Policy Number: 2
Title: Activities Subject to IRB Jurisdiction
Date of Last Revision: 01/29/09, 10/18/10, 01/28/15, 05/01/16

Policy:
It is the policy of the UC Irvine (UCI) Institutional Review Board to have jurisdiction over all human subjects research subject to its Federalwide Assurance (FWA).

I. Review and Approval of Human Subjects Research

A. All human subjects research, clinical investigations, and all other activities, which in part involve human subject research, regardless of sponsorship, must be reviewed and approved by UCI's IRB or by an IRB designated as the IRB of record. An IRB is designated as the IRB of record when UCI has entered into an IRB Authorization Agreement or a Memorandum of Understanding with the IRB.
   1. No intervention or interaction with human subjects in research, including advertising, recruitment, and/or screening, may begin until the IRB or IRB designees have reviewed and approved the research.
   2. Whether a proposed activity constitutes human subject research can be determined by the Human Research Protections (HRP) staff. See Policy 16.
      a. Researchers may also make their own assessment utilizing the "Non-Human Subject Research Determination Form", available on the HRPP webpage.

B. UCI's FWA defines its jurisdiction over the review of human subjects research. Regardless of sponsorship, the IRB or a designated IRB must review all human subjects research if any of the following apply:
   1. The research is conducted by or under the direction of any UCI employee (i.e., faculty, staff, student) or agent in connection with his/her institutional responsibilities;
   2. The research uses UCI property, facilities, or resources to support or carry out the activity;
   3. The name of the University of California, Irvine is used in applying for funds (intra or extramural);
   4. The name of the University of California, Irvine is used in explanations and/or representations to subjects;
   5. The UCI employee or agent plans to use their University of California, Irvine association in any dissemination, publication or public presentation resulting from the research;
   6. The research involves the use of non-public information maintained by UCI to identify or contact human subjects or prospective subjects.

C. The State of California IRB reviews research involving California issued death records (certificates and indices). See Policy 29.

D. If an Investigator begins a non-research activity and later finds that analysis of the private identifiable data would contribute to generalizable knowledge, the Investigator must submit an application to the IRB for approval prior to analysis of the data for research purposes or prior to publication or presentation with the intent to contribute to generalizable knowledge (e.g., journal article, poster session, public speech or presentation, or project report).

E. Only faculty with paid appointments of 50% or more, Emeriti faculty, and Academic Administrators may serve as Lead Researchers on research proposals. Students, volunteer (i.e., non-salaried) faculty members and staff may also assume the Lead Researcher (LR) role as long as they have a formal affiliation with UCI and have a Faculty Sponsor (FS) who fulfills the Lead Researcher eligibility criteria.

II. Failure to Obtain IRB Approval

A. The implications of engaging in activities that qualify as human subjects research therefore requiring IRB review and approval without obtaining such approval are significant. Results from such studies may not be published or presented unless IRB approval had been obtained prior to collecting the data. The IRB will determine whether the data may be used to satisfy thesis or dissertation requirements.

B. Investigators who request approval to continue human subjects research under 45 CFR 46 and/or under 21 CFR 50 and 56 that was not previously reviewed, or request approval to use data that was collected without IRB approval, face the possibility that the IRB will recommend withdrawal or request that the Investigator administratively withdraw his/her application, as the IRB cannot give post-hoc (retroactive) approval.

C. The IRB may not approve applications where the Investigator has attempted to circumvent IRB policies and procedures regarding human subjects research by collecting data as non-research and then applying to use it as existing data. It is therefore in the Investigator's best interest to consider carefully the likelihood that he or she will want to use the data for research purposes in the future, and to err on the side of inclusion and seek IRB approval prior to commencing the work.

D. General Counsel of the Regents of the UC has stated that: "If a principal investigator conducts an activity involving human subjects, but does not obtain the approval of the campus Human Subjects committee or designated IRB, the Regents would not be obligated to defend or indemnify the principal investigator if legal action were instituted by the subject."

III. Exempt Human Subjects Research

A. Per UCI's Federalwide Assurance (FWA), only the IRB or an experienced HRP staff member has the authority to determine which proposed research activities qualify as exempt from federal regulations as identified in 45 CFR 46.101(b)(1)-(6), 45 CFR 406.301(a), 45 CFR 46.401(b) and 21 CFR 6.104(d).

B. Investigators do not have the authority to make an independent determination that research involving human subjects is exempt.

IV. Requests for Confirmation that Activities do not Constitute Human Subjects Research

Requests for confirmation that activities do not constitute human subject research are reviewed by experienced HRP staff. An IRB Chairperson or designee is consulted as needed. See Policy 16 for further information on Human Subject Research/Non-Human Subject Research Determinations.

References:

45 CFR 46
21 CFR 50 and 56
21 CFR 812
University Policy on Protection of Human Subjects in Research
UCI Research Policy for the Protections of Human Subjects in Research

Procedure Number: 2.A
Title: Procedure for Activities Subject to IRB Jurisdiction

Procedure:
This procedure provides guidance on the types of activities that are subject to review and approval by the UCI Institutional Review Board.

I. Lead Researcher (LR) Responsibilities
- A. The LR submits an IRB Application which includes a description of his/her activity for review and obtains a determination of exemption or approval prior to the initiation of human subjects research.
- B. The table below identifies typical activities that may require UCI IRB review and approval/registration, prior to initiation of such activities:
- C. The LR must consider carefully the likelihood that he or she will want to use clinical or routinely collected data for research purposes in the future. If it is likely the Researcher should err on the side of inclusion and seek IRB approval prior to commencing the work.

II. IRB Responsibilities
- A. The IRB reviews the proposed activity in accordance with applicable regulatory, institutional and IRB policies and procedures.
- B. If a human subjects research study has been completed without prior IRB approval, the IRB Chair or Committee requests withdrawal of the application for research and notifies the LR of the regulatory requirements regarding prospective IRB approval of human subjects research. The LR and Faculty Sponsor, if applicable, are notified that the data may not be used for any publications, presentations, thesis, or dissertation requirements.
- C. If the IRB Chair or Committee determines that an Investigator has attempted to circumvent IRB policies and procedures regarding human subjects research by collecting data as non-research and then applying to use them as existing data the IRB Chair or Committee requests the application for research be withdrawn. The LR and Faculty Sponsor, if applicable, are notified that the data may not be used for any publications, presentations, thesis, or dissertation requirements.

III. Human Research Protections (HRP) Staff Responsibilities
- A. The HRP staff processes the research protocol in accordance with applicable IRB policies and procedures.
- B. If the HRP staff receives a completed publication (e.g., thesis, manuscript) as part of an initial IRB submission of human subjects research, the Director of Research Protections or designee, and the IRB Chair or Committee are notified. The IRB Chair or Committee requests withdrawal of the application for research. The LR and Faculty Sponsor, if applicable, are notified that because the research was not prospectively approved by the IRB, the data may not be used for any publications, presentations, and may not be used to satisfy thesis, or dissertation requirements.

TABLE 1

TYPE	DESCRIPTION	IRB REVIEW REQUIRED
Clinical Investigation	Experiments using a test article on one or more human subjects that are regulated by the Food and Drug Administration or support applications for research or marketing permits for products regulated by the Food and Drug Administration. Products regulated include foods, including dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products.	YES
Standard Diagnostic or Therapeutic Procedures	The collection of data about established and accepted diagnostic, therapeutic procedures, or instructional methods for dissemination or contribution to generalizable knowledge.	YES
	An alteration in patient care or assignment for research purposes.	YES
	A diagnostic procedure added to a standard treatment for the purpose of research.	YES
	An established and accepted diagnostic, therapeutic procedure or instructional method, performed only for the benefit of a patient but not for the purposes of research.	NO
Novel Procedures, Treatment, or Instructional Methods	A systematic investigation of innovations in diagnostic, therapeutic procedure or instructional method in multiple participants in order to compare to standard procedure. The investigation is designed to test a hypothesis, permit conclusions to be drawn, thus to develop or contribute to generalizable knowledge.	YES
	The use of innovative interventions that are designed solely to enhance the well being of an individual patient and have a reasonable expectation of success. The intent of the medical or behavioral science practitioner is to provide diagnosis, preventive treatment, or therapy to the particular individual.	NO
Pilot Study	Preliminary activities typically designed to help the Investigator refine data collection procedures. This data is to be included in the publication.	YES

TYPE	DESCRIPTION	IRB REVIEW REQUIRED
Repositories (e.g., storage of data and/or biospecimens for future research)	A storage site or mechanism by which identifiable human tissue, blood, genetic material or data are stored or archived for research by multiple Investigators or multiple research projects.	YES
	Storage of human tissue, blood, genetic material or data that has been de-identified by UCI/UCIMC personnel at the time of collection.	YES May qualify as "non-human subject research."
UCI functioning as the Coordinating Center for a Multi-center Research Project	UCI is *NOT* an enrolling site and the UCI LR has agreed to serve as the coordinating center for a multi-center trial, which may include activities such as data collection, data analysis, reporting of an unanticipated problem involving risk to participants or others to regulatory authorities, and/or oversight of the research at participating sites.	YES LR should be aware of additional responsibilities
	UCI *IS* an enrolling site and the UCI LR has agreed to serve as the coordinating center for the multi-center trial, which may include activities such as data collection, data analysis, reporting of an unanticipated problem involving risk to participants or others to regulatory authorities, and/or oversight of the research at participating sites.	YES LR should be aware of additional responsibilities
Emergency Use of an Investigational Drug or Device	UCI Policies do not permit research activities involving an Investigational Drug or Device to be started, even in an emergency, ***without prior IRB notification***. 1. This does not limit the physician's ability to deliver emergency care. The physician may deliver such care, but the data derived from such care may not be used in any prospectively conceived research. 2. Emergency care involving investigational drugs, devices or biologics must meet the Food and Drug Administration (FDA) requirements and data from such use may not be used in any manner of research.	*IRB NOTIFICATION REQUIRED PRIOR TO USE*
	Sponsor requires IRB approval to release drug/device in emergency use situation.	YES
Educational Activities/Field Study Courses/Research Methods Classes	Activities designed for educational purposes only. The data will not contribute to generalizable knowledge or will not result in a master's thesis, doctoral dissertation, poster session, abstraction or result in any other publication or presentation.	NO

TYPE	DESCRIPTION	IRB REVIEW REQUIRED
Case Studies	A single subject study with clear intent, before recruiting or interacting with the participant, to use data that would not ordinarily be collected in the course of daily life. The intent is to report and publish the case study.	YES
	Retrospective review of no more than three (3) patients' medical records with intent to document a specific situation or the experience of the individuals individual without intent to form a research hypothesis, draw conclusions or generalize findings. Data published will be de-identified (i.e., none of the 18 PHI identifiers).	NO
	Retrospective review of more than three (3) patient's medical record(s).	YES
	Retrospective review of a patient's medical records for use in an educational setting. The data will be de-identified.	NO
Ethnographic Research	The Investigator or his/her staff will participate, overtly or covertly, in people's daily lives for an extended period of time. They will be watching what happens, listening to what is said, asking questions and collecting data to create a broader understanding of a particular environment, ethnic group, gender, etc.	YES
Internet Research	Use of internet websites (e.g., Amazon Turk, Twitter, Facebook, chat rooms) are used to conduct research regarding a particular topic. This may include the completion of questionnaires/surveys, cognitive tasks, or the collection of personal data, etc.	YES
Oral Histories	Oral history activities, such as open ended interviews, that ONLY document a specific historical event or the experiences of individuals without intent to draw conclusions or generalize findings.	NO
	Systematic investigations involving open-ended interviews that are designed to develop or contribute to generalizable knowledge (e.g., designed to draw conclusions, inform policy, or generalize findings)	YES
	Oral historians and qualitative investigators may want to create archives for the purpose of providing a resource for others to do research. The intent of the archive is to create a repository of information for other investigators to conduct human research.	YES

TYPE	DESCRIPTION	IRB REVIEW REQUIRED
Quality Assurance and Quality Improvement Activities	Evaluations of a specific project, process, or resource utilization review, etc. where the primary intent (design) of the activity is solely for internal assessment or improvement.	NO
	Activities conducted for the purpose of (a) implementing a practice to improve the quality of patient care, and (b) collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes	NO
Pilot Activities	Activities including those involving only one individual may be subject to the same scrutiny as a full scale research project. Although the data derived from a pilot activity may not be included in the full scale research project, the activity would still need IRB review prior to conducting the activity.	YES