ABOUT IACUC

In addition to protecting human research subjects, the Office of Research is also responsible for overseeing the humane and ethical use of live animals in research and teaching. UCI has three full-time, board-certified veterinarians and a small army of dedicated staff to manage nearly 50,000 square feet of state-of-the-art animal housing space populated on any given day by 50,000 rodents, aquatic animals, and other species. The Institutional Animal Care and Use Committee (IACUC) oversees the program to ensure the welfare of every animal. Our program has an approved Assurance of Compliance from the Office of Laboratory Animal Welfare at NIH and enjoys full accreditation from the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC, International).

IACUC RESEARCH MANAGEMENT SYSTEM (RMS)

The IACUC has exciting news! After considerable review and assessment of our data-management needs, we’ve purchased a comprehensive software system to efficiently organize all aspects of animal research management, including submission and maintenance of protocols, animal ordering, census control and documentation. The system is web-based, so users can easily access the system from anywhere to create, sign and submit protocols; review approved documents; and even submit animal orders. A team consisting of IACUC and ULAR staff and dedicated support from the Office of Information Technology is finishing up the final configurations and interfaces with existing databases (personnel, KFS, etc.). We will send additional announcements as soon as the RMS becomes available for new submissions.

HUMAN STEM CELL RESEARCH OVERSIGHT

The Human Stem Cell Research Oversight (hSCRO) Committee launched new documentation for submission. The Protocol Narrative has been streamlined and given a new look, and a new form has been developed to simplify the tracking and documentation of cell lines used in the lab. Researchers will be asked to maintain the new Cell Tracking Table Appendix for submission with each transaction. The new documents can be found on the Applications and Forms page.

The hSCRO Committee has also revised their Policy Statement. The revisions clarify the types of materials that fall under the purview of the hSCRO Committee, and outline the types of activities allowed at UCI. The new policy statement can be found on our website.

New decision making tools have been developed to assist in determining when a submission is required, and if proposed materials are acceptable for use. The new tools can be found on our website:

- Submission Decision Tree
- Acceptable Materials Checklist
NEW **UNANTICIPATED PROBLEMS ONLINE FORM**

To streamline and ease the reporting of Unanticipated Problems that meet the three regulatory criteria a new web-based report has been launched.

The HRP Unanticipated Problems web page also includes new guidance for reporting adverse events related to devices (UADE), Humanitarian Use Device (HUD), and data breaches.

Incidents of Noncompliance are now reported using the [New Information Report form](#). Noncompliance is failing to comply with Federal regulations, IRB Policy, or the determinations or requirements of an IRB. Examples of noncompliance include (but not limited to) carry out research procedures without IRB approval, conducting research during a lapse in IRB approval, and not obtaining informed consent in the manner required by an IRB. For anticipated and/or intentional and known protocol deviations affecting three or fewer subjects, researchers should complete the new [Prospective Deviation Request Form](#) to secure prior IRB approval. Additionally, an [Internal Unrelated Mortality Log form](#) is now available, and can be completed and included with your [Continuing Protocol Application](#).

**NIH HAS CHANGED ITS POLICY REGARDING RECOMBINANT DNA ADVISORY COMMITTEE’S (RAC) REVIEW OF INDIVIDUAL HUMAN GENE TRANSFER TRIALS**

Effective April 27, 2016, the UCI Institutional Biosafety Committee will determine whether investigator-initiated research requires RAC review based on specific criteria. Please review the [RAC Revision Factsheet](#), includes a list of the criteria and a summary of the changes. For more information, please review the [IBC](#) and [IRB](#) related web pages for more information.

**GENETIC INFORMATION NON-DISCRIMINATION ACT**

The [biomedical consent](#) form has been updated to include the [California](#) requirement, which states that employers with five or more employees may not use a participant’s genetic information obtained from research when making a decision to hire, promote, etc., an individual when setting the terms of an individual’s terms of employment. Please update the GINA language in your consent form at the time of continuing review or when submitting a modification request.

**NATIONAL INSTITUTES OF HEALTH (NIH) CERTIFICATES OF CONFIDENTIALITY**

The [Consolidated Appropriations Act of 2016](#) (page 367) mandates that NIH require investigators to obtain a Certificate of Confidentiality (CoC) for “new and competing research projects designed to generate and analyze large volumes of data derived from human research participants”. The certificates are currently encouraged by the agency in some instances, such as when submitting large-scale human genomic datasets to NIH-designated repositories. In addition, the IRB routinely requires that researchers secure a CoC from NIH when subject identifiable information is collected and maintained with sensitive research data.
CITI TRAINING
New optional courses and modules are now available! Researchers and research personnel have the option of completing the following courses: Clinical Research Coordinator (CRC), Non-US Centric Modules for the International Research Community (includes 4 courses), Recognizing and Reporting Unanticipated Problems involving Risks to Subjects or others in biomedical research, Unanticipated Problems and Reporting Requirements in Social and Behavioral Research, Consent in the 21st Century, Consent Tools Used by Researchers, GCP FDA Refresher, and GCP Device Refresher.

RAFFLES, DRAWINGS, AND LOTTERIES
The HRP webpage now includes guidance on the use of lotteries in research. In the context of research, the IRB will determine whether lotteries, raffles, and/or drawings may be used to recruit or retain participants. The use of Lotteries in research may be appropriate when: 1) the study involves minimal risk, 2) the prize is less than $600 and will not unduly coerce participation in the research, 3) the protocol narrative and consent form must describe a fair method of choosing a winner, indicate that participation in the research is not required to participate in the lottery regardless and the approximate (i.e., 1 in 1,000) chance of winning.

ETHNOGRAPHY
Ethnography involves the researcher’s study of human behavior in the natural settings in which people live. Ethnographic research is subject to the Common Rule because it involves "a systematic investigation...designed to develop or contribute to generalizable knowledge." Although ethnographic research takes place in natural settings and differs significantly from clinical research, ethnographic research requires prior IRB review and approval to ensure that the research meets the criteria for IRB approval regarding the informed consent process, risk minimization and disclosure, participant selection, and when vulnerable populations are the subject of the research that additional protections are considered.

CLOUD FILE STORAGE OPTIONS
When storing or sharing university information, it is recommended to use a service for which a contract has been established. UCI-contracted services provide tools which facilitate sharing within the University community, and give the University a variety of guarantees and protections—options include:
- Google Drive, a part of UCI Google Apps
- Microsoft OneDrive, a part of Office 365
Consult with your departmental IT support, as local situations vary.
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