USE THE UCI IRB APPROVED (STAMPED) CONSENT FORM

The UCI IRB approved (stamped) version of the consent form must be used when obtaining informed consent from subjects enrolling in a research study at UCI (unless the UCI IRB has granted a waiver or alteration of informed consent).

To ensure that your research team is using the most current version of the IRB approved consent form, always download your approved consent documents from the e-Doc Depot, upon receiving email notification that the submission (i.e., continuing protocol application, modification or new study application) has been approved by the IRB. Also be sure to download the most recent UCI IRB approval letter. The requirements for UCI IRB approval (among institutional requirements) are noted on the letter. Further, when obtaining consent, remember to double check the dates of approval stamped on the consent—ensure that the date of consent is within the IRB approval period.

For more information about the requirements for informed consent at UCI, please refer to the Human Research Protections Policies and Procedures.

THE HONEST BROKER PROCESS

**What is an Honest Broker (HB)?** It is a neutral person or system between the individual whose data and biospecimens are being used for research, and the investigator. An HB must be approved by the IRB and the Privacy Officer and cannot be engaged in the research.

**What is the role of an HB?** The HB collects and collates information from a repository or registry relevant to the research and removes all individual identifiers. The dataset is then released to the researcher for analysis. The information provided to the investigator by the HB may incorporate linkage codes that permits data collation and/or subsequent inquiries. The HB retains the linkage codes. Any subsequent inquiries on the dataset can be conducted through the HB. The UCI Clinical Informatics team serves as the HB for clinical data contained in Clinical Data Warehouse at UCI.

UCI’s Institute for Clinical & Translational Science has announced a call for Biomedical Informatics Pilot Projects. Two, one-year grants in the amount of $20,000 each will be awarded. For more information about the RFP, or for more information about the HB process, including what type of IRB approval is required based on the type of data being requested from the HB, see the ICTS website at [http://www.icts.uci.edu/awards/CBMI2012info.cfm](http://www.icts.uci.edu/awards/CBMI2012info.cfm).
UCI’s Federalwide Assurance (FWA# 00004071)* provides some flexibility in applying the federal regulations regarding the protection of human subjects to non-federally supported research.

UCI Human Research Protection Program is currently pilot testing an Extended IRB Approval process whereby IRB approval can be granted for up to 3 years.

**STUDIES ELIGIBLE FOR THE EXTENDED IRB APPROVAL MUST MEET THE FOLLOWING CRITERIA:**

- Research that involves no more than minimal risk to participants (as defined by 45 CFR 46.102);
- Research that is not subject to federal oversight; and
- Research not subject to Conflict of Interest Oversight Committee management.

**STUDIES NOT ELIGIBLE FOR THE EXTENDED IRB APPROVAL:**

- **Research Subject to Federal Oversight:** Projects that receive federal support, projects implemented at the direction of federal agencies, or otherwise subject to federal oversight are excluded from this policy.
- **Studies that involve greater than minimal risk**
- Studies with **contractual obligations or restrictions that preclude eligibility** in this policy (e.g., the nonfederal sponsor or funder of the research requires an annual review).
- Studies involving **direct intervention or intervention with prisoners or parolees** as subjects
- Studies **funded by the California Institute for Regenerative Medicine** (CIRM)

The UCI IRB reserves the right to make exceptions to this policy, and inclusion/exclusion of any research project under this procedure will be at the IRB’s discretion. For continuing applications, researchers may be asked to “refresh” their IRB documents to comply with current standards (i.e. similar to the de-novo process) prior to granting 3 year approval.

If the UCI IRB determines that the study is eligible for the Extended IRB Approval, the determination will be listed on the IRB approval letter. Studies that are granted extended approval period will continue to have the same post-approval submission requirements.

**If the study becomes ineligible for an extended approval period because of new federal funding or other changes, the lead researcher is responsible for notifying the IRB of this change via a modification or an application for continuing review.** The study will be reviewed and reset for an annual (no more than 365 days) approval cycle. Should a study be confirmed as ineligible and an application for continuing review not submitted to the IRB, the study will be closed within 30 days of notification of ineligibility. For more information about the Extended IRB Approval process go to: [http://www.research.uci.edu/ora/hrpp/extendedirbapproval.htm](http://www.research.uci.edu/ora/hrpp/extendedirbapproval.htm)

Any questions on this process? Contact HRP Staff.

*The Federal Policy (Common Rule) for the protection of human subjects requires that each institution "engaged" in Federally-supported human subject research file an Assurance with the Office of Human Research Protections. The Assurance formalizes the institution's commitment to protect human subjects.*
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## Education & Reminders:  
**CRFA**

**CLINICAL RESEARCH FINANCE ADMINISTRATION (CRFA)**

CRFA reviews all greater than minimal risk human research studies and is responsible for proper registration and billing practices for all human subjects receiving clinical care while enrolled on a clinical research study.

- **Securing CRFA approval is required before clinical research procedures can be initiated.**
- **If CRFA requires changes to the informed consent document, a modification request must be submitted for IRB approval before any study procedures can be initiated.**
- **This is the Lead Researcher’s responsibility.**

For a summary on CRFA visit:  

For detailed information about the CRFA review process, visit the CRFA [website](http://www.research.uci.edu/ora/hrpp/clinicalresearchfinance.htm). **Note:** this website is located on the UCIMC Intranet. If you do not have HSIS intranet access, or have questions on how to submit for CRFA review, Nurse Paula Hilbert, the Clinical Research Cost Analyst can be reached at philbert@uci.edu.