

HRPP Contacts

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Did you know?

Researchers are required to submit the "Human Subjects" section of their grant proposal along with their IRB Application when the research is DHHS-funded.

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UNIVERSITY of CALIFORNIA • IRVINE

Human Research Protections Program

News Brief

AAHRPP Site Visit Announced

The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) **site visit** is scheduled for April 21-23, 2008. All individuals involved with Human Subjects Research are potential interviewees during the AAHRPP site visit. Five AAHRPP site reviewers will conduct individual interviews with UCI administrators, faculty, staff, and students.

The site visit is a major component in AAHRPP's accreditation decision. It provides site reviewers with a candid and critical look at UCI's Human Research Protection Program. The interviews are used to assess knowledge and commitment to human subjects protection, and are conducted in a professional and serious manner.

In preparation for the site visit and the interviews, the UCI HRPP will host **two education sessions** to provide information, answer questions, and prepare. We will also prepare interview guides to aid interviewees in the preparation for the site visit. Everyone's cooperation and preparation are needed during and prior to the site visit.

Privacy and Confidentiality

What do Privacy and Confidentiality have to do with research?

Per DHHS and FDA regulations, in order to approve human subjects research, the IRB must determine, when appropriate, that there are adequate provisions to protect the privacy of subjects and to maintain confidentiality of data. Privacy and confidentiality are also supported by two principles of the **Belmont Report**:

- **Respect for persons** – Individuals should be treated as autonomous agents able to exercise their autonomy to the fullest extent possible, including the right to privacy and the right to have private information remain confidential.
- **Beneficence** – Maximize benefit and minimize harm. Maintaining privacy and confidentiality helps to protect participants from potential harms including psychological harm such as embarrassment or distress; social harms such as loss of employment or damage to one's financial standing; and criminal or civil liability.

What is the difference between Privacy and Confidentiality?

Privacy is...

- About **people**
- A **sense of being in control of access that others have to ourselves**
- A **right** to be protected
- **In the eye of the participant**, not the researcher or the IRB

Confidentiality is...

- About **identifiable data**
- An **extension of privacy**
- An **agreement about maintenance and who has access to private identifiable data**
- In regards to HIPAA, **protection of patients from inappropriate disclosures of Protected Health Information (PHI)**

What should researchers know?

- The IRB must decide on a protocol-by-protocol basis whether there are **adequate provisions** to protect the privacy of subjects and to maintain the confidentiality of the identifiable data **at each segment of the research...** recruitment to maintenance of the data.
- The committee must **consider the sensitivity of the information collected** and the **protections offered the subjects**.
- During the informed consent process, **subjects must be informed of the precautions that will be taken to protect the confidentiality of the data and be informed of the parties who will or may have access** (e.g., research team, FDA, OHRP). This will allow subjects to decide about the adequacy of the protections and the acceptability of the possible release of private information to the interested parties.
- Especially in social/behavioral research the primary risk to subjects is often an **invasion of privacy** or a **breach of confidentiality**.

Data Security and Human Subjects Research

In order to ensure that risks related to a potential breach of confidentiality are minimized, all human subjects research protocols must have acceptable, effective, and documented procedures for the protection of identifiable and/or confidential information collected or examined for research purposes.

What does this mean to Researchers at UCI?

Researchers should make every effort to reduce the likelihood of a potential breach in confidentiality; especially when a breach of research data could reasonably place subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation.

- **Section 12 of the IRB Protocol Narrative** - Researchers must address the method of collecting, recording, coding and maintaining data, as well as specify who will have access to the data and at what point subject identifiable data will be de-identified or destroyed.
- **Informed consent document** - Researchers must describe the extent, if any, to which confidentiality of records identifying the subject will be maintained.

How to Secure Research Data

1. Collect only the necessary subject identifiers.
2. Remove/destroy subject identifiers as soon as they are no longer needed. See UCI HRPP [Recordkeeping Responsibilities](#) for guidance on research record retention.
3. Limit physical access to any area or computer that contains subject identifiers.
4. Limit electronic access to any computer that contains subject identifiers.
5. Avoid storing data on portable devices which are particularly susceptible to loss or theft (such as laptop computers, PDAs, USB memory sticks, iPods or similar devices). If there is a necessity to use portable devices for initial collection of subject identifiers, the data files should be encrypted, and subject identifiers transferred to a secure system as soon as possible.
6. Remove necessary subject identifiers from data files, and encrypt data files if stored electronically. Identifiers should be stored in a physically separate and secure location from the data files, and associated with the data files through a key code that is also stored in a separate and secure location.
7. If subject identifiers will be retained in the data files because of the specific needs of the research study, additional justification must be provided by the Researcher to justify retention. Again, if the data are stored electronically the files should be encrypted.
8. Use only secure modes of transmission of data; subject identifiers submitted over a public network should be encrypted.

See UCI [Network and Academic Computing Services](#) for additional recommendations on how to best secure confidential data.

Unanticipated Problem Involving Risk to Subjects or Others

Any inadvertent breach of confidentiality of the research data which causes harm or places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) must be reported to UCI IRB through the electronic [Adverse Event/Unanticipated Problems reporting](#) process within 10 working days of the researcher becoming aware of the event.

IRB Protocol Submission Deadlines for March Meetings:

- IRB B: February 27
- IRB C: March 5
- IRB A: March 12

UCI IRB Statistics for 2007

Did you know that the UCI Human Research Protections Program (HRPP) had over 2000 active IRB research protocols during the 2007 calendar year? This represents a 1.5% increase over 2006 and a 5% increase over 2005.

Transactions Submitted

Moreover, **UCI Researchers submitted over 3700 transactions** to the IRB for review and approval. **Transactions** include new IRB Applications (830), Continuing Review Applications (850), Modifications/Amendments (1175), and Adverse Events and Unanticipated Problems Involving Risk to Participants or Others reports (850). The biomedical IRBs received 1315 (IRB A) and 1380 (IRB B) transactions respectively, while IRB C (social/behavioral) received over 1000.

Turnaround Time

For the biomedical IRBs the average **turnaround time (TAT)** from submission to approval for transactions requiring full board review was 30 days. For expedited or exempt transactions, the average TAT from submission to approval was 19 days. For the social/behavioral IRB the average TAT from submission to approval for transactions requiring full board review and for expedited and exempt transactions was 17 days.

In 2008 UCI's IRBs and the HRPP staff will continue to facilitate, strengthen, and advance the research goals of UCI.

Active IRB Protocols 2007

Full Board	450
Expedited	1020
Exempt	590
	2060