the Older Americans Act);
(2) The research or demonstration project must be conducted pursuant to specific Federal statutory authority;
(3) There must be no statutory requirements that the project be reviewed by an IRB; or
(4) The project must not involve significant physical invasions or intrusions upon the privacy of participants.

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.
e. This exemption is for projects conducted by or subject to approval of Federal agencies and requires authorization or concurrence by the funding agency.

6. 45 CFR 46.101(b)(6) and 21 CFR 56.104(d): Taste and food quality evaluation and consumer acceptance studies;
a. If wholesome foods without additives are consumed; or
b. 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.

II. Exceptions to exempt research:
A. These categories do not apply to research involving prisoners.
B. Exempt categories 1-4 do not apply to FDA regulated research.
C. None of these exemption categories apply to research involving derivation and use of human embryonic stem cells or human embryonic germ cells, including somatic cell nuclear transplantation.
D. Observational research involving sensitive aspects of subjects’ behavior, or in settings where subjects have a reasonable expectation of privacy, does not qualify for exemption from IRB review.
E. Under FDA regulations at 21 CFR 56.104(c), the emergency use of test articles is exempt from IRB requirements. However, OHRP at 45 CFR 46 does not address emergency use of test articles. Emergency use constitutes emergency medical care, the patient is not considered to be a research subject; therefore prior IRB review and approval is not required. Such emergency care may not be claimed as research, nor may the outcome of such care be included in any report of a research activity.

III. All research conducted under exempt review is subject to all applicable UCI institutional and IRB policies and procedures.

IV. Exempt research activities are subject to the same subject protections and ethical standards as outlined in The Belmont Report.

V. The full Committee is advised of research proposals/activities that have been registered under the exempt review procedure. As a means of notifying the Committee and allowing for comments regarding a review conducted utilizing exempt review procedures, a report documenting
registration of exempt research for the previous month is provided to the IRB Committee as a standing item on the IRB Committee meeting agenda.

VI. Modifications to Exempt protocols are reviewed and approved by an HRP Staff Reviewer or an IRB Chair. If the modification affects the status of the protocol review level, the IRB Chair will determine the appropriate review level (i.e. Expedited or full Committee review).

References:
OHRP 45 CFR 46
45 CFR 46.101(b)
45 CFR 46.101(i)(footnote 1)
45 CFR 46.102(i)
45 CFR 46.201(b)
45 CFR 46.401(b)
21 CFR 56.104(c) and (d)
OHRP Compliance Activities: Common Findings and Guidance -7/10/2002
Procedure Number: 12.A
Title: Procedure for IRB Review of Human Subjects Research – Exempt

Procedure:
This procedure provides guidance in accordance with regulations to review and approve human subjects research in an exempt category.

I. Lead Researcher (LR) Responsibilities
   A. The IRB Application is completed in its entirety and electronically submitted to the Human Research Protections (HRP) staff for processing. The IRB application and instructions on what to submit are located on the IRB website: http://www.research.uci.edu/ora/forms/.
   B. The IRB website also includes information on who to contact with questions about whether research involving human participants is exempt from regulation.
   C. The Investigator replies to all requests for revisions and/or clarifications requested by the HRP Staff Reviewer or IRB reviewer, when applicable.
   D. The Investigator is responsible for assuring that the exempt research is carried out in an ethical manner that includes appropriate participant protections (e.g., confidentiality).

II. Reviewer Responsibilities
   A. The Reviewer reviews the “Application for IRB Review” and validates or declines the researcher’s claim for review under the exempt category.
   B. The Reviewer reviews the proposed research, consents, and applicable documents to determine if the research meets the ethical standards of the Belmont Report. The Reviewer documents the exempt determination on the “Reviewer’s Checklist.”
   C. When the research involves interaction with subjects, a determination is made by the Reviewer whether some type of consent process is appropriate. The Reviewer documents the consent process on the “Reviewer’s Checklist.” The Reviewer utilizes the checklist to ensure that the consent document provided to subjects contains such information as:
      1. a statement that the activity involves research;
      2. a description of the procedures;
      3. a statement that participation is voluntary;
      4. a statement that there are adequate provisions to protect the privacy and confidentiality of the subjects; and
      5. the name and contact information for the researcher.
   D. If the Reviewer disagrees with the proposed level of risk, the appropriate level of review is determined (i.e., Expedited). An IRB Chair will be consulted if the appropriate level of review is full Committee.
   E. If the Reviewer approves the request, the Reviewer signs the “Reviewer’s Checklist” and a letter of Exempt Registration is generated.
   F. When revisions are requested prior to initial registration, the modified documents are re-reviewed and, if acceptable, exempt registration is granted.
   G. If proposed changes to an exempt study are submitted for review and approval, the Reviewer will review and approve.
   H. If needed, the IRB Chair or designated IRB Committee member is available to assist the Reviewer in determining if the study meets exemption criteria. If the Reviewer has a conflict of interest, another experienced Reviewer will conduct the review.
   I. HRP Staff Reviewers are delegated the authority to register IRB applications and approve modifications related to research activities deemed exempt from the federal regulations.
regarding the protection of human subjects under 45 CFR 46.101 (b). Exempt studies are accepted on a rolling basis and are administratively reviewed weekly by an HRP Staff Reviewer.

J. Exempt Research receives a three year registration with the UCI IRB. An abbreviated version of the CPA may be submitted to continue the research. The abbreviated CPA prompts the LR to confirm currently registered information about the research, as well as the status of enrollment. Finally, the LR can upload any relevant documents that the study team may want reviewed as part of the Exempt CPA.

K. Delegation is provided in the HRP Staff Reviewer Delegation of Authority document maintained on the HRP WIKI page – and signed by the IRB Chairs for A, B and C, as well as the Executive Director of Research Protections.

1. An HRP Staff Reviewer is defined as follows:
   a) **HRP STAFF REVIEWER:**
      (1) **Tier 1:** Administrator or above, CIP or CCRP certified and appointed as IRB members or alternate members may review and approve transactions related to exempt and expedited level protocols. Exceptions are noted as applicable.
      (2) **Tier 2:** Analysts or above, CIP or CCRP certified may review and approve transactions related to exempt and expedited level protocols. Those without current CIP or CCRP have been designated by an IRB Chair or the Executive Director of Research Protections to have the appropriate experience to review and approve transactions related to exempt and expedited protocols. Exceptions are noted as applicable.

2. An HRP Staff Reviewer (both tiers) may review and approve exempt protocols except under the following conditions:
   i. 45 CFR 46.101(b)(1): Research conducted in established or commonly accepted educational settings when research involves:
      1. pregnant women (where they are the focus of the research)
      2. children
      3. individuals with cognitive or medical impairments
      4. students (e.g., undergraduates, medical students)
   ii. 45 CFR 46.101(b)(2 & 3): Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior when the research involve:
      1. pregnant women (where they are the focus of the research)
      2. children
      3. individuals with cognitive or medical impairments
      4. research involving deception/incomplete disclosure
   iii. Exempt applications that involve a disclosure of financial interest

3. HRP Staff Reviewers (both tiers) may review and approve modifications related to exempt protocols in accordance with HRP Policy # 17.

III. Human Research Protections (HRP) Team Responsibilities
A. The HRP team assures that the submission is complete. Documentation submitted for IRB review includes:
   1. IRB Application
   2. Protocol Narrative
   3. Investigator’s Assurance document
4. Disclosure of Investigators’ Financial Interest form
5. Proposed Data Collection instruments, or citations, if standardized, if applicable
6. Proposed Consent document, if applicable
7. Assent form, if applicable
8. Recruitment advertisements, if applicable

B. The Analyst or Administrator communicates (via e-mail) the Reviewer’s findings to the LR, Faculty Sponsor (FS) and Administrative Contact (AC), when applicable and provides assistance with IRB submission requirements.

C. The HRP team will also review the proposed research to determine if it meets the ethical standards of the Belmont Report.

D. The Analyst or Administrator prepares the letter of Exempt Registration.

E. The HPS database entries are completed.

F. Registered documents are processed.

G. The Protocol File is collated and filed.