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AAHRPP Site Visit a Success!

The week of June 13-15, UCI’s Human Research Protection Program (HRPP) went through a reaccreditation site visit with the Association for the Accreditation of Human Research Protection Programs (AAHRPP). Our site visit was a success!

The AAHRPP site visitors noted three strengths of our HRPP:

1. Our UCI Investigators and research staff for their understanding and commitment to human subjects protections,
2. UCI’s Human Research Protections (HRP) Staff for their dedication to the facilitation of human research at UCI,
3. The collaboration between HRP and other research units in the Office of Research, specifically Sponsored Projects Administration. Individuals in these units are dedicated to working together to assist in facilitating human research at UCI

We do have two procedural changes to make, one related to the IRB member evaluations, and the other related to Radiation Safety Review. More information will be provided soon.

In addition, we need to enhance the research community’s understanding on the concepts of privacy and confidentiality. Look in this issue for more information about privacy vs. confidentiality.

Our application will be given a final review by AAHRPP in September 2011. We anticipate receiving reaccreditation, which will be valid for 5 years.

Privacy vs. Confidentiality: Main Differences

In the context of human subject research, it is important to understand the differences between privacy and confidentiality and how researchers should address these concerns as part of their research activity. So, what is the difference anyway?

Privacy vs. Confidentiality

- **Privacy Applies to the Person**
  - The way potential participants are identified and contacted
  - The setting that potential participants will interact with the researcher team and who is present during research procedures
  - The methods used to collect information about participants
  - The type of information being collected
  - Access to the minimum amount of information necessary to conduct the research

- **Confidentiality Applies to the Data**
  - An extension of privacy
  - Pertains to identifiable data
  - An agreement about maintenance and who has access to identifiable data
  - What procedures will be put in place to ensure that only authorized individuals will have access to the information, and
  - Limitations (if any) to these confidentiality procedures
  - In regards to HIPAA, protection of patients from inappropriate disclosures of Protected Health Information (PHI)
**PRIVACY:** Privacy refers to an individual’s desire to control who has access to him/herself. Privacy is seen through the eye of the participant, not the researcher or the IRB. The federal regulations define ‘private information’ as “information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical or education record).” In regards to privacy, the following issues should be considered and addressed in the Protocol Narrative as needed.

**Section 3 of the Protocol Narrative (Procedures):**

In developing strategies for the protection of participants’ privacy, consideration should be given to:

- If passively observing the subject; could the individual have an expectation of privacy (e.g., chat room for breast cancer patients)?
- Will the researcher collect information about a third party individual that is consider private (e.g., mental illness, substance abuse in family)? If yes, consider if informed consent should be obtained from the third party.
- How to access the minimum amount of information necessary to conduct the study.
- The appropriateness of all personnel present for research activities.
- The methods used to obtain information about participants.
- The nature of the requested information.
- Information that is obtained about individuals other than the “target participants,” and whether such individuals meet the regulatory definition of “human participant” (e.g., a subject provides information about a family member for a survey).
- Privacy guidelines developed by relevant professional associations and scholarly disciplines (e.g., oral history, anthropology, psychology).

**Section 5B of the Protocol Narrative (Recruitment):**

Researchers should think about the following:

- The methods used to identify and contact potential participants.
- The settings in which an individual will be interacting with an investigator. For example, persons may not want to be seen entering a place that might stigmatize them, such as a pregnancy counseling center that is clearly identified as such by signs on the front of the building.
- Will subjects feel comfortable providing the information in this manner?
- The proposed subject population?
- What are the cultural norms of the proposed subject population? Some cultures are more private than others.
- What are the ages of the proposed subject population? There may be age differences in privacy preferences (e.g., teenagers less forthcoming than older adults)
- Sensitivity of the information being collected – the greater the sensitivity, the greater the need for privacy
Understanding How to Address Confidentiality

**CONFIDENTIALITY:** Confidentiality refers to maintenance of the researcher’s agreement with the participant about how the participant’s identifiable private information will be handled, managed, and disseminated. While the term ‘Confidentiality’ is not formally defined in the federal regulations, the regulations make it clear that investigators have an obligation to inform research participants:

- how their data will be used,
- who will have access to it,
- what procedures will be put in place to ensure that only authorized individuals will have access to the information, and
- the limitations (if any) to these confidentiality procedures

**Section 12 of the Protocol Narrative (Measures of Confidentiality):**

Section 12 of the Protocol Narrative is the section that addresses confidentiality of research data. In this section, researchers describe the methods to be used for collecting, recording, coding and maintaining data, as well as specify who will have access to the data and at what point the subject identifiable data will be de-identified or destroyed.

Are there adequate provisions to maintain the confidentiality of data?

Researchers should give consideration to:

- Information obtained preparatory to research. For example, information collected from personal records to determine potential participants. Destroy information obtained about individuals who were not recruited or who refused research participation.
- Methods to shield participants' identity to adequately protect participant privacy (e.g., encryption of data file, Certificate of Confidentiality).
- Whether there is a long-range plan for protecting the confidentiality of research data, including a schedule for destruction of identifiers associated with the data.
- Whether the consent form and other information presented to potential participants adequately and clearly describe confidentiality risks.
- Whether the informed consent process and the informed consent document, and if applicable the HIPAA Research Authorization Form, clearly delineate who will have access to the subject’s information and under what circumstances data may be shared (i.e., regulatory agencies, sponsors).

**Additional Resources Regarding Privacy & Confidentiality:**


### Institutional Review Board “A”
**Biomedical**

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<tr>
<th>Name</th>
<th>Title</th>
<th>Phone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Matt Kinder, CIP</td>
<td>Administrator</td>
<td>949-824-9819</td>
<td><a href="mailto:mkinder@uci.edu">mkinder@uci.edu</a></td>
</tr>
<tr>
<td>Mihaela Nistor</td>
<td>Senior Analyst</td>
<td>949-824-3711</td>
<td></td>
</tr>
<tr>
<td>Joy Chu</td>
<td>Analyst</td>
<td>949-824-6068</td>
<td></td>
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### Institutional Review Board “B”
**Biomedical**

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<th>Name</th>
<th>Title</th>
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<th>Email</th>
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<tbody>
<tr>
<td>Valerie Sanchez, MA, CCRP</td>
<td>Administrator</td>
<td>949-824-7109</td>
<td><a href="mailto:valerie.ms@uci.edu">valerie.ms@uci.edu</a></td>
</tr>
<tr>
<td>Cheree DuBose, CIP</td>
<td>Senior Analyst</td>
<td>949-824-5622</td>
<td><a href="mailto:cheree.dubose@rgs.uci.edu">cheree.dubose@rgs.uci.edu</a></td>
</tr>
<tr>
<td>Theresa Sanchez, CIP</td>
<td>Analyst</td>
<td>949-824-2125</td>
<td><a href="mailto:tmsanche@uci.edu">tmsanche@uci.edu</a></td>
</tr>
</tbody>
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### Institutional Review Board “C”
**Social - Behavioral**

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<tr>
<th>Name</th>
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<tbody>
<tr>
<td>Christine Hegel Cantarella, PhD</td>
<td>Administrator</td>
<td>949-824-4779</td>
<td></td>
</tr>
<tr>
<td>Alicia Asgari</td>
<td>Senior Analyst</td>
<td>949-824-7114</td>
<td><a href="mailto:alicia.asgari@uci.edu">alicia.asgari@uci.edu</a></td>
</tr>
<tr>
<td>Kaycie Craib</td>
<td>Analyst</td>
<td>949-824-6662</td>
<td><a href="mailto:kcrailb@uci.edu">kcrailb@uci.edu</a></td>
</tr>
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### IRB Team “D”
**Biomedical Expedited and Exempt Submissions**

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<tr>
<th>Name</th>
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<th>Phone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jessica Sheldon, CIP</td>
<td>Administrator</td>
<td>949-824-3831</td>
<td><a href="mailto:jessica.sheldon@uci.edu">jessica.sheldon@uci.edu</a></td>
</tr>
<tr>
<td>OPEN POSITION</td>
<td>Senior Analyst</td>
<td>949-824-5057</td>
<td></td>
</tr>
<tr>
<td>Kin Hang</td>
<td>Analyst</td>
<td>949-824-0665</td>
<td><a href="mailto:kin.hang@uci.edu">kin.hang@uci.edu</a></td>
</tr>
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### Human Research Protections
- **U.S. Mail:**
  - Office of Research
  - University of California, Irvine
  - 5171 California Ave., Suite 150
  - Irvine, CA 92697-7600
- **The Office is Open:**
  - Monday—Friday
  - 8am—5pm
- **General Email:**
  - IRB@research.uci.edu
- **We’re on the Web!**

### Methods of Recruitment

#### Tips to Remember

- **Acceptable Methods of Recruitment:**
  - advertisements, notices, and/or media
  - Send introduction letter to colleagues to distribute to eligible individuals – interested individuals contact researcher
  - Primary care staff contact those patients that qualify to determine interest

- **Unacceptable Methods of Recruitment:**
  - Search through medical records for qualified subjects or existing database (e.g., registry); then have a researcher with no previous contact with potential subject recruit; this method violates the individuals’ privacy
  - Recruit subjects immediately prior to sensitive or invasive procedure (e.g., in pre-op room)
  - Retain sensitive information obtained at screening without the consent of those who either failed to qualify or refused to participate for possible future studies participation