New Directions: Putting the broad based Consent Capacity Policy into operation with the NEW FORM T

Research Involving Adults with Impaired Consent Capacity

Consistent with national efforts, the UK IRB has adopted an updated policy first introduced in the March 2009 IRB Review Newsletter and presented at the CRDOC Clinical Research Update program that same month (copy of presentation). This new policy and tools were designed to enable investigators to ethically include subjects who have limited or impaired consent capacity in research. The new version of form T incorporates the novel concepts introduced in the policy as follows:

<table>
<thead>
<tr>
<th>Concept</th>
<th>Process</th>
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<tr>
<td>Capacity to consent is not simply absent or present but occurs along a continuum and in a wide range of conditions, situational factors, and disease states.</td>
<td>The updated Form A will prompt Investigators to consider a comprehensive list of therapeutic conditions and complete Form T if the study seeks or has potential to encounter even one prospective subject with impairment.</td>
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<td>The method used to assess capacity, (and when appropriate, the documentation of this assessment), should be tailored to the study population, the level of study risk and the likelihood of enrolling participants with impaired or fluctuating capacity.</td>
<td>The new Form T provides an interactive multidimensional tool to aid investigators in developing a systematic assessment plan.</td>
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<td>Enhancements to the consent form and process may serve to improve a prospective participant’s understanding and enable individuals who otherwise have limitations in consent capacity, to make competent decisions.</td>
<td>The new Form T includes specific enhancements options for consideration.</td>
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<tr>
<td>Investigators should use fair and equitable recruitment practices in research and avoid practices that place participants at risk for coercion or undue influence.</td>
<td>The new Form T retains questions regarding subject safeguards and equitable recruitment.</td>
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</table>

Electronic Format

The form launches from an electronic tool that the investigator uses to tailor a consent capacity assessment plan and additional safeguards appropriate for the study population and research protocol. After completing the form the investigator saves and prints hard copies for inclusion with the IRB submission. Non-electronic versions of Form T will be available upon request.

Transition Time

The new Form T has been available as a pilot test since first introduced. ORI and the IRB appreciate the investigators who have utilized the pilot Form T and provided feedback.

Investigators, who have submissions in process including any subjects whose clinical condition presents a likelihood of impaired or fluctuating consent capacity, should complete the new version of Form T which should be available on the ORI Forms Web Page by August 10th. After September 15th, the IRB will only accept the new form for new IRB submissions.

Additional guidance on the new directions in impaired consent capacity and brochures to assist Legally Authorized Representatives may be found on the ORI website at http://www.research.uky.edu/ori/human/guidance.htm#ImpConsent.
New Form Y: Disclosure of Financial Interest Form for non-externally funded research

The Office of Sponsored Projects Administration (OSPA) recently announced that UK is amending the Research Financial Interest Disclosure Statement to enhance transparency and management of conflict of interest. The new Form, (linked from the ORI Forms Web Page as Form X), is now required for externally funded projects. In addition, the version of the form available to investigators conducting non-externally funded research, (Form Y), has been updated consistent with Form X to include the second set of questions to be answered for research projects that involve human subjects. The updated version of Form Y should be available on the ORI Forms Web Page by August 10th. After September 15th, the IRB will only accept the new form Y for new IRB submissions.

UPCOMING EVENTS & ANNOUNCEMENTS

RESEARCH WITH CHILDREN:
ORI is sponsoring visiting expert Bruce Gordon, MD, Professor of Pediatrics and IRB Chair, University of Nebraska Medical Center to present ethical and regulatory responsibilities of research including children. Clinicians, investigators and research staff will have two opportunities to hear Dr. Gordon. Mark your calendars for the following events and watch for future registration information:

- **September 16th, 1:00 pm**
  - IRB Members Only: applying subpart D in review of research with children
  - Contact—Belinda Smith, Office of Research Integrity, 323-2446, belinda.smith@uky.edu

- **September 17th, 8:00 am**
  - Pediatrics Grand Rounds
  - Contact—Maria Price, Pediatrics, 323-2820, mmpric1@uky.edu

- **September 17th, 12:00 pm**
  - Clinical Research Updates
  - Contact—Ryan Vicini, Clinical Research Development & Operations Center (CRDOC), 323-8545, rvicin2@uky.edu

UK Human Research Protection Regional Conference

October 8, 2009
Northern Kentucky Convention Center

Conference Brochure with Registration Form specific for UK staff and faculty is available at:
www.research.uky.edu/ori/upcoming_events.htm

Registration forms may be sent to:
UK Office of Research Integrity, C/O Stephanie Morris, 314a Kinkead Hall, Lexington, KY 40506-0057
Email: samo222@uky.edu  FAX: 859-257-8995

Attendance at the regional conference satisfies the U.K. human subject protection continuing education requirement.

Co-sponsors: