IRB 7

Network for Clinical Research Professionals (NCRP) Seminar
June 18, 2013
What is IRB 7?

• IRB 7 is a new electronic IRB solution from Huron Consulting Group
  • Same underlying software as eProst, but more streamlined configuration
  • Same vendor – Huron Consulting Group
  • Similar look and feel to eProst
• Designed to be an out-of-the-box solution, but can be customized to meet UM’s reporting and operational needs
• Built around Huron’s HRPP Toolkit
  • Available for download at http://www.besthrppops.com/
  • A set of SOPs, checklists, and worksheets designed to ensure regulatory compliance and built around best practices
# eProst vs. IRB 7 – A Few Key Differences

<table>
<thead>
<tr>
<th></th>
<th>eProst</th>
<th>IRB 7</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Maximum Length of SmartForms</strong></td>
<td>70 pages for new study</td>
<td>10 pages for new study</td>
</tr>
<tr>
<td><strong>Study Team Members</strong></td>
<td>Must be added individually to each new study</td>
<td>PI has the option of setting up a “standard” study team so study team members will be pre-populated in each new study (with the option to remove individuals as needed)</td>
</tr>
<tr>
<td><strong>Protocol form vs. sponsor protocol</strong></td>
<td>Must copy/paste text from sponsor protocol into eProst forms</td>
<td>Simply upload the sponsor protocol – IRB 7 is more document-centric</td>
</tr>
<tr>
<td><strong>Continuing Reports/Amendments</strong></td>
<td>Must be submitted separately</td>
<td>Can be submitted as a single submission</td>
</tr>
<tr>
<td><strong>Department-level Review</strong></td>
<td>Mandatory and must be completed before submission can move forward to Ancillary review</td>
<td>Optional and can be completed in parallel with ancillary and HSRO/IRB reviews</td>
</tr>
<tr>
<td><strong>Ancillary Committee Reviews</strong></td>
<td>Must be completed after department review and before HSRO/IRB review</td>
<td>Can be completed in parallel with ancillary and HSRO/IRB review</td>
</tr>
<tr>
<td><strong>Parallel Amendments</strong></td>
<td>Not possible in eProst; limited to one amendment at a time</td>
<td>May have two Amendments open at a time; one for study team changes, the other for changes to any other aspect of the study</td>
</tr>
<tr>
<td><strong>Reportable Events</strong></td>
<td>A reportable event associated with multiple studies must be created for each study individually</td>
<td>A single reportable event can be tied to multiple studies</td>
</tr>
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</table>
Workflow – parallel review

IRB 7 Basic Workflow

For New Study submissions

Study Team

PI submits

Study team makes changes if requested

HSRO requests changes

Study team submits changes

HSRO Pre-Review

IRB Review (Committee Review or Non-Committee Review; can send back to study team for changes)

HSRO Post-Review (send determination letter or send back to study team for changes)

HSRO/IRB

Ancillary Committee Review

Ancillaries/Dept Approvers

Department Review
## eProst vs. IRB 7 – Differences (cont’d)

<table>
<thead>
<tr>
<th></th>
<th>eProst</th>
<th>IRB 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol</td>
<td>Protocol</td>
<td>Study</td>
</tr>
<tr>
<td>Amendment</td>
<td>Amendment</td>
<td>Modification</td>
</tr>
<tr>
<td>Reportable Event/Notification</td>
<td>Reportable Event/Notification</td>
<td>Reportable New Information (RNI)</td>
</tr>
<tr>
<td>Expedited Review or Exempt Review</td>
<td>Expedited Review or Exempt Review</td>
<td>Non-Committee Review</td>
</tr>
<tr>
<td>Full Board Review</td>
<td>Full Board Review</td>
<td>Committee Review</td>
</tr>
</tbody>
</table>
Other IRB 7 Advantages

- No major changes to basic functionality
  - Basic functionality will be the same as in eProst (i.e. uploading documents, printer-friendly version, continue/back buttons, Hide/Show Errors)

- Limits data collection to the minimum necessary
  - Don’t ask investigators when the IRB already knows the answer
  - Helps mitigate risk by eliminating duplicative data entry

- Education/training materials incorporated into the system
  - Integrated on-line help and user documentation
  - Checklists and Worksheets will help ensure consistency in reviews

- Limited customization = Easier to maintain and upgrade
  - Toolkit Checklists and Worksheets can be updated as needed, so regulatory changes and process changes won’t necessarily require an update to the system
When IRB 7 is implemented

• eProst system will remain available as read-only, but all new submissions will be created in IRB 7
• We will create snapshots of all active studies as of the implementation date and IRB 7 will link back to eProst
• Timeline for implementation and roll-out plan: September 2013
### My Current Actions
- Create New Study
- Report New Information

### Shortcuts
- My Inbox
- Meetings
- Reports
- Help
- Study Submission Guide
- IRB Reviewer's Guide

### My Inbox

<table>
<thead>
<tr>
<th>ID</th>
<th>Name</th>
<th>Date Created</th>
<th>Date Modified</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td>MOD00000009</td>
<td>Modification #1 for Study 20130040</td>
<td>6/11/2013 12:59 PM</td>
<td>6/11/2013 12:59 PM</td>
<td>Pre-Submission</td>
</tr>
</tbody>
</table>
Basic Information

1. *Title of study:*

2. *Short title:*

3. *Brief description:*

4. *Principal investigator:*
Rebecca Simms (pi)

5. *Does the investigator have a financial interest related to this research?*
- [ ] Yes
- [ ] No

6. *Will an external IRB act as the IRB of record for this study?*
- [ ] Yes
- [ ] No

7. *Attach the protocol: (include the investigator protocol and full sponsor protocol)*

   Use one of these templates:
   - HRP-503 - Protocol
20130044: Test - 06/13/2013

Principal investigator: Rebecca Simms (pi)
Submission type: Initial Study
Primary contact: Rebecca Simms (pi)
IRB coordinator:

Pre-Submission → IRB Pre-Review → IRB Review → Post Review → Modifications Required → Review Complete

My Current Actions
- Edit Study
- Printer Version
- View Differences

History
Filter by Activity → Go
Activity: Study Created
Author: Simms (pi), Rebecca
Date: 6/13/2013 1:36 PM PDT