State of the HSRO
IRB Grand Round Session
January 13th, 2015

Dushyantha Jayaweera, MD, MRCOG (UK), FACP, CIP
Associate Vice Provost for Human Subject Research
Professor of Medicine
Overview

1. Current volumes/productivity
2. Measures to improve
3. Year in review - 2014
4. Goals for 2015
Some components of our HRPP

- Institution
- Sponsor
- IRB
- Ancillary Review
- Grants and Contracts
- Other Compliance Units
- Researcher/Research Staff
Current Volumes & Productivity
Active Studies Funding Breakdown

For the year ended 2013, 44% of our active studies* were funded

<table>
<thead>
<tr>
<th>Funding</th>
<th>Percent Funded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federal</td>
<td>21.72%</td>
</tr>
<tr>
<td>Foundation</td>
<td>4.77%</td>
</tr>
<tr>
<td>Gift</td>
<td>0.62%</td>
</tr>
<tr>
<td>Industry</td>
<td>15.26%</td>
</tr>
<tr>
<td>No Funding</td>
<td>56.01%</td>
</tr>
<tr>
<td>State</td>
<td>1.62%</td>
</tr>
<tr>
<td><strong>Grand Total</strong></td>
<td><strong>100.00%</strong></td>
</tr>
</tbody>
</table>

* # of active studies 2896
Active Studies Funding Breakdown

For the year ended 2014, 42% of our active studies* were funded.

<table>
<thead>
<tr>
<th>Funding</th>
<th>Percent Funded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federal</td>
<td>19.59%</td>
</tr>
<tr>
<td>Foundation</td>
<td>4.19%</td>
</tr>
<tr>
<td>Gift</td>
<td>0.32%</td>
</tr>
<tr>
<td>Industry</td>
<td>16.49%</td>
</tr>
<tr>
<td>No Funding</td>
<td>57.92%</td>
</tr>
<tr>
<td>State</td>
<td>1.48%</td>
</tr>
<tr>
<td>Grand Total</td>
<td>100.00%</td>
</tr>
</tbody>
</table>

* # of active studies 3099
- Steady increase in the amount of new studies
- Increase in modifications/amendments – IRB 7 allows for parallel submission when Reportable Events have dramatically decreased due to SOP changes (to include but not be limited to external SAE reporting, IND safety, minor deviation at CR only etc...)
Impact to Regulatory Staff

- April 2012- Lost (4) FTEs
- March 2013- Completed recruitment cycle for (4) FTEs
- Initial training curve- 6 to 9 months
January IRB Grand Rounds Session: State of the HSRO

**Old eProst System**

This timeline represents the way that we used to measure IRB turnaround time in the old eProst system — from the time a submission was received by the HSRO to IRB approval. In the old system, a submission did not arrive at the HSRO until AFTER departmental and ancillary reviews were completed. (corresponds to graphs 1 and 2)

**New eProst System (IRB 7)**

This timeline represents the way that we now measure IRB turnaround time in the new eProst system (IRB 7) — from the time a submission was received by the HSRO to IRB approval - but because IRB review, department review and ancillary review are now conducted in parallel, the difference here is that this block of time now includes time for departmental and ancillary reviews, and some of these reviews may hold up final IRB approval. (corresponds to graphs 3 and 4)
# Summary 2013 - Review Times

## January 1, 2013-December 31, 2013

<table>
<thead>
<tr>
<th></th>
<th># Submission Approved</th>
<th>Average # Days from Creation to Submission by the PI</th>
<th>Average Turnaround Time</th>
<th>Average Adjusted Turnaround Time</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>New studies</strong></td>
<td>719</td>
<td>59.84</td>
<td>44.15</td>
<td>30.03</td>
</tr>
<tr>
<td><strong>Amendments</strong></td>
<td>3104</td>
<td>13.68</td>
<td>21.51</td>
<td>16.74</td>
</tr>
<tr>
<td><strong>Continuing/Final Reports</strong></td>
<td>2129</td>
<td>13.52</td>
<td>20.48</td>
<td>16.48</td>
</tr>
<tr>
<td><strong>Reportable Events/Notifications</strong></td>
<td>3108</td>
<td>9.80</td>
<td>20.08</td>
<td>17.65</td>
</tr>
</tbody>
</table>

## IRB 7

<table>
<thead>
<tr>
<th></th>
<th>#</th>
<th>Average Turnaround Time</th>
<th>Average Adjusted Turnaround Time</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>New studies</strong></td>
<td>0</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Modifications</strong></td>
<td>4</td>
<td>2.00</td>
<td>1.97</td>
</tr>
<tr>
<td><strong>Continuing/Final Reports</strong></td>
<td>3</td>
<td>4.00</td>
<td>2.68</td>
</tr>
<tr>
<td><strong>MOD/CRs</strong></td>
<td>1</td>
<td>5.00</td>
<td>5.00</td>
</tr>
<tr>
<td><strong>RNIs</strong></td>
<td>1</td>
<td>1.00</td>
<td>1.00</td>
</tr>
</tbody>
</table>
## Summary 2014 - Review Times

January 1, 2014-September 30, 2014

<table>
<thead>
<tr>
<th># Submission s Approved</th>
<th>Average # Days from Creation to Submission by the PI</th>
<th>Average Turnaround Time</th>
<th>Average Adjusted Turnaround Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>eprostarchive</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>New studies</td>
<td>118</td>
<td>83.44</td>
<td>85.63</td>
</tr>
<tr>
<td>Amendments</td>
<td>241</td>
<td>34.78</td>
<td>40.38</td>
</tr>
<tr>
<td>Continuing/Final Reports</td>
<td>204</td>
<td>22.01</td>
<td>37.07</td>
</tr>
<tr>
<td>Reportable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Events/Notifications</td>
<td>279</td>
<td>13.69</td>
<td>41.12</td>
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<tr>
<td>IRB 7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New studies</td>
<td>587</td>
<td>21.36</td>
<td>49.22</td>
</tr>
<tr>
<td>Modifications</td>
<td>3287</td>
<td>6.16</td>
<td>20.36</td>
</tr>
<tr>
<td>Continuing/Final Reports</td>
<td>1378</td>
<td>9.06</td>
<td>28.17</td>
</tr>
<tr>
<td>MOD/CRs</td>
<td>235</td>
<td>9.99</td>
<td>35.24</td>
</tr>
<tr>
<td>RNIs</td>
<td>376</td>
<td>0.00</td>
<td>46.26</td>
</tr>
</tbody>
</table>
Measures to Improve
IRB Workflow Analysis

Alican Oksayoglu
Yasmine Asfour*

December 18 2014 - UMIT Clinical Applications PMO
January IRB Grand Rounds Session: State of the HSRO

IRB 7 Current Workflow

Study Team

- PI Submits
  - Resubmission
    - Study Team makes changes
      - YES: Changes Asked?
        - NO: B
        - YES: A

HSRO/IRB

- HSRO Pre-Review
  - Any Correction Needed?
    - YES: HSRO Pre-Review
    - NO: Ancillary or Departmental review required?
      - NO: HSRO Review
        - NO: IRB Review
          - NO: End
          - YES: HSRO Post Review
          - YES: End
        - YES: IRB Review
          - NO: End
          - YES: HSRO Post Review
          - YES: End
      - YES: HSRO Review
        - NO: IRB Review
          - NO: End
          - YES: HSRO Post Review
          - YES: End
        - YES: IRB Review
          - NO: End
          - YES: HSRO Post Review
          - YES: End

Ancillaries/Dept. Approvers

- Ancillary Committee Review
  - Pass?
    - YES: B
    - NO: A

- Department Review
  - Pass?
    - YES: B
    - NO: A

Draft
Connected Flight Analogy

- MIA to JFK over ATL
- Total Time Spent: Time arrived JFK – Time in gate MIA
- Layover Time: Time Boarded at ATL – Time arrived ATL
## Overall

<table>
<thead>
<tr>
<th>Entered IRB – Created</th>
<th>Time to Exclude from HSRO Process*</th>
<th>Pre Review Completed-Entered by IRB-Time to Exclude</th>
<th>Forwared to Reviewer-Pre Review Complete d</th>
<th>Assigned to Meeting - Forwarded to reviewer</th>
<th>Forwarded to Committee Reviewer-Assigned to meeting</th>
<th>Determination - Forwarded to Committee Reviewer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adjusted Average</td>
<td>7.8917</td>
<td>4.90</td>
<td>13.91</td>
<td>0.3561</td>
<td>0.5871</td>
<td>0.3469</td>
</tr>
<tr>
<td>Total</td>
<td>1.7253</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effect Percentage</td>
<td>26.55%</td>
<td>%16.49</td>
<td>46.81%</td>
<td>1.20%</td>
<td>1.98%</td>
<td>1.17%</td>
</tr>
<tr>
<td>Total</td>
<td>5.80%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ratio Vs. Overall</td>
<td>96.59%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Initial Studies

<table>
<thead>
<tr>
<th>Entered IRB – Created</th>
<th>Time to Exclude from HSRO Process*</th>
<th>Pre Review Completed-Entered by IRB-Time to Exclude</th>
<th>Forwarde d to Reviewer-Pre Review Complete d</th>
<th>Assigned to Meeting - Forwarded to reviewer</th>
<th>Forwarded to Committee Reviewer</th>
<th>Determination - Forwarded to Committee Reviewer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adjusted Average</td>
<td>20.0227</td>
<td>11.53</td>
<td>25.52</td>
<td>1.1520</td>
<td>0.1720</td>
<td>0.2411</td>
</tr>
<tr>
<td>Effect Percentage</td>
<td>30.90%</td>
<td>17.79%</td>
<td>39.39%</td>
<td>1.78%</td>
<td>0.27%</td>
<td>0.37%</td>
</tr>
</tbody>
</table>

Total

64.80

Ratio Vs. Overall

98.99%
Problem with Current State

Dependency on Reviews

Extra load by resubmission process
Recommendations

• Don’t wait for committee decisions to go forward with application
• Provide a training to submitters
Educational Initiatives

- IRB Grand Round Sessions
- IRB Member Education
- PRIM&R
- Lunch & Learn Sessions
- Expansion of educational initiatives on Coral Gables Campus
- Desktop sharing and call triage by creating trouble tickets
Deliver Fast and Secure Support with Bomgar

• Bomgar’s remote support solution enables organizations to provide support instantly, no matter where their end-users are located or what systems they’re using

• Provide fast, effective support. Gain remote desktop control of multiple systems simultaneously. Automatically pull system info for quick diagnosis

• Maintain data security and compliance. Keep data and system access behind your own firewall, and automatically maintain a full audit trail with Bomgar's session logging and video recording functionality
Study Submission Aids for the Study Teams
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
• 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.)
Year in review- 2014
Human Subject Research Community Conference

- 9/11 & 9/12, Student Activities Center
- Community Partners: JHS, Miami VA, MCH, BHSF, FIU Research
- Speakers included: OHRP, AAHRPP, Office of Research Protections (DoD), Duke, UPenn, UF, NYU Langone, Clinical Trials Transformation Initiative, WIRB, Pfizer, Huron
January IRB Grand Rounds Session: State of the HSRO
HSRO Community Conference

- 324 Registered
- 297 Signed-in
- 84 Faculty (CME and CE credits)
- 112 Research Personnel (SOCRA eligible)
- 18 Attorneys (CLE credits)
- 30 Nurses (CEU credits)
- 53 Other Compliance Representation (CIP, CIM, CHC, CHRC, CHPC credit eligible)
Process Enhancement & Expansion of Central IRBs

- NeuroNEXT
- StrokeNet
- IRB Share
Submission of Association for the Accreditation of Human Research Protection Programs (AHRPP) application

- **Step 1 (application & supporting documents)**- Submitted April, 2014/ Approved August 2014
- **Step 2 (active study list, additional materials)**- Submitted August 2014/ Approved September 2014
- **Positive Feedback thus far**
AAHRPP Site Visit- Know your resources

Prepare for the site visit (Scheduled for April 2015)

AAHRPP interviewers will want to see that you are familiar with the information and services available to you, and that you know where to find assistance if you have questions.

**WE WILL HAVE A ULEARN MODULE AVAILABLE AND WILL BE EMAILED TO ALL EPROST USERS. YOU MUST HAVE A COPY AND PLEASE READ IT BEFORE YOU MEET THE AAHRPP SITE VISITORS**

http://hsro.med.miami.edu
http://eprost.med.miami.edu

Note: Visit the IRB Library: to access library, you must have an eprost account established)

Know how to access Policies and Procedures for other areas related to human subject research protection

http:// uresearch.miami.edu/
Some components of our HRPP

- Institution
- Sponsor
- IRB
- Ancillary Review
- Grants and Contracts
- Other Compliance Units
- Researcher/Research Staff
Goals for 2015

• Accreditation Site Visit: April 1-3, 2015 (Handout)
  • 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)
• Trial Net
• Electronic Consenting
Thank you for your ongoing support of HSRO & UM IRB