NCRP Seminar - HSRO Updates
January 28th, 2015

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Director, Regulatory Affairs and Educational Initiatives
Human Subject Research Office
Overview

1. HSRO/IRB Process Flow
   a) IRB7 Implementation and challenges faced
2. Year in review – 2014
   a) Volumes/productivity
3. What’s needed to help increase efficiency in review
4. Goals for 2015
HSRO/IRB Process Flow
IRBs

• 3 Medical; 1 Social and Behavioral Sciences
• Each meets twice a month
  – Meeting schedule and deadlines for receipt of submissions posted on HSRO website
• Dedicated staff
Issues Faced

• Training on new system
• Problems with new software implementation
  – Watermarking
  – Approval date inconsistencies
  – Document management
• Staffing
Volumes & Productivity
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<tr>
<th>Funding</th>
<th>2013 (N=2896)</th>
<th>%</th>
<th>2014 (N=3099)</th>
<th>%</th>
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Summary of Number of Items where the HSRO/IRB has made a determination

<table>
<thead>
<tr>
<th>Year</th>
<th>New Study</th>
<th>Amend/Mod</th>
<th>Reportable Event/Notification</th>
<th>Continuing/Final Report</th>
<th>Mod &amp; Continuing Review</th>
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# Summary 2013 - Review Times

January 1, 2013-December 31, 2013

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<th># Submissions Approved</th>
<th>Average # Days from Creation to Submission by the PI</th>
<th>Average Turnaround Time</th>
<th>Average Adjusted Turnaround Time</th>
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# Summary 2014 - Review Times

January 1, 2014-September 30, 2014

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<th># Submission s Approved</th>
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<th>Average Turnaround Time</th>
<th>Average Adjusted Turnaround Time</th>
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Documentation needed for review
Documents to upload/submit as supporting documentation - **New study**

- Protocol
- If industry-sponsored, protocol supplement to define site-specific procedures
- IB or device brochure
- Draft CTA or grant application
- Consent and HIPAA forms
- Questionnaires
- Recruitment/Advertising material
- Ancillary committee application forms
Documents to upload/submit as supporting documentation - CR

- CR Supplement Form
  (http://hsro.med.miami.edu/forms/miscforms)
- Redacted Velos enrollment summary for studies tracked in Velos
- DSMB/DMC reports, if applicable
- Grant progress report, if applicable
- Summary response for any item left unchecked in Q4
- Minor deviation log
- Minor AE log
- Sponsor closure letter (if study is being closed)
Documents to upload/submit as supporting documentation – MOD/RNI

Modification

• Revised documents (using the ‘Update’ feature)
• New documents (using the ‘Add’ feature)
• Participant enrollment status report (determines need to re-consent)

RNI

• Summary of RNI and its implications
  – Corrective actions implemented
  – Submit modification, if necessary
• Other supporting documents (Letter from sponsor, etc.)
UM/HSRO Policies and Procedures

• It is the expectation that all research personnel are familiar with the requirements defined in the Investigator Manual and other guidance documents to ensure:
  – culture of compliance with all applicable regulations
  – ethical conduct of human subject research
  – a knowledgeable research community is fostered

• HSRO website should be checked periodically for updated information and forms
  – http://hsro.med.miami.edu/resources
  – http://hsro.med.miami.edu/announcements
Educational Initiatives

- IRB Grand Round Sessions *(CME credits)*
- eProst Mentoring Sessions *(Bring your work)*
- HSRO eNews
- eProst Listserv
- Educational presentations (Departmental, etc.)
- Expert Seminars

Registration available in ULearn
Things to Remember

• Must be CITI certified to engage in HSR
  – Course in the Protection of Participants in Research and COI Mini-course
  – Recertification every 2 years (HSR) or 4 years (COI)

• Submit complete and accurate information to the HSRO/IRB for review

• Read your determination letters for conditions of approval to avoid non-compliance

• Pay attention to deadlines
Goals for 2015
Goals for 2015

- Accreditation Site Visit: April 1-3, 2015
  ✔ Become Accredited- 4th Q, 2015
- Decrease Turn-Around Times
- Increase Collaboration with other Compliance Units for a variety of educational training initiatives
- Single IRB Review (NIH)
  - NeuroNext, StrokeNet, FredHutch, etc.
- Pursue new initiatives (e.g. Electronic Consenting)
Thank you for your ongoing support of HSRO & UM IRBs