Welcome to the PPHS Quarterly Review. This new feature will highlight key initiatives, updates, and other information to keep you abreast of the ongoing activities of the PPHS office.

The PPHS has revised and remodeled its educational series. These training classes offer learners the opportunity to become familiar with, or more knowledgeable about, the PPHS process:

IRB 101: Basis Steps of the IRB Submission
- Intro level course
- Course is 1 hour with short lecture and hands-on exercises

- Course offers help in protocol and consent writing
- 90-minute course with short lecture and hands-on exercises

IRB 301: Special Projects and Specific Submissions

Courses are held on a monthly basis

email Fernando.baez@mssm.edu to register

PPHS Educational Retreat: Retreat to Advance

Over 125 individuals attended our Educational Retreat on May 17, 2012. Dean Charney kicked off the day with a discussion on the future of research at MSSM followed by a presentation by Dr. Silverstein on the 2011 PPHS Annual Report.

Other speakers included:
- Dr. Jeremy Sugarman, Johns Hopkins Berman Institute of Bioethics, provided an insightful talk about his research results on financial conflicts of interest in research including what subjects want to know and how they react.
- Dr. Mark Schreiner, Children’s Hospital of Philadelphia, spoke about assessing risk and benefit for research involving minors. His talk highlighted different approaches that institutions take, and the differences of opinion between OHRP and FDA on making these assessments.
- Dr. Joseph Konstan, University of Minnesota, concluded the day presenting on the topic of identifiability and anonymity; as well as what privacy means in the context of widespread social media usage.

PPHS Suggestion Box

Dr. Bruce Gelb offered a suggestion that was selected as the SUGGESTION of the MONTH by the PPHS office!

Introducing a quick and easy way to update study contact information with the PPHS!

You can now send an email to IRB@mssm.edu with the name of the new contact person and request that this information be updated. Please indicate if this is study specific or a global replacement. This person will not be added to the study, but will receive official PPHS notifications.*

*If your contact person will be involved in the design, conduct or reporting of the research, submit a HRP-213 and HRP-211.
There are 1,768 active human research projects being conducted at Mount Sinai Medical Center. Human research activities are being carried out by 1,435 investigators (Principal Investigator and Co-Investigators), supported by 1,686 research staff across 24 departments.

Human Research at MSSM

629 PIs:

9 IRB Analysts:

Nadia Andrianov
Avery Block
Elizabeth Boyland
Bryan Elliot

Manjit Gill
Amanda Howard
Phillip Miner
John Roberts
Ali Smith

Since the PPHS introduced e-submissions on April 23, 2012, the office has received:

292 E-submissions

197 Paper Submissions

New projects approved Jan 1-June 8, 2012 by Department
Total: 281 (75 full board, 206 expedited)

<table>
<thead>
<tr>
<th>Department</th>
<th>New Projects Approved</th>
<th>Full Board</th>
<th>Expedited</th>
</tr>
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<tbody>
<tr>
<td>Medicine</td>
<td>81(29, 52)</td>
<td>7 (2, 5)</td>
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<tr>
<td>Surgery</td>
<td>24 (6, 18)</td>
<td>7 (0, 7)</td>
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<tr>
<td>Psychiatry</td>
<td>18 (6, 12)</td>
<td>6 (2, 4)</td>
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<tr>
<td>Pediatrics</td>
<td>16 (3, 13)</td>
<td>5 (1, 4)</td>
<td></td>
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<tr>
<td>Dermatology</td>
<td>14 (11, 3)</td>
<td>5 (2, 3)</td>
<td></td>
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<tr>
<td>Neurology</td>
<td>11 (2, 9)</td>
<td>5 (0, 5)</td>
<td></td>
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<tr>
<td>Orthopedics</td>
<td>11 (1, 10)</td>
<td>5 (0, 5)</td>
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<td>Radiology</td>
<td>11 (0, 11)</td>
<td>4 (0, 4)</td>
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<tr>
<td>Otalaryngology</td>
<td>10 (0, 10)</td>
<td>4 (0, 4)</td>
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<tr>
<td>Genetics &amp; Genomics</td>
<td>9 (2, 7)</td>
<td>4 (0, 4)</td>
<td></td>
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<tr>
<td>Onc. Sciences</td>
<td>9 (5, 4)</td>
<td>3 (0, 3)</td>
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<tr>
<td>Obstetrics/Gyn</td>
<td>9 (0, 9)</td>
<td>2 (2, 0)</td>
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<td>Cardio. Surgery</td>
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<td>Health Policy</td>
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<td>Anesthesiology</td>
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<td>Ophthalmology</td>
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<td>Pathology</td>
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<td>Geriatrics</td>
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<td>Neurosurgery</td>
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<td>Urology</td>
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<td>Emergency Med.</td>
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<td>Neuroscience</td>
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<tr>
<td>Rehab. Med.</td>
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Most Common Submissions made to the PPHS Jan-May 2012:

- New: 307 expedited
  116 full board

- Modifications: 642 expedited
  145 full board

- Continuing: 415 expedited
  170 full board

- New Information: 214 Reports

Total Submissions Processed Jan-May 2012: 2,009

per IRB analyst: 223
Funding Distribution for New Projects approved so far this year:
Total (see right) and by level of IRB review (below)

Expedited = minimal risk studies, such as surveys, chart reviews, and non-medical interactions
Full Board = greater than minimal risk studies, including clinical trials and medical interventions

All New Studies approved Jan. - June 8, 2012

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Federal</th>
<th>Industry</th>
<th>MSSM</th>
<th>Non-profit</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expedited</td>
<td>8%</td>
<td>1%</td>
<td>11%</td>
<td>18%</td>
<td>62%</td>
</tr>
<tr>
<td>Full Board</td>
<td>15%</td>
<td>47%</td>
<td>32%</td>
<td>9%</td>
<td>1%</td>
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</table>

UPDATE on the Use of Central IRBs

MSSM has entered into agreements with 3 commercial IRBs:
- WIRB
- Quorum Review
- Schulman Associates

These agreements will enable MSSM investigators to add MSSM as a site to an approved industry-sponsored study that is using one of these IRBs as their central IRB, for certain clinical trials. Consent/HIPAA authorization language has already been negotiated so the investigator does not need to submit the MSSM consent template for these studies.

If you have a sponsor that uses another AAHRPP-Accredited commercial IRB, contact Liz Carroll so we can make inquiries into entering into an agreement with them. Contract and consent document negotiations take time.

PPHS Book Club: Reading List

PPHS launched a book club in 2011 as a way for the office to learn, think and discuss ethical issues related to human research outside of study-specific considerations. So far, we have read:
- Sway: The Irresistible Pull of Irrational Behavior, by Ori and Rom Brafman
- The Spirit Catches You and You Fall Down, by Anne Fadiman
- Organizing Genius, by Warren Bennis & Patricia Ward Biederman
- The Immortal Life of Henrietta Lacks, by Rebecca Skloot
- Intuition, by Allegra Goodman
- PPHS READS: Open Wound, by Jason Karlawish
- The Emperor of All Maladies, by Siddhartha Mukherjee
Putting a Face to the Name

Nadia Andrianov has a Bachelors in Physiology and Neurobiology with a minor in Molecular and Cellular Biology from the University of Connecticut. This July she’s starting her graduate degree in Bioethics here at Mount Sinai. She says her favorite thing about working for the MSSM community is learning about the up and coming research. In her words, “The research being done here is incredible; it’s a wonderful thing to be a part of!”

William Benjamin holds a BS degree in Accounting from the University of Scranton; Scranton, PA. Before joining us here at Mount Sinai, he worked in retail branch operations for both national and community banks in PA. William currently is the IRB/PPHS Financial Coordinator.

Bryan Elliott holds a BA in German Language and Literature from Binghamton University, State University of New York. He is fluent in English and German, as well as speaking a number of other languages including Farsi. Bryan has previously worked at the New York State Department of Taxation and Finance Corporation Tax Bureau where he was involved with regulatory issues regarding annual reporting and dissolutions. Bryan currently works on expedited review projects.

Amanda Howard holds a Masters degree in Public Administration from Baruch College of the City University of New York. Her research interests have included program evaluation, policy analysis and urban studies. She currently works on full board projects for the IRB Boards A and C with a special interest in helping study teams successfully navigate the IRB submissions process.

Phillip Miner holds a BS in psychology from Truman State University and a Masters in Liberal Studies from the University of Minnesota with a focus in Digital Marketing for Nonprofit Organizations. Phil previously worked for the IRB at the University of Minnesota, currently sits on the board for The Center for Homicide Research, and occasionally contributes articles on trends in homicide research to The Huffington Post. He currently reviews expedited submissions.

Alicia Smith holds an MA in Rhetoric and Writing from San Diego State University in San Diego, CA. Her research interests have included bilingual and multicultural education in special education settings and adaptive technology for people with disabilities. Alicia has recently moonlighted for CUNY at York College and John Jay College teaching. She currently works on expedited projects for the IRB with a special interest in helping new investigators with their project submissions.

Getting Started: Basic PPHS Forms

What do I need to get started with IRB review?
- HRP-211 Application Form
- HRP-502 Consent template
- HRP-503 Protocol template
- IF# (from Sinai Central Investigator Form - disclosure of financial interest process)
- GCO submission (through InfoEd)

What do I need to ask to continue my projects approval?
- HRP-212 Continuation/Final Report Form
- HRP-502 Consent template (if still recruiting)
- HRP-503 Protocol template
- IF# (from Sinai Central Investigator Form - disclosure of financial interest process)
- GCO submission (through InfoEd)

What do I need to submit to change my project?
- HRP-213 Modification Form
- Track changes version of any changed documents
- Clean copy of any changed documents requiring an IRB stamp (ICF, ads)

What do I need to close my project?
- HRP-212 Continuation/Final Report Form
- GCO submission (through InfoEd)

Proud to be the IRB of the NFL

Appendix B is used to provide basic information to the IRB about any drugs, biologics, supplements or nutraceuticals used in the course of the research.

The IDS reviews the plan for the storage, handling and control of the drug and signs Appendix B, which is then returned to the study team for submission to the PPHS office as part of the official application.

This IDS review must be complete prior to final IRB approval, but the signature is not required to make the initial submission to the PPHS office.

If nothing on Appendix B, or on the previous Drug Information Sheet changes, the IDS does not need to review or sign the document again for the IRB.

IDS Signature on Appendix B