Human Subjects Research Review Newsletter  
Spring 2011

Research is constantly evolving along with new techniques and guidelines. We would like to use this newsletter as a means to keep the research community aware of these changes.

Additional emails will be provided in a timely manner when they consist of the following issues:

- new federal regulations
- revised policy and procedures
- revised applications

Spring Meeting Schedule

<table>
<thead>
<tr>
<th>Protocol Deadline</th>
<th>Meeting Date</th>
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<tbody>
<tr>
<td>January 25(^{th})</td>
<td>February 8(^{th})</td>
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<td>February 22(^{nd})</td>
<td>March 8(^{th})</td>
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<td>March 29(^{th})</td>
<td>April 12(^{th})</td>
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<td>April 26(^{th})</td>
<td>May 10(^{th})</td>
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<td>May 31(^{st})</td>
<td>June 14(^{th})</td>
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Recruiting 17 year old Binghamton University Students

The HSRRRC reviewed and discussed the issue of recruitment of 17 year old Binghamton University students in research being conducted at Binghamton University. The discussion included parental permission and the recruitment of vulnerable populations (i.e. children 0-17).

The following procedures were reviewed and accepted by the committee:

- PI’s could indicate on their IRB application that only those 18-65 will be used. If one takes this option, one should require ID with age when subjects appear, declining anyone under 18 from participating in the experiment. Should an underage subject be run, the IRB has indicated that the data from that person may not be used.
- Alternatively, PI’s could indicate on the IRB application that in addition to those 18-65, those aged 0-17 years will also be used. Concern about using a vulnerable group will be addressed if the PI explains that the basis for the request is only because some of the student participants (e.g., freshmen) may be 17. The PI would then request from the IRB a waiver on behalf of such students from the requirement that their parent provide consent. Federal regulations allow the IRB to waive parental consent for any age group, regardless of the review type, depending on the circumstances and the minimal or negligible risks to that group.

Office of Human Research Protection (OHRP) New Guidance Regulations

Guidance on IRB Approval with Conditions

OHRP has posted on its website two finalized guidance documents:

"Guidance on IRB Approval of Research with Conditions." The guidance document provides OHRP’s first formal guidance on this topic. The guidance document finalizes the draft guidance that was made available for public comment through a notice in the Federal Register on November 6, 2009 (74 FR 57486). website at http://www.hhs.gov/ohrp/policy/conditionalapproval2010.html
Listed below is a sample of this new guidance:

“G. May an IRB approve some components of a proposed research study and defer taking action on other components at the time of initial review?

Yes, at the time of initial review an IRB may approve some components of a proposed research study and allow an investigator to initiate research activities only related to those approved components, while deferring taking action on other components of the proposed study. In such circumstances, the IRB must ensure that the approved components of the research study are scientifically valid and satisfy all criteria required for IRB approval, even if the other components are never approved and conducted. The IRB may require that the investigator, in order for the investigator to secure approval for the unapproved components of the initially proposed research study, submit to the IRB for review (a) changes to the protocol or informed consent documents, or (b) clarifications or additional documents. http://www.hhs.gov/ohrp/policy/conditionalapproval2010.html#section-g

Guidance on IRB Approval with Conditions
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Protocol Closure Reminder
Upon completion of your research protocol, please submit the protocol closure form. Research is considered closed when all four (4) criteria noted below is met:

1. The research is permanently closed to enrollment
2. All subjects have completed all research-related interventions
3. Collection of private identifiable information is completed
4. Analysis of private identifiable information is completed

The Protocol Closure Form may be found at this link:
http://research.binghamton.edu/compliance/humansubjects/Forms.php

Quality Monitoring Program takes effect Spring 2011
Binghamton University is implementing a Quality Monitoring Program for Human Subjects Research. The objective of the Quality Monitoring Program is to provide Binghamton University Investigators and the Human Subjects Research Review Committee (HSRRC) with: 1) an internal mechanism for quality assurance, quality improvement and education in human subjects research, 2) practical support in the conduct of human subjects research which optimizes compliance with Federal Regulations, State laws, institutional policies, and the provisions of HSRRC approved protocols.

Association for the Accreditation of Human Research Protection Programs, Inc (AAHRPP)
We are in the process of completing AAHRPP re-accreditation. Similar to the initial accreditation you may be selected by AAHRPP for an interview during their Fall 2011 site visit. We will notify you if you have been selected and also provide briefing material for these interviews.

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