RESEARCH COMPLIANCE ADVISORY COMMITTEE
MEETING NOTES NOVEMBER 24, 2015


MISSING: Blazar, Campbell, S. Legge, Tolar, Tranquillo, Voytas

1. AGENDA ITEMS

1) Discuss Advancing Human Research Protections Implementation:

   a) IRB Membership and Updates (Debbie Dykhuis, Joanne Billings, Michelle Biros)
      4:00 – 4:30
   b) COI Policy draft discussion (Will Durfee, Lynn Zentner and Jon Guden)
      4:30 – 5:15
   c) Progress report on other work areas (Herman)
      5:15 – 5:30

2) Meeting pre-read materials are attached (IRB Membership and COI policy draft).

Two other draft final reports are attached for comment and future meeting discussion: For Cause Investigations and Research Compliance Office

Past RCAC meeting summaries are available at: http://research.umn.edu/advancehrp/committee.html

2. DOCUMENTS REFERENCED

   Report on IRB Membership
   Report on Research Compliance Office
   Report on For Cause Investigations
   Conflict of Interest revised policy

3. OUTCOMES

Advancing Human Research Protections – Implementation Lead Updates

   a) IRB Membership and Updates (Joanne Billings, Michelle Biros)

   - The U of M must promote measures to increase the value of service on the IRB:
     Senior university officials have been engaged to identify qualified members to serve on the IRB, however in order to promote the value of IRB membership department heads or chairs and senior officials must encourage IRB service by considering it as a contribution during, for example, faculty promotions. Because department heads or chairs are responsible for the day-to-day operations of the department they lead, they are being formally engaged in the request for additional IRB members to ensure consideration for balancing the needs of their department within the overall needs of the institution.

     Considerable discussion ensued with respect to the perceived value of this kind of service to more junior faculty members’ requirements for promotion and tenure and/or annual performance reviews. While the 712 statements endorse a level of community service as a responsibility, decisions on promotion and tenure typically revolve around teaching, research and publications.
Does this type of service (serving on an IRB) put faculty at risk for attaining promotion and tenure? Should revisions to the 712 statements be considered? Senior AHC leadership will need to value service as highly as other productivity areas to maintain faculty involvement.

- **Increase the number of full IRB committees and limit the number of items on each agenda:**
  Four medical IRB rosters have been developed that will more closely align IRB member expertise with submission types. The rosters have been created to ensure compliance with federal regulations as well as accreditation standards. As required by regulations, each of these IRBs will be qualified through the experience and expertise of its members to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants.

- **Increase number of IRB members**
  Thirteen members will be included on each new medical roster and a majority of members must be present during each convened IRB review including at least one member whose primary concerns are in non-scientific areas. Each roster for the newly created IRBs will include: six physician scientists, two scientists, three non-scientists, and two non-affiliated members (Physician Scientist, Scientist, or Non-Scientist). Quorum will require a specific composition of seven members to be in attendance during each meeting.

  *Discussion focused on how best to define a physician scientist and the level of commitment possible given the breadth of responsibilities these people face – providing clinical care, conducting research and advising/teaching medical students. Again, the question of the impact such service could have on the progress toward promotion and tenure arose. IRB Executive Chair, Joanne Billings pointed out that she is in just such a position but feels strongly that this service is a responsibility that all researchers should share and which should be recognized in annual reviews and promotion consideration. Several members of the RCAC members agreed including a former department head who valued and required service along with teaching and research.*

- **Compensate board members**
  Compensation of board members is a critical consideration and should be directly proportional to the scope of work performed, volume of work undertaken, and in correlation to frequency of meeting attendance. It is clear that there will be significant differences in IRB membership commitment between the medical and non-medical committees. Additional evaluation of appropriate rate of compensation for non-clinical faculty who serve on medical and non-medical IRBs is under evaluation as well as whether additional commitment by clinical faculty serving on non-medical IRBs is required before this plan is put into place.
  Clinical faculty board members would be compensated by the U of M through the provision of salary support to their department or division to allow 10 percent protected time. IRB chairs should be compensated by providing salary support to their department or division to allow 25 percent protected time from other responsibilities to serve on the IRB. Community members on all the medical and nonmedical IRBs should be compensated $3-5K yearly, and also receive parking vouchers, and be invited to an appreciation dinner at least once yearly.

  *Discussion focused on what other comparable institutions do and whether or not this has proven effective in developing and maintaining review boards with the depth of expertise and strength of membership numbers. Implementation team considered other institutions and compensation is prevalent at other major research universities.*

- **Scientific Review**
  Ensuring scientific merit is a key component in protecting the rights and welfare of human research participants. Changes with respect to scientific review include elimination of the department led peer review process, engagement of additional expertise by scientific members of the IRB, and revisions to the Human Research Protection Program (HRPP) managed scientific review process and corresponding policy.
In alignment with the work plan recommendations and external panel report the minutes recording process for convened IRB review was revised to incorporate deliberate documentation of the IRB’s assessment of the acceptability of the scientific review. During each IRB deliberation of new applications that are greater than minimal risk, the IRB is prompted to discuss and document its conclusion of the acceptability of the scientific assessment. The process for verifying the acceptability of the scientific assessment is one critical step in the IRB’s review of each application.

b) COI Policy draft discussion (Lynn Zentner and Jon Guden)

- Extensive vetting of the policy has been undertaken across the institution, faculty governance and benchmarking of other institutions. Two comparable institutions were found with similar COI policies: Mayo and UC San Francisco.
- This was policy decision endorsed and put forward by Implementation Team, the institution has to decide the scope.
- The implementation team did not discuss institutional COI. A separate team has been looking into this.

**RCAC discussion points and questions included:**

- **Proposed policy provides no opportunity for exception. What if expertise is so unique or specialized it cannot be obtained elsewhere (inventor/investigator)?** Should uniqueness alone engender exception? There must be some way to appeal – everything cannot be anticipated. Implementation Plan allows exception, policy does not.
- **What if a department head is running a study, where would funds go then to provide balance and manage potential conflict?**
- **Need to have check and balance, an independent person/entity to review potential conflicts.**
- **What are unintended consequences?**
- **Would researchers do the work without receiving the funds?**
- **This could interfere with the science.**
- **What is wrong with current policy? Is it just a response to bad publicity? Institution needs to determine how to preserve good people doing good things.**
- **How big a problem is this now? In 7.5 years there have been two bad eggs.**
- **Nothing is broken in the system now, industry is changing as well, more clearly discriminating between research conversations and consulting conversations.**
- **Legislative Auditor thought conflicts were inherent. Can B&I research be done in ways that are not coercive? Based on how clinical trials get patients, enrollment serves as an income generator, again, need to bench mark best practices at comparable institutions. Was his point institutional conflict or individual conflict.**
- **If public is concerned that enrollment is inappropriate because of COI, how can we provide education and clarity.**
- **What are the rules for publication?**

**RCAC Member Recommendations:**

- Additional benchmarking of public and private institutions of comparable size and complexity needs to occur.
- Feedback from clinical scientists should be sought – Herman and Jackson should facilitate these meetings and discussions.
- AAMC should be consulted
- Consultation with faculty should continue

c) Progress report on other work areas (Herman)

Time did not permit this discussion.
4. ANY OTHER BUSINESS ARISING
None

5. ACTION ITEMS

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<td>1</td>
<td>See RCAC recommendations above related to COI</td>
<td>Lynn, Jon</td>
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6. FUTURE MEETINGS

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

- 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:

- Advancing Human Research Protections progress report
- Use of Fetal Tissue in Research