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Important Points to Remember When Conducting Human Subjects Research (HSR)

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Important Points to Remember When Conducting HSR

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- ◆ It is mandatory to **secure IRB approval *prior* to the initiation of research** involving human subjects; even if the research procedures involve secondary analysis of existing identifiable private information.
- ◆ If you are **engaged in HSR**, you **must be listed on the Protocol Narrative** as a study team member. Individuals are "engaged" in HSR if they will:



Data and Biospecimen Repositories

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- ◇ intervene with subjects by performing research procedures, or by manipulating the environment for research purposes;
- ◇ participate in the recruitment and/or selection of subjects;
- ◇ participate in the informed consent process;
- ◇ access or collect identifiable private information; or
- ◇ analyze or report subject identifiable study data.



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- ◆ **Respect confidentiality.** Confidentiality is an agreement about maintenance and access to subject identifiable research data. In regards to HIPAA, confidentiality protects patients from inappropriate disclosures of "Protected Health Information" (PHI).

It is important to maintain confidentiality of subject identifiable research data especially if any disclosure of the data outside the research context could reasonably place the subjects at risk or be damaging to their financial standing, employability, or reputation.

UCI AAHRPP Reaccreditation

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- ◆ Remember to comply with all IRB determinations regarding **informed consent**. These determinations are put in place to ensure that subjects are provided with the information necessary to make an informed decision about whether to participate in the study. Informed consent is related to the Belmont Report ethical principle, Respect for Persons.



HRP Staff Contact Information AND Education & Reminders

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- ◆ **Do you have questions about the IRB process or about human subjects protections?** The HRP Staff and the EQUIP team can help answer your questions. The role of the HRP Education and Quality Improvement Program (EQUIP) is to ensure human subjects protections by providing education and outreach to investigators, as well as conducting periodic quality improvement reviews of research protocols, and for cause audits, as necessary. See Page 4 of this News Brief for HRP Staff contact information.

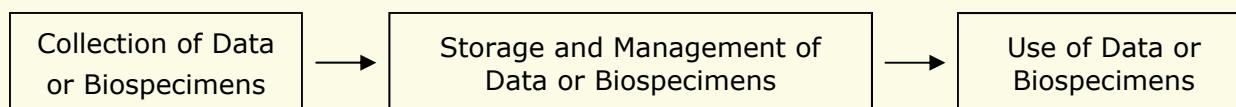
Data and Biospecimen Repositories



Data and biospecimen repositories (sometimes called registries or banks) involve the collection, storage and later distribution of information and/or biospecimens for some future purpose. Federal regulations and UCI policies that protect the privacy of research subjects apply to both the creation and the use of research repositories.

The establishment of a research repository gives the investigator the authority and responsibility for distributing data and/or biospecimens from the repository, and defines future uses of the data and/or biospecimens in a manner that protects subjects' rights yet supports scientific inquiry.

Repository activities involve three components:



Some repositories are created and maintained explicitly for research purposes. Others are created and maintained for non-research purposes, but may be accessed for research uses. **Any repository holding identifiable or coded data/biospecimens that will be used for research purposes must have IRB approval.**

Key issues the IRB will consider in repository protocols include:

- ◆ The conditions under which data and biospecimens may be accepted into the repository,
- ◆ How the data/biospecimens will be stored, and
- ◆ The procedures under which they will be shared in order to ensure that adequate measures are employed to protect the privacy of subjects, maintain the confidentiality of the data and the integrity of biospecimens.



When do I need an IRB approval for my repository?

- ◆ The collection and storage of data/biospecimens becomes a research repository when there is a specific intention for the data/biospecimens to be used repeatedly for research purposes, or stored for future research or shared with other investigators.
- ◆ Data/biospecimens collected and stored as part of routine clinical care or hospital procedures, for example, blood banks, pathology, surveillance, or quality assurance purposes **do not** require IRB approval. However, IRB approval **is** required when data/biospecimens from these sources are then stored for future research.
- ◆ The prospective collection and storage of data/biospecimens for defined research purposes (including holding samples to "batch" them for assays), as part of a single IRB-approved protocol **is not** considered a repository. If there is no explicit plan to destroy the data/biospecimens when the specific original research project ends, the investigator may maintain the data/specimens under continued IRB approval for uses as approved in the original protocol.

Once an investigator wants to use the data/biospecimens beyond the primary research goals of the original protocol, the Lead Researcher must establish an IRB-approved protocol for storage and maintenance of the data/biospecimens for any future research use or submit the data/biospecimens into an existing IRB-approved repository.

- ◆ Research repositories require informed consent and HIPAA Research Authorization by the subjects for the storage and future research use of their data/biospecimens OR a waiver of informed consent and a waiver of HIPAA Research Authorization must be approved by the IRB.
- ◆ Requests by investigators to access subject identifiable data/biospecimens from a repository require IRB approval.

For more information on repository research, see the following website:

<http://www.hhs.gov/ohrp/policy/reposit.html>

SUBMITTING E-CPAs—Timing to Avoid Expiration of Approval

As a courtesy, Human Research Protections (HRP) sends the Lead Researcher and Administrative Contact(s) an e-mail reminder to submit for continuing approval. The e-mail reminder is sent 90 days prior to the expiration date for full committee studies and 60 days prior to expiration for expedited studies.



- ◆ Investigators should submit their e-CPA and the required hard copy documentation to the Office of Research at least **60 - 90 days prior to expiration** for full Committee studies.
- ◆ For expedited studies, an e-CPA should be submitted **30 days prior to expiration**.

UC Irvine Pursues Reaccreditation from AAHRPP

WHAT: Step 1 Submitted!

UC Irvine's HRPP received initial accreditation from the Association for Accreditation of Human Research Protection Programs, Inc. (AAHRPP) in September 2005. **UC Irvine was the first university in California and the first UC campus to receive AAHRPP accreditation.** Organizations must renew their accreditation every 5 years by performing a self assessment and analysis of their HRPP. In addition, AAHRPP accredited institutions are now required to meet additional regulatory requirements of other Department of Health and Human Services (DHHS) entities regarding human subject research (e.g. Department of Defense, Department of Energy and Department of Justice).

UC Irvine's HRPP submitted "Step 1" of the application for reaccreditation in December 2010. Step 1 involves a comprehensive self-assessment of the Institutions HRPP and evaluates compliance with the current AAHRPP standards and elements. AAHRPP staff reviews our application and documentation. They determine whether UCI's submission meets the accreditation standards. If changes are needed, revisions are incorporated and the revised documents are submitted to AAHRPP as part of "Step 2" of the application process. Following final acceptance of UCI's documentation, the site visit is scheduled.

WHY: AAHRPP Accreditation has Value

AAHRPP accreditation enhances UC Irvine's reputation, the quality of our research and gives us a competitive edge with sponsors. The Office for Human Research Protections (OHRP) and the FDA recognize the value of accreditation. Moreover, through the self-assessment process, the UC Irvine HRPP continues to develop effective and efficient processes. Written policies and procedures are revised and developed as necessary to reduce the need for the IRB to make decisions on a case-by-case basis, and to provide guidance to investigators about human research protections issues and the IRB review process.

WHEN: AAHRPP Site Visit

We anticipate that AAHRPP Site Visitors will be visiting the campus in late May / early June 2011. During their visit, **interviews will be scheduled with investigators, research personnel**, University officials, IRB members and staff selected by AAHRPP. Specific information about the site visit will be shared with the research community as they become available. Also, the Office of Research will conduct **education and outreach** efforts to assure investigators, research coordinators, IRB members and staff understand their roles and responsibilities in UC Irvine's HRPP. **Stay tuned for more details!**

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Education & Reminders:

DOES YOUR IRB-APPROVED STUDY REQUIRE HIPAA RESEARCH AUTHORIZATION?

HIPAA Research Authorization: As you already may know, HIPAA is the acronym for the Health Insurance Portability and Accountability Act of 1996. The intention of HIPAA is to protect patients from inappropriate disclosures of "Protected Health Information" (PHI) that can cause harm to a person's insurability, employability, etc.

HIPAA affects only that research which accesses, uses, creates, or discloses PHI. Researchers have legitimate needs to use, access, and disclose PHI to carry out a wide range of health research studies. The IRB acts as a Privacy Board to review the use/disclosure of PHI and to determine whether the subjects should sign a HIPAA Research Authorization Form or if a Waiver of Authorization may be granted.

When the IRB determines that subjects should sign a HIPAA Research Authorization form in order to access, use, create or disclose PHI for research, subjects are to sign the UC HIPAA Research Authorization form as a part of the informed consent process.

For new studies approved by the IRB after August 2009, a completed HIPAA Research Authorization form is required at initial submission to the IRB. Once the study is approved by the IRB, the HIPAA Authorization form can be accessed in the "IRB docs depot".

For older studies, go to "ORA Applications and Forms" and then "IRB Forms" to access the HIPAA Research Authorization Form: http://www.research.uci.edu/ora/forms/hrpp/hipaa_authorization.doc

Remember: the HIPAA Research Authorization form is not the same as the HIPAA Medical form that patients sign when receiving medical care.