AAHRPP Reaccreditation

On February 24th, the site review team for the Association for the Accreditation of Human Research Protection Programs, Inc (AAHRPP) held a final close-out session to share observations about the University of Kentucky (UK) Human Research Protection Program (HRPP). UK’s response to the formal AAHRPP report will be acted upon at the June meeting of the Council on Accreditation.

Of the five domains which categorize the 77 accreditation standards [i.e., organization, research review unit (including IRBs), investigator, sponsored research, and participant outreach], the site visitors had minimal recommendations on only three standards.

In addition, the team highlighted three areas that will be recommended “with distinction” to the Council on Accreditation. They were also impressed that all of the 100+ individuals on the agenda were present and participated in group interviews as scheduled.

For a copy of the investigator education packet including the current AAHRPP standards, sample interview questions, and material pertinent for research investigators, contact Stephanie Morris at (859) 257-0582 or samo222@email.uky.edu.

Accolades to all who contribute each day to the quality of our HRPP through dedication and commitment to quality research and protection of our research participants.

Navigating the IRB Process

Need help navigating the IRB application process or want to know more about human research protection regulations?

The Office of Research Integrity is available upon request to present to your UK office, class, or research group.

Forward requests or questions to Belinda Smith at belinda.smith@uky.edu or (859) 323-2446.
Be Waiver Wise

Can informed consent be altered or waived?
Only under certain conditions can the IRB waive the requirement for the informed consent process. The IRB may approve a waiver or alteration of informed consent if it finds and documents that the research meets the following conditions:

- a) no more than minimal risk involved,
- b) rights and welfare of subjects not adversely affected,
- c) research COULD NOT be practicably done without the waiver or alteration, and
- d) when possible, subject is provided with additional pertinent information after participation.

For example, if you are conducting research involving deception, or conducting medical record reviews, your research may meet the conditions for waiving informed consent. However, the IRB would need to be confident that the request was justified, the study could not be conducted absent the waiver and the request was not made as a matter of convenience. Absence of objection, sometimes referred to as “passive consent” or “implied consent” is NOT informed consent and if used, requires a waiver with appropriate justification and documentation. See IRB Application “Form E” instructions and “Form E” on the Initial Review Forms Webpage [http://www.research.uky.edu/ori/human/HumanResearchForms.htm].

Can documentation of informed consent be waived?
The IRB may waive the requirement to obtain a signed consent document for some or all subjects if certain conditions are met. Waiver of the requirement for obtaining documentation of informed consent means the subject does not put in writing his/her agreement to participate in the study. Waiver of documentation could apply for a study where the only record linking the subject and the research would be the consent document. If based on the sensitive nature of the research the primary risk of potential harm would be a breach of confidentiality, waiving the documentation of participation could be warranted.

The other common application for this type of waiver is the conduct of research that presents no more than minimal risk to participants and involves NO procedures for which a signed consent form is normally required. The subject is still informed about the study and given the opportunity to decide whether to participate. The consent process may in fact include a document in the form of a standard consent form, survey cover letter, internet survey invitation, or phone script. To ensure the required informed consent elements are included, ORI provides a cover letter template as a guide. What is waived in this case, is the subject’s signature or documentation of their agreement to participate. See IRB Application “Form F” instructions and “Form F” on the Initial Review Forms Webpage [http://www.research.uky.edu/ori/human/HumanResearchForms.htm].

**NOTE:** If HIPAA applies to the protocol, there are additional criteria for waiving HIPAA authorization. See the UK HIPAA in Human Research Website [http://www.research.uky.edu/ori/HIPAA/main%20page.htm].

<table>
<thead>
<tr>
<th>Waiver type (not applicable to most FDA regulated protocols)</th>
<th>Brief Description</th>
<th>IRB Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waiver of the requirement for informed consent 45 CFR 46.116(d)</td>
<td>If the conditions are met, the IRB may waive the requirement for some or all elements of the informed consent process (i.e., high volume medical record review, deception research).</td>
<td>Form E</td>
</tr>
</tbody>
</table>
| Waiver of documentation of informed consent 45 CFR 46.117(c)(1) | Waiver of documentation means the subject does not put in writing his/her agreement to participate in the study. The IRB may waive the requirement for obtaining documentation of informed consent for some or all subjects if:  
- the research presents no more than minimal risk and involves procedures that do not require written consent when performed outside of a research setting, or  
- the principle risks, are those associated with a breach of confidentiality and the consent document is the only record linking the subject with the research. The subject is still informed about the study and is given ample opportunity to decide whether to participate. | Form F |