Disclosure

No relevant disclosure
Discussion Overview

- ORRC organization structure
- Policies and procedures
- Education and training
- Committees’ review processes
- Post-approval monitoring
- Reportable events
- Export control
- Scientific misconduct
- Conclusion
Updates: Policy and Procedures

• IRB Policies and Procedures
• IRB Charge Policy
• Conflict of Interest
• Laboratory Safety and Security
• Export Control
• Research Misconduct
Human Research Subject Protection and Institutional Review Boards (IRB)
Standard Operating Policies and Procedures (SOPP)

Office of Regulatory Research Compliance

May 26, 2014
HOWARD UNIVERSITY POLICY

Policy Number: Series 100: Academics and Research
Policy Title: INSTITUTIONAL REVIEW BOARD (IRB) FOR HUMAN SUBJECTS — REVIEW OF PROTOCOLS FEE POLICY

Responsible Officers: Provost and Chief Academic Officer
Associate Vice President for Research and Compliance

Responsible Offices: Office of the Provost
Office of Regulatory Research Compliance and Research Administrative Services

Effective Date: (Required by October 1, 2014)
Education and Training
Updates: Education and Training

- **Training (staff, board members, the academic community)**:
  - **CITI**: Collaborative Institutional Training Initiatives - enhanced with more modules (Standard Human Subject Modules, GCP, RCR, OHS, biosafety & biosecurity, export control)
  - **Public Responsibility in Medicine and Research (PRM&R)**:
    - Ethical Research Oversight Course (EROC)
    - “PRM&R At Your Doorsteps”
  - **IRB Rounds**: Interacting with your IRB (Per request/perceived needs)
  - **In-house training schedule**: IRB, IACUC, IBC, Lab Safety, OHS, RCR
  - **OHRP training videos**: downloaded and posted on the ORRC website
### Updates: Education and Training Cont.

<table>
<thead>
<tr>
<th>Which CITI Modules Must You Complete?</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Conflict of Interest</strong></td>
<td>All faculty, staff and students conducting research</td>
</tr>
<tr>
<td><strong>Responsible conduct of research</strong></td>
<td>All faculty, staff and students conducting human subject research</td>
</tr>
<tr>
<td><strong>Standard CITI IRB</strong></td>
<td>All faculty, staff and students conducting human subject research</td>
</tr>
<tr>
<td><strong>Good clinical practice (GCP) modules</strong></td>
<td>All faculty, staff and students conducting human subject research/clinical trials</td>
</tr>
<tr>
<td><strong>HIPAA module</strong></td>
<td>All faculty, staff and students conducting research using PHI/EMR (Clinicians and Clinician Scientists)</td>
</tr>
<tr>
<td><strong>Export control modules</strong></td>
<td>International studies/sharing of non-publicly available/restricted information with foreign nationals</td>
</tr>
<tr>
<td><strong>IACUC</strong></td>
<td>Conducting studies on animals</td>
</tr>
<tr>
<td><strong>Biosafety and biosecurity</strong></td>
<td>Animal/laboratory-related/some translational studies</td>
</tr>
</tbody>
</table>
THE REVIEW PROCESS
Note:

☑ Plan ahead:
   ☐ Do not wait until JIT/funded before submitting your protocols for review
   ☐ Advised to submit as soon as your application is submitted to the funding agency

☑ Pick your battle with the compliance committees

☑ Timely response: Respond to committees’ concerns in a timely manner

☑ In case of disagreement with expressed concerns: Gently and respectfully re-orient
IACUC Review Process
I.) Pre-application Consultation

II.) Application Pre-review

III.) Initial Application Submission and Review by the IACUC

- Prior to the IACUC meeting: Encourage reviewers to engage the investigators, clarify minor issues, and request correction of errors or modifications as appropriate.
- This communication can be channeled through the ORRC (documentation)

- Resubmission
  - Designated Member Review (DMR)
  - Full Committee Review (FCR)

- Approval Letter from the ORRC
## IACUC Pre-Application Checklist to Expedite The Application Process

Please, respond “YES” or “NO” to the following questions/items

<table>
<thead>
<tr>
<th>Question</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assess whether your protocol needs Institutional Biosafety Committee (IBC) review and approval. (A “YES” response means that your protocol requires IBC review.)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Are you using body fluid of any kind, tissues, cells or established cell lines?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2. Are you using viruses, viral vectors or potentially infectious materials?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3. Does your protocol involve recombinant DNA/RNA?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4. Does your protocol involve toxins or pathogenic microorganisms?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5. Does your protocol require a material transfer agreement (MTA)?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>6. Does your protocol require IBC review/approval?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>7. If IBC Review is required, have you submitted the protocol to the IBC?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>8. If your protocol was submitted to IBC, has it received IBC approval?</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

**Other Assessments**

<table>
<thead>
<tr>
<th>Question</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>9. Have you completed occupation health and safety assessment?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>10. Has your laboratory undergone a laboratory safety inspection (Dr. Nandedkar)?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>11. Do you need a Biological Safety Cabinet (BSC) to carry out your work (Mr. Jackson and Dr. Nandedkah)?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>12. If you respond “YES” to item 11 (need BSC) above, is the BSC currently certified?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>13. Do you need a Chemical Fume Hood (CFH) to carry out your work</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>14. If you respond “YES” to item 13 (need CFH), is the CFH currently certified?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>15. Do you need a Radiation Safety Cabinet (RSC) to carry out your work?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>16. If you respond “YES” to item 15 (need RSC), is the RSC currently certified?</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

**Training/Certification**

<table>
<thead>
<tr>
<th>Question</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>17. Completed Responsible conduct of research training (RCR)? (Needed)</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>18. Completed Institutional Animal Care and Use 101? (Needed)</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>19. Completed Conflict of Interest (COI)? (Needed)</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>20. Completed Biosafety and Biosecurity (B&amp;B) (if protocol needs IBC-approval)</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>21. Completed relevant Veterinary hands-on training (if required)</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
Pre-Application Consultation (Complete within 1 Week of Initiation)

a) Investigators may directly contact all of the following or go to “b”
   - Veterinary services (strongly recommended)**
   - IBC Chair
   - IACUC Chair
   - Laboratory Safety Officer
   - The ORRC

b) Investigator Contacts the ORRC

ORRC coordinates a 30-minute Teleconference – Investigator with:
   - Veterinarian
   - Veterinary Services Manager
   - IACUC Chair/designated expert
   - IBC Chair: Determine whether IBC approval is needed
   - Laboratory Safety Officer: Arrange for lab inspection
   - ORRC staff: Informs PI of the need for occupational health safety evaluation, IACUC/RSC/RCR/COI/Biosafety and Biosecurity training and certification

Investigators’ One-on-one meeting with Veterinarian (Strongly recommended**) and or IACUC Chair or Designated Expert
Pre-Review (no more than 1 - 2 weeks)

- Investigator Submits Application to the ORRC
  - Veterinarian Pre-Review (within 1 week, ≤ 2 weeks maximum)
  - IACUC Chair or Designated Expert Pre-Review (within 1 week, ≤ 2 weeks maximum)
  - Veterinarian/IACUC Chair or Designated Expert Pre-Reviewer returns comments to ORRC
  - Investigator uses comments from IACUC Chair or Designated Expert Pre-Reviewer and Veterinarian comments to enhance protocol
IACUC Review (no more than 6 weeks)

Investigator Officially Submits Protocol to the

IACUC Reviews Protocol (FCR/DMR)

- Protocol is approved
  - Back to IACUC for FCR
  - Protocol is approved
  - Approval Letter Issued by the ORRC (within 48 Hours)
- Protocol needs revision
  - Designated Member Review
  - Approval Letter Issued by the ORRC (within 48 Hours)
<table>
<thead>
<tr>
<th>IACUC/ORRC Member</th>
<th>Office Telephone Numbers</th>
<th>Email Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Emmanuel Akala</td>
<td>202-806-5896</td>
<td><a href="mailto:eakala@howard.edu">eakala@howard.edu</a></td>
</tr>
<tr>
<td>Dr. Doris Hughes</td>
<td>202-806-6296</td>
<td><a href="mailto:dhughes@howard.edu">dhughes@howard.edu</a></td>
</tr>
<tr>
<td>Mr. James Bell</td>
<td>443-865-0913</td>
<td><a href="mailto:James.bell@howard.edu">James.bell@howard.edu</a></td>
</tr>
<tr>
<td>Theorrc (ORRC)</td>
<td>202-865-8597</td>
<td><a href="mailto:theorrc@howard.edu">theorrc@howard.edu</a></td>
</tr>
<tr>
<td>Ms. Elyse Holtz</td>
<td>202-865-8549</td>
<td><a href="mailto:Elyse.holtz@howard.edu">Elyse.holtz@howard.edu</a></td>
</tr>
</tbody>
</table>
IRB Review Process
Post Approval Monitoring
Post Approval Monitoring

- IACUC (is ongoing)
- IRB post approval monitoring
  - Clinical Research Unit (CRU): Research Subject Advocate (RSA)
  - Focus: Prevent non-compliance (not punitive)
Post Approval Monitoring

What Is Need?

Regulatory documents:
- Approval/Expiration dates

Communication with:
- IRB/Sponsor/DSMB

Subject selection and study progress:
- Informed consent obtained and properly documented
- Number approved/enrolled/dropouts/consent withdrawal
- Process: Reviewer observe the informed consent process (?RSA)

Recruitment
- Subjects reimbursement: Consistent with IRB approval
Post Approval Monitoring

**Research Methods**
- Protocol violation/deviation
- Introduction of new procedures (?IRB approval)

**Risks**
- Known risks (frequency/severity of occurrence)
- Unanticipated problems
- Data safety, confidentiality, and security (cabinets, doors, computers)

**Institutional and Investigators’ issues**
- Laboratory space/general support
- Change in leadership
- Lack of support
- Complaints?
Reportable Events
USDA Reportable Events

2 CATEGORIES

- Failure to correct significant program or facility deficiencies by the scheduled date
  
  9 CFR § 2.31 (c)(3)

- IACUC suspension of any animal activity
  
  9 CFR § 2.31 (d)(7)

Jodie Kulpa-Eddy --USDA; Axel Wolff --OLAW; Mary Lou James --Consultant
March 28, 2006
PRIM&R ARENA
OLAW Reportable Events

3 CATEGORIES

• **Serious or continuing** non-compliance with the PHS Policy

• **Serious deviation** from the provisions of the Guide for the Care and Use of Laboratory Animals

• **Suspension** of an activity by the IACUC
The Reporting Structure

IACUC

Reportable event

INSTITUTIONAL OFFICIAL

FULL EXPLANATION

APHIS, OLAW, Funding Agency

Jodie Kulpa-Eddy –USDA; Axel Wolff –OLAW; Mary Lou James –Consultant; March 28, 2006 PRIM&R ARENA
IRB Reportable Events
What The IRB Have to Report to OHRP & FDA

- Unanticipated problems involving risk to participants or others:
  - Any incident, experience or outcome that meets all of the following:
    - Unexpected
    - Related or possibly related to participation in the research
    - Suggests that the research place Human Subjects or others at a greater risk of harm than previously known

- Serious and continuing non-compliance

- Suspensions and terminations
• **Scientific Integrity:**
  - Responsible conduct of research (education and training)
  - **Research misconduct** (plagiarism, falsification and fabrication)

• **IBC:** Inadequate reporting (recent NIH request)

• **Laboratory Safety:**
  - Ongoing inspections
  - Annual cabinet inspections
  - MTA: Plan ahead
Summary of Reportable Events

Collectiveness of IRBs, Researchers and Regulators – Working Together
Export Control
Export controls

Federal laws:
That govern how technology, technical data, technical assistance, and items or materials (from software to satellites and more) are physically or electronically exported, shipped, transmitted, transferred, or shared from the U.S. to foreign countries, persons, or entities.
Export controls: Intent of The Law

- Protects: national security and U.S. foreign policy interests
- Prevent:
  - Terrorism
  - Proliferation of weapons of mass destruction, and
  - Preserve U.S. economic competitiveness
- Penalties for violating these laws:
  - Can be severe, both for the individual researcher and the university.
What is an Export?

In broad terms, an export is:

- Shipment of a controlled commodity, equipment, material, or software outside of the U.S.
- Disclosing controlled technology or technical data to a foreign national, whether in the U.S. or abroad
- Performing technical assistance or defense services for or on behalf of a foreign national, whether in the U.S. or abroad.
- Exports within the U.S. are considered to be “deemed” export to the foreign national’s home country.
What Activities are Subject to Export Control Regulations in Academic Centers?

Export Control regulations apply to all university personnel and visiting scientists whose academic work involves, but is not limited to, the following:

- Activities or research in **controlled areas** (e.g., encryption technology, nuclear technology, chemical/biological weapons, military technologies)
- Activities involving the shipping or taking of equipment, technology, or software overseas
- Activities involving teaching and research collaborations with **foreign colleagues** or the participation or training of foreign nationals here or abroad
- Activities involving **travel or work outside the U.S.**
- Conducting tours of **foreign nationals through research areas**
- Conducting research sponsored by any entity **restricting publication** or participation by foreign nationals
- Activities involving the receipt and/or use of **export controlled information** or technologies from other parties
Fundamental Research Exclusion: What is Excluded from Export Control

The Federal regulations provide a broad exemption from Export Controls for:

- Basic or applied academic research that is normally published and shared with the research community.

- To qualify as “Fundamental Research,” and thus be exempt from export controls:
  - Research must be conducted free of any publication restrictions, access or dissemination controls.

- Caveat to Fundamental Research Exclusion:
  - If a university activity involves an export or deemed export,
    - the university must document that an “Export Control” review and analysis was performed before the export or release of information takes place.
Export regulations


- U.S. Commerce Department – Export Administration Regulations (EAR) (http://www.access.gpo.gov/bis/ear/ear_data.html) - 15 CFR §§730-774

- U.S. Bureau of Industry and Security (BIS) (http://www.bis.doc.gov/)


Scientific Misconduct
**HU Policy and Procedures For Handling Allegations of Scientific Misconduct**

### Responsible Offices
- Office of the President
- Office of the Provost and Chief academic Officer
- Office of Regulatory Research Compliance

### Process
- **Scientific Misconduct Process**
  - **Misconduct Policy Officer**
    - AVP for ORRC
  - **Inquiry board:**
    - 3 Members appointed by the Chair (SMC)
  - **Investigating Board:**
    - 5 Members appointed by the President

### Charges/Allegations
- Misconduct Policy Officer (AVP-ORRC)

### Insufficient evidence to warrant and inquiry (end)
- Inquiry Board
  - Formal investigation warranted
  - Notify funding agency
  - ≤ 120 days

### Enough evidence to warrant an inquiry
- Inquiry Board
  - Formal report to Dean/VP/President
  - ≤ 5 days

### Notify: Respondent/Dean
- ≤ 3 days

### No investigation warranted (end)
- ≤ 30 days from the above

### Decision
- ≤ 120 days
In Closing

• The “LEAST” of the collectiveness of our individual efforts is overwhelmingly better than the “BEST” of our individual efforts.

Thanks