UIC IRB Review of Domestic Research Involving Non-UIC Sites, Agencies, Organizations, or Institutions

Version: 3.2
Date: 06/18/2009
Approved by: Interim Vice Chancellor for Research
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POLICY:

I. UIC OPRS and UIC IRBs ensure that the appropriate approvals and/or written agreements are completed when human subjects research involves domestic non-UIC performance sites; and

II. The UIC OPRS, UIC IRBs, and UIC faculty, staff, students, and UIC-authorized affiliates are required to comply with the terms of the UIC FWA regardless of the geographic location of the research or the research being conducted. (This policy and procedure addresses domestic research only. Please refer to UIC HSPP policy International Research for further information).

PROCEDURE:

Review and Oversight of Research Conducted at Multiple Sites.
I. The UIC OPRS staff and IRB will review each research protocol and application, as well as all supporting grants, contracts, and/or subcontracts to determine the status of each non-UIC site for which UIC has chosen to act as the IRB of Record.
   A. The UIC IRB may request additional documentation necessary to ascertain the UIC PI’s knowledge of local context issues at the non-UIC site, as well as the UIC PI’s capacity for overseeing compliance with UIC HSPP policies at the non-UIC site.
   B. After the receipt of the UIC PI’s documentation, and an assessment of the UIC IRB’s composition and capacity to review local context issues, the need for an ad hoc consultant regarding local context issues will be made in accordance with UIC HSPP policy Identification and Use of Ad Hoc Consultants.

II. The UIC IRB may accept, for any non-UIC site with an IRB registered with OHRP, DHHS, either an IRB approval from the non-UIC site or a letter stating that IRB approval is not necessary for the non-UIC site to be involved in the research. When UIC accepts the IRB approval of a non-UIC site, it will be assumed that the UIC HSPP standards of human subjects protection are being met via the non-UIC sites’ IRB. IRB approval from a non-UIC site may be accepted by the UIC IRB in lieu of
requirements outlined in Section III below whether the research is supported by a federal sponsor, non-federal sponsor, or is not funded.

III. The UIC PI must submit, at a minimum, the appropriate documentation below from non-UIC sites that do not have an OHRP-registered IRB. The UIC IRB may request additional documentation, particularly regarding local context issues, as necessary.

A. When the research is supported by a non-federal sponsor or is not funded:
   1. The UIC PI must submit a Letter of Support from each non-UIC site to the UIC IRB. Letters of Support must be signed by an authorized executive from the non-UIC site and outline the research activities for which the non-UIC site has agreed to serve as host, provide resources (including personnel), and/or participate.
   2. Other special requirements may apply when research is conducted in schools (see, for example, Guidelines for Requests to Conduct Research in the Chicago Public Schools).
   3. The UIC IRB may require that personnel from non-UIC site(s) be listed on UIC OPRS form Appendix P, as key research personnel, and that certification be submitted attesting to their completion of investigator training in human subjects protection and, where applicable, HIPAA investigator education.

B. When the research is supported by a federal sponsor and the UIC OPRS/IRB has determined that the non-UIC site is not actively engaged in the research:
   1. The UIC PI must submit a Letter of Support from each not-engaged non-UIC site to the UIC IRB. Letters of Support must be signed by an authorized executive from the not-engaged non-UIC site and outline the passive or supportive activities which the non-UIC site has agreed to host or accommodate. Passive or supportive activities may include, but are not limited to:
      a) Allowing recruitment materials to be posted, distributed, and/or announced;
      b) Providing space for research activities conducted by UIC personnel; and/or
      c) Allowing UIC personnel to observe subjects or otherwise collect data at the non-UIC site.
      d) Other special requirements may apply when research is conducted in schools (see, for example, Guidelines for Requests to Conduct Research in the Chicago Public Schools).

C. When the research is supported by a federal sponsor and the UIC OPRS/IRB has determined that the non-UIC site is actively engaged in the research, the UIC PI is responsible for ascertaining, facilitating the procurement of, and/or maintaining, as well as submitting evidence of, the following to the UIC IRB at initial review, continuing review, and each relevant amendment:
   1. An individual FWA for each engaged non-UIC site. The UIC PI may direct non-UIC sites that do not have an FWA to the OHRP website for filing instructions and sample FWAs:
      http://www.hhs.gov/ohrp/assurances/assurances_index.html
2. When the FWA is obtained by the engaged non-UIC site, the non-UIC site may then request that UIC act as the IRB of Record for purposes of overseeing a specific research protocol via an IRB Authorization Agreement (IAA; also UIC OPRS form Appendix L1).
   a) The IAA must be completed and signed by an authorized official at the engaged non-UIC site, and submitted by the UIC PI to the UIC IRB.
   b) The completed IAA will be forwarded by UIC OPRS staff, accompanied by any relevant documentation, to the UIC OPRS Director. The Director may, at their discretion, request a meeting with the UIC PI to discuss the research and the significance of the IAA. The Director may also request the attendance of a representative from the non-UIC site.
   c) When the UIC OPRS Director recommends approval of the IAA, it is routed to the UIC Vice Chancellor for Research for approval and signature. Note: The Vice Chancellor for Research is the only UIC official authorized to sign the IAA.
   d) When the IAA has been signed by the UIC Vice Chancellor for Research, UIC OPRS staff revises the IRB protocol approval letter to indicate that research activities may commence at the engaged non-UIC site. A copy of the signed IAA and revised protocol approval letter are retained in the protocol file, and UIC OPRS staff forwards the original, signed IAA and revised protocol approval letter to the UIC PI.

D. When UIC becomes the IRB of Record, the UIC OPRS/IRB may accept the use of a single non-UIC-affiliated individual by the UIC PI as a collaborating contractor/consultant/investigator, particularly regarding local context issues.
1. An Individual Investigator Agreement (IIA; also UIC OPRS form Appendix L2) must be submitted by the UIC PI to extend UIC’s FWA to cover the individual non-UIC investigator. The UIC PI must direct and supervise all activities of the individual non-UIC investigator, and is responsible for initiating and processing the IIA through the UIC OPRS/IRB. The UIC IRB’s oversight responsibilities include, but are not limited to, ensuring that the individual non-UIC investigator and/or the UIC PI:
   a) Comply with all 14 Conditions for Extending an FWA to Cover Collaborating Individual Investigators available online at: http://www.hhs.gov/ohrp/humansubjects/assurance/guidanceonalternativetoFWA.htm;
   b) Have and maintain any certification, licensure, or other qualifications required to fulfill the research role for which the individual non-UIC investigator has been retained; and/or
   c) Provide documentation of current, specific knowledge of local research context and/or the capacity to address local research context issues (for example, fluency in a language other than English).
(1) The UIC PI must submit an IIA, completed by the individual non-UIC investigator, to the UIC OPRS/IRB.

(2) The completed IIA will be forwarded by UIC OPRS staff, accompanied by any relevant documentation, to the UIC OPRS Director. The Director may, at their discretion, request a meeting with the UIC PI to discuss the research and the significance of the IIA. The Director may also request the attendance of the individual non-UIC investigator.

(3) When the UIC OPRS Director recommends approval of the IIA, it is routed to the UIC Vice Chancellor for Research for approval and signature. **Note:** The Vice Chancellor for Research is the only UIC official authorized to sign the IIA.

(4) When the IIA has been signed by the UIC Vice Chancellor for Research, a copy of the signed IIA and an appropriate IRB approval letter are retained in the protocol file, and UIC OPRS staff forwards the original, signed IIA and protocol approval letter to the UIC PI.

**REVISION LOG:**

<table>
<thead>
<tr>
<th>Version (#, date)</th>
<th>Replaces (#, date)</th>
<th>Summary of changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.0, 10/01/08</td>
<td>2.0, 8/3/07</td>
<td>Revised entire document</td>
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<tr>
<td>3.1, 3/13/09</td>
<td>3.0, 10/01/08</td>
<td>Removed engaged/not engaged section and moved it to stand alone policy</td>
</tr>
<tr>
<td>3.2, 6/18/09</td>
<td>3.1, 3/13/09</td>
<td>Removed local research context section and moved it to stand alone policy</td>
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