RESEARCH COMPLIANCE ADVISORY COMMITTEE – MEETING SUMMARY
SEPTEMBER 19, 2015

ATTENDEES: Bates, Blazar, Herman, Lawrenz, Legge, Rao, Tranquillo, Voytas, Wolf

MISSING: Campbell, Thompson, Tolar, Wagner

1. AGENDA ITEMS

   - Advancing Human Research Protections
     - Legislative Progress Reporting and Audit Committee update
     - Implementation Proposals Submitted and Approved – RCAC members have access to those proposals on Google Drive
     - December 2, 2015 “Research with Human Participants: The National Debate” Susan Wolf’s conference

   - Update on status of Stem Cell Panel and Dual Use Research of Concern

2. DOCUMENTS REFERENCED

   September 2015 Progress Report
   http://advance-hsr-alerts.umn.edu/2015_09_01_archive.html

   RCAC Google Drive access to implementation work area proposals:
   You need to be logged in with a UMN x.500 to view:
   https://drive.google.com/open?id=0B1H3SzKHlHHHRGFlhVhVNktZDE

   December 2, 2015 “Research with Human Participants: The National Debate” conference agenda

3. OUTCOMES

   Advancing Human Research Protections
     - Legislative Progress Reporting and Audit Committee update
       Regent Omari shared with Vice President that the Legislature is pleased with the reports thus far. As reminder, the progress reports are provided to the Legislature after having been approved by the Regents including the Audit and Compliance Committee.

       On September 10th, Vice President Herman presented progress-to-date activities related to the Advancing Human Research Protections implementation. Board responded positively to the update and reaffirmed their commitment to the original 63 recommendations from the external review.

     - Implementation work area proposals submitted and approved – RCAC members have access to those proposals on Google Drive
       Please look at them, communicate thoughts and questions back to
Brian. Resources are in the process of being assigned but groups can start work. It is only eight days to first deliverable deadline of 09/30/15.

As discussed there has been assignment of RCAC members to the work groups. Feedback from RCAC members:

- It is difficult to engage by periodically joining a meeting, if there are burning questions team lead could meet with RCAC members,
- Would like a targeted RCAC discussion about the IRB projects – which items on list are still open? If there are decisions that haven’t already been made or for which input could be critical RCAC would like to have input
- Regular Lead reports provided at the RCAC meetings would be useful.

Other implementation progress includes:

- External Advisor – David Strauss has been engaged in this role. He will meet with team leads and others which may include this group. At the request of David Strauss, VP Herman will be presenting at the November PRIM&R meeting.
- Community Outreach Board – Board Chair has been chosen, other positions are being filled.
- COMPASS external review of approved protocols –
  - Contract established with COMPASS to audit 100 psychiatric studies
  - HRPP is supporting COMPASS with their reviews.
- All suspended studies in Psychiatry have either been reactivated or closed
- FDA and AAHRPP will be on campus in the coming week. We have been given an “Accreditation pending” status by AAHRPP. AAHRPP has requested quarterly progress reports for a year prior to granting full accreditation.
- Progress has been made on selecting an electronic IRB system. Site visits have been conducted with Penn State and Maryland. One additional visit is planned.

- **Lead report:** Cultivating a Culture of Ethics, Susan Wolf

  - December 2, 2015 “Research with Human Participants: The National Debate” conference will be a ground-breaking event which will include sessions on national best practices. Speakers include high profile experts. The goal to be very inclusive, invite debate. The conference is part of implementation team’s final report – how to ensure research ethics are integrated into DNA of researchers, staff. Susan asked the RCAC members to review the agenda and let her know if there were any of the speakers with whom the RCAC wants to meet?

  - Group has been talking to external ethics culture experts. They have identified a SOURCE 28 question survey that could be used as measure/metrics of an organization’s ethical culture. The survey has been validated across at least five universities

  - Code of Conduct revisions are needed – get top down and bottom up change, do we know what the baseline is? Simple compliance with regs is no longer sufficient. Concerns with
exceeding regulatory requirements were voiced. Too much stringency will drive faculty and trials away.

- Update on status of Stem Cell Panel and Dual Use Research of Concern Policies have been updated and panel members have been identified and charged.

Meeting Adjoumed

4. ANY OTHER BUSINESS ARISING

Additional discussion

- Safety culture in engineering labs—analogous to the issue of ethics and human subjects. As the issue was investigated it became clear that culture was the culprit, not regulations. Practitioners needed to take ownership of the problem. They got funding to implement changes. Post docs and grad students now “own” the process—they formed an organization and manage safety at their level rather than at the faculty level.

- Administrative burden is driving quality researchers away. Can we get people focused not on regulations but on “safety” or “ethics”? This move away from academia is not just here, it is a national trend.

5. ACTION ITEMS

<table>
<thead>
<tr>
<th>Action</th>
<th>Description</th>
<th>Who</th>
<th>When</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Arrange for Debbie Dykhuis, Joanne Billings, and Michele Biros to attend the November meeting</td>
<td>Lisa</td>
<td>11/24/15</td>
</tr>
<tr>
<td>2</td>
<td>Review team proposals on Google Drive</td>
<td>RCAC members</td>
<td>By Nov mtg</td>
</tr>
<tr>
<td>3</td>
<td>Let Susan Wolf know if there are presenters at the December conference that the RCAC wants to meet while they are in town.</td>
<td>RCAC members</td>
<td>ASAP</td>
</tr>
</tbody>
</table>

6. FUTURE MEETINGS

Meetings will be scheduled on a bi-monthly basis. The following meetings were added to member Google calendars:

- Tue, November 24, 2015, 4pm – 5pm
- Tue, January 26, 2016, 4pm – 5pm
- Tue, March 22, 2016, 4pm – 5pm
- Tue, May 24, 2016, 4pm – 5pm

All meetings will be held in 433 Johnston Hall.

Agenda for Next Meeting:

1. Progress reports
2. IRB update from work teams (Debbie, Joanne, Michele)