Establish Research Compliance Office

Advancing Human Research Protection

Pamela Webb, Lead
Sarah Waldemar, Staff
September 30, 2015
EXECUTIVE SUMMARY

Background & Approach
The Advancing HRP report recommended the creation of a Research Compliance Office within the OVPR, with responsibility for:

1. Investigations into allegations of investigator noncompliance or ethical violations;
2. Review of data on consent/ongoing capacity to consent determinations for vulnerable populations;
3. Targeting of studies that may be appropriate for post-approval review;
4. Monitoring follow-through on recommendations for changes in study procedures;
5. Communication to departmental and collegiate leadership about IRB follow-up to PAR reports;
6. Independent oversight of research participant satisfaction surveys and reported concerns.

The recommendations contained in this report considered all of these items. The group was also asked to provide recommendations that include the larger context of research compliance, including similar types of activities relevant to animal subjects and institutional biosafety.

In working toward the recommendations in this report, the staff interviewed 19 key university stakeholders (See Appendix 3), and considered various organizational structure and placement models, including benchmarking of 10 other universities (See Appendix 3 and Appendix 5) over the course of the seven week period of August 10 through September 30, 2015.

Workgroup Goals
The workgroup was tasked with making recommendations to the Vice President for Research to:

1. Identify the functional scope of duties of the proposed Research Compliance Office (hereafter referred to as “RCO”);
2. Identify organizational structure and placement for the RCO
3. Create an action plan for initiating the RCO
4. Hire staff and launch the RCO

This report covers the first three items listed above; the remaining item will be addressed following approval or refinement of the report’s recommendations.

Summary Recommendation:

RECOMMENDATION: The OVPR should create a Research Compliance Office (RCO) responsible for for-cause investigations, institutional oversight (but not conduct) of related quality assurance activities, institutional oversight of research compliance training and training infrastructure, and the functions currently assigned to Research, Education and Oversight. In addition, RCO should be assigned responsibility for tracking and reporting of institutional research compliance data and cross-topical/unit trend analysis. OVPR can best accomplish these goals via changes in certain organizational reporting within the division and adding resources necessary to staff the office.

See Appendix 1 for Organizational Placement for the RCO
See Appendix 2 for the Staffing for the RCO
The Advancing HRP report recommended that the new RCO be responsible for:

1. Investigations into allegations of investigator noncompliance or ethical violations;
2. Review of data on consent/ongoing capacity to consent determinations for vulnerable populations;
3. Targeting of studies that may be appropriate for post-approval review;
4. Monitoring follow-through on recommendations for changes in study procedures;
5. Communication to departmental and collegiate leadership about IRB follow-up to PAR reports;
6. Independent oversight of research participant satisfaction surveys and reported concerns.

We recommend that the RCO be responsible for most of these activities, but believe that certain activities can best be performed by the individual compliance offices/committees responsible for protocol review or ongoing monitoring. Specific responsibilities should be assigned as follows:

**FOR-CAUSE INVESTIGATIONS**

Recommendation: The new Research Compliance Office should be assigned responsibility for conducting For-Cause Investigations for financial compliance on sponsored projects, as well as for-cause investigations related to human participants, animal subjects, and institutional biosafety issues. This should include any investigations arising from DURC or Stem Cell research.

It is not expected that for-cause investigations will overlap with scientific misconduct investigations, but we recommend that the AVP Lawrenz be informed of the existence of any for-cause investigations (note that bi-directional communication may not always be possible given privacy expectations on scientific misconduct inquiries/investigations).

Specific recommendations regarding For-Cause investigations are detailed in a separate document (See Sarah Waldemar’s report on For-Cause Investigations). It is estimated that the total annual volume of such investigations, based on peer institutions, will be 10 or fewer per year. [Last year, UMN had 3 human subject related for-cause investigations]. Because of sensitivity, duration and intensity, and based on feedback provided by the institutions we benchmarked, the staffing needed to manage the investigative process can be expected to be .50 to .75 of one FTE, with lead responsibility assigned to the Director of RCO. Other RCO staff would assist in investigative support activities.

For-Cause Investigations would include:

- Issues forwarded from the IRB, IACUC, IBC, DURC or SCRO committee because the alleged failure exceeds in frequency or severity that which is typically handled in a post-approval review/monitoring activity.
- Issues arising from external complaints (U Report complaints, complaints from staff, other faculty, patients, outside the U, etc.)

The RCO should be expected to work closely with any involved compliance committee to ascertain facts, take advantage of topical expertise, and to determine whether there are qualified University or Fairview non-conflicted individuals who could serve on an investigative committee. In most cases, it would be expected that a member of an applicable compliance committee (IRB, IACUC, etc.) would serve as a full member or, at minimum, as an ex officio member of the investigative committee. Investigative committees should be comprised of internal members when sufficient qualified individuals are available to provide a timely, fair and appropriate review. When applicable, a Compliance Committee would have first action responsibility to consider and act on the recommendations of a For-Cause Investigation. This would be followed by any additional action deemed necessary by the Vice President for Research.
QUALITY ASSURANCE ACTIVITIES

RECOMMENDATIONS: Except for Biosafety, responsibility for conducting quality assurance activities (PAR and PAM) should be retained in the respective administrative compliance office and compliance committee responsible for those protocols. This includes monitoring follow-through on recommendations they have made as a part of their post-approval review process. The RCO should play an active oversight role, conducting an annual review and approval of each unit’s monitoring plan before it is undertaken, as well as performing periodic monitoring throughout the year to document progress made against such plans. In addition, RCO should assist CTSI in their task of identifying all trials needing regulatory review, and receive data from CTSI’s monitoring efforts. The results of these reviews should be incorporated into RCO’s institutional trends and communications.

ADDITIONAL SUGGESTION: Compliance Offices should consider whether “administrative pre-review” or “concurrent review” of some or all of their protocols could be expected to result in fewer stipulations and/or a reduction in post-approval findings identified in PAR/PAM review. It should be noted that additional administrative resources would almost certainly be required to undertake such an activity, but that it may be in the institutional best interest to perform such reviews – at least on certain types of protocols.

Concerns were voiced during some of our interviews about the current processes for selecting studies (randomized, risk-based, extent of coverage) to undergo post-approval reviews, as well as the limited numbers of reviews in the human subjects area. This limitation may be a function of the resources previously available for this function. No concerns were raised about the quality of the reviews themselves. Post-approval monitoring per se is not routinely occurring for institutional biosafety protocols. We believe that post-approval monitoring should be conducted for institutional biosafety protocols and DURC protocols, but this can probably best be performed by the office already responsible for lab safety reviews – University Health & Safety. RCO should work with University Health & Safety and the Institutional Biosafety Office and Committee to devise an appropriate monitoring strategy. It may be necessary to invest OVPR or UHS resources to ensure this monitoring is able to occur.

An exploration of the data provided by our 10 peer institutions identified a wide range in the selection process, content, numbers, and institutional staffing for post-approval review and monitoring processes. The range was sufficiently broad that no definitive pattern or baseline “average” was readily available. Several institutions seemed to aim for a total of 5-10% of their active protocols to undergo a post-approval review each year. Additional insight is expected to be available when Debbie Dykhuis releases her Refining PAR report at the end of 2015.

RCO, assisted by Internal Audit, should guide selection methodology and provide data analysis support to compliance offices/committees. Specifically, RCO should be involved in selecting an appropriate design strategy (random, stratified risk-based, extent of review coverage decisions, etc.) and collect/distribute information about national trends and good practices. RCO should be responsible for determining adequacy of each compliance office/committee’s annual monitoring plan to meet institutional oversight objectives. These decisions must be made within the context of staffing available in the compliance offices to undertake monitoring; any resource shortfalls must be resolved, an alternative acceptable plan adopted, or a determination must be made to accept risk. Each individual compliance office/committee should remain responsible for selecting the actual studies to be reviewed, for determining the content of the review and for deciding on appropriate regulatory responses to the results of each review, as well as engaging in follow-up to determine whether appropriate action was taken. Keeping post-approval reviews/monitoring in the compliance offices/committees has the added benefit that each office/committee will be more likely to be viewed as a form of “assistance” to investigators, rather than “enforcement.”

Throughout the year, quality assurance and regulatory review data should be furnished to RCO and available to verify that annual monitoring plans are proceeding normally (or to help understand and proactively manage where
barriers exist), as well as to allow RCO to perform trend analysis, and institutional reporting. Aggregated data must in turn be shared back with the relevant compliance committees as well as other oversight groups.

We noted that CTSI is performing regulatory clinical research and clinical trial monitoring of investigator-initiated clinical research and clinical trial monitoring. As of September 2015, 206 regulatory review visits have occurred on approximately 95 studies, within a total population of 260 studies. This process is staffed by 4 FTE, including 1 Director. It is the goal of CTSI to visit each study at least once per year (100% coverage) to provide regulatory monitoring and to provide advice/assistance to investigators about their oversight programs. There is some overlap with PAR monitoring activities. CTSI is already providing individual reports on each review to the IRB on these reviews, but the ability to aggregate data from the reviews has not existed in the past. A new “Monitoring Tool” deployed by CTSI in July 2014 may allow data aggregation in the future; CTSI review data should also be furnished to RCO and used in the same way as PAR/PAM data to better understand institutional trends and to provide analysis support to the CTSI. We also learned that CTSI does not have a single, reliable “source of truth” to enable them to confidently identify all the studies that they are reviewing – though there have been recent improvements in study identification. RCO should assist CTSI with ensuring institutional pathways exist to correctly identify the core data CTSI requires to fully perform its review function.

**COMPLIANCE REPORTING**

**RECOMMENDATIONS:** RCO should undertake collection, analysis and institutional reporting on the Accountability Metrics. Included should be cross-functional analysis to understand where challenges may exist across functional boundaries. In addition, RCO should track the results of research participant satisfaction surveys performed by others, as well as trend analysis for use by FUROC and other institutional oversight committees. RCO should continue to perform the compliance reporting already in the REO portfolio.

One new institutional opportunity afforded by enhanced compliance reporting is the ability to do cross-functional reviews. For example, a researcher who has struggled with record keeping related to animal research may also be at risk for unallowable or inappropriate expenditures from project funds. Linking these data points will provide a more robust risk mitigation process as well as opportunities for educating researchers and staff.

Additional compliance reporting, referred to as Accountability Metrics, is covered in a separate document. According to the workplan, accountability metrics need to be developed to monitor and ensure the changes put in place via the implementation teams’ work are meeting the expectations of research participants, the U of M community, and our partners. Metrics can also facilitate continued quality improvement.

Some of these represent additions or modifications to data collection activities which are ongoing (IRB Membership, IRB Protocol Review Process) and can be accomplished almost immediately. Some will require developing data collection and study monitoring plans with the compliance offices/committees to ensure the monitoring efforts are conducted on a stratified sample of studies as well as inclusion of targeted reviews (new faculty, IND/IDE, vulnerable populations, etc.).

Work will also include process development for the RCO to access, analyze and report on the CTSI data collection related to the Department of Psychiatry, and Engaging Research Participants. Methods and communications regarding the requirements related to education of Investigators will be developed and registration and reporting processes streamlined to facilitate compliance.

**RESEARCH EDUCATION**

**Recommendations:** RCO should be assigned responsibility to coordinate and ensure tracking of research training across the university, be the liaison between the research training providers across the University (including CTSI) and externally and institutional education tracking and monitoring systems. In addition, RCO should monitor institutional training practices and tools of our peer institutions and provide recommendations to local research training providers.
At the time of this report the new processes related to research education requirements, delivery, content, and monitoring are not available, and thus no specific recommendations can yet be included. This function has the potential to be the single largest component of the RCO office. The REO office currently has responsibility for the provision of Responsible Conduct of Research and the ethics training required by NSF and USDA/NIFA. It is assumed that these functions will be subsumed into RCO. REO also facilitates the provision of CITI training related to human participant research on multiple topics (basic, refresher, GCP, etc.). The RCO workgroup will work closely with the Education and Training of Researchers workgroup to assist in ensuring research education training requirements are available to researchers in a clear, consistent manner and that monitoring and reporting compliance with training requirements can be accomplished with minimal burden.

GOAL 2: ORGANIZATIONAL STRUCTURE AND REPORTING

Reporting lines were examined at 10 peer institutions to determine if there is a preferred mode for the reporting of a Research Compliance Office; to determine the scope of Research Compliance Offices and whether that scope of responsibility correlated to their reporting relationship; whether there were any known organizational advantages or disadvantages associated with harmonizing the reporting of Compliance Committee offices (IRB, IACUC, IBC) and that institution’s Research Compliance Office; and to determine the typical level of the institutional official to which such offices report.

The 10 peer institutions included Harvard University Medical School, the University of Indiana, Case Western Reserve University, University of Maryland, Penn State University, Emory University, Duke University, University of Iowa, University of Michigan, and the University of Chicago. Institutions were selected because they were known to have active compliance programs and/or were large, complex organizations that were willing and able to share their information within the time frame available.

Organizational Reporting - Research Compliance Office.

There proved to be a myriad of organizational pathways for organizational reporting for Research Compliance Offices. No clear preferred model emerged, though all offices reported to a senior, central official (Associate VP or higher). Of the institutions reviewed, all had some form of a Research Compliance Office. These offices reported variously to a Vice President for Research (6), to an Associate or Assistant Vice President for Research (3), or to another senior institutional official (1). Likewise, there did not appear to be a clear preferred model for reporting lines for IRB, IACUC and IBC offices. Some reported to a Research Compliance Office, others had different reporting lines. Our conclusion was that the University of Minnesota should feel comfortable selecting an organizational reporting model for its new Research Compliance Office that best meets its internal needs, provided that the following occurs:

- The model selected has the active and visible support of the Vice President for Research and the Vice President for Health Sciences
- The office reports to an Associate Vice President or higher

The organizational reporting model shown in Appendix 1 was chosen after internal discussions with the Vice President for Research.

It should be noted that regardless of reporting lines for associated administrative offices, the faculty-run Compliance Committees committees (IRB, IACUC, IBC, DURC, SCRO) must continue to have direct access to the Vice President for Research in his capacity as the University’s institutional official.
GOAL 3: CREATE AN ACTION PLAN FOR INITIATING THE RCO

ORGANIZATIONAL STEPS
The organizational reporting reflected in Appendix 1 and the organizational staffing for the RCO reflected in Appendix 2 represents significant change from the status quo. We therefore recommend the following:

1. The recommendations in this report should be accepted, or refined. If refined, the organizational reporting structure, organizational chart, and list of functional responsibilities will need to be reviewed and refined to match the changes requested, and then final approval for launch obtained.

2. The organizational reporting structure impacts the direct reporting or structure of a number of OVPR units in addition to the creation of RCO. The Vice President for Research or his delegate should allow a period of time (at least 1 week) and assign internal responsibility for notifying each impacted unit of the changes. The Research Education and Oversight Office staff should be the first office notified. This step should be performed before any public posting of the organizational changes.

3. The AVP assigned responsibility for RCO should initiate the hiring process for the Director soon thereafter. A draft job description exists (see Appendix 4); that description/level should be finalized, and classified by HR, and a search committee formed. The search committee should include key stakeholders.

4. Space and budget for RCO should be determined following consultation with the Chief of Staff and the OVPR Finance Director.

RCO STAFFING
The recommended organizational chart for RCO can be found in Appendix 2.

A preview of the forthcoming report on the responsibilities and effectiveness of the Research Education and Oversight Office, and well as discussions with benchmarked schools and internal stakeholders interviewed for this report indicated what resources may be needed to perform the functions described in this report. There was support for the main financial compliance oversight and education functions currently housed in the REO continuing. There were also indications that this office is not currently fully deploying its approved resources. This means that some (but not all) of the staffing needed to perform the additional responsibilities noted in Appendix 2 can be absorbed through deployment of already-approved resources:

The main additive functions for RCO (beyond that already provided by REO) are as follows. These additional responsibilities are expected to be significant:

- Research compliance coordination with other U compliance units (Internal Audit, Institutional Compliance, CTSI)
- For-Cause Investigations (estimated to be .5 - .75 FTE)
- Oversight of QA monitoring plans and progress of responsible offices (PAR, PAM, CTSI, IBC)
- Accountability metrics and reporting, including cross-unit reporting
- OVPR Business lead for institutional education/training technical infrastructure & interfaces to OVPR/other systems
- Oversight of research education

The additional recurring staffing needed to perform these functions is viewed as follows:

- One FTE Director (at Director 1 level) – approximate salary of $115,000
- Wise use of current vacant position ($41,000 salary available, will probably need another $20,000-25,000)

It should be noted that the modesty of this staffing request reflects both the need to better deploy existing resources and the fact that certain data are not yet available. Specifically, the Refining PAR report is not due until December 2015, and the Accountability Metrics report and the Education and Training of Investigators report are
not due until June 2016. Without the data contained in those reports, it is not possible to finalize staffing needs for the RCO. However, those reports can inform any additional revisions to these numbers. Hiring for the current vacancy in REO would likely be delayed for a few months until the best use/level of that position can be determined. Recruitment for the Director position would proceed quickly after approval of these recommendations (see below.)

GOAL 4: HIRE STAFF AND LAUNCH THE RCO

This goal will be undertaken following approval or refinement of the recommendations in this report, and completion of Goal 3. A portion of this process should involve establishing short-term goals for the RCO (for the remainder of FY16) soon after the hiring of the Director.
Appendix 1
Research Compliance Office

AVP Webb

Research Compliance

COMPLIANCE OVERSIGHT
- Research Compliance Coordination among other U Compliance units (Internal Audit, Institutional Compliance, CTSI)
- For Cause Investigations
- Oversight of QA Monitoring performed by other offices (PAR, PAM, CTSI, IBC)
- Financial Monitoring
- Accountability Metrics & Reporting, including Cross-Unit Trending
- Ad Hoc Member of IRB, IACUC, IBC Committees

- 1 FTE (Director)
- 1 FTE (Sarah Waldemar)
- 1 FTE (David March)
- 1 FTE (Mary Olsen)
- 1 FTE (Rachel Rud)
- 1 FTE (Vacant)
- .5 FTE (Nicole Herbenson)

EDUCATION OVERSIGHT
- CA PROGRAM
- Education/Training Technical Infrastructure & Interfaces
- Oversight of Research Education (HRPP, IACUC, IBC, SPA, SFR, CTSI)
- Provision of Research Education (RCR and NSF/USDA)

50% of one existing FTE in REO is currently paid for by Fairview to conduct oversight; it is assumed that this arrangement will continue unchanged
### Establish Research Compliance Office

**Advancing Human Research Protection**

**Key Stakeholder Interviews and External Contacts**

<table>
<thead>
<tr>
<th>Institution/Affiliation</th>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harvard Medical School</td>
<td>Ara Tahmassien, Chief Research Compliance Officer and Pam Caudill, Chief of Research and Administrative Operations</td>
</tr>
<tr>
<td>University of Indiana</td>
<td>John Baumann, Executive Director, Human Research Protection Program</td>
</tr>
<tr>
<td>Case Western Reserve University</td>
<td>Kim Volarcik, Executive Director, Research Compliance</td>
</tr>
<tr>
<td>University of Maryland</td>
<td>Joseph Smith, Manager, Research Compliance Office</td>
</tr>
<tr>
<td>Penn State University</td>
<td>Debra D. Thurley, J.D. Director of Research Compliance Office for Research Protections, Sarah Horn, IRB Director, Josie Lyan, Justin Snyder, IRB Quality Assurance</td>
</tr>
<tr>
<td>Emory University</td>
<td>Kerry Peluso, Assoc. VP-Research Administration</td>
</tr>
<tr>
<td>Duke University</td>
<td>Tina Tyson, Chief Ethics and Compliance Officer</td>
</tr>
<tr>
<td>University of Iowa</td>
<td>Michele Countryman, Interim Director, IRB Human Subjects Office</td>
</tr>
<tr>
<td>University of Michigan</td>
<td>Terry VandenBosch, Managing Director, Office of Human Research Compliance Review</td>
</tr>
<tr>
<td>University of Chicago</td>
<td>Mike Ludwig, Associate Vice President, Research</td>
</tr>
</tbody>
</table>

### University of Minnesota and Affiliates

<table>
<thead>
<tr>
<th>Institution/Affiliation</th>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal Audits</td>
<td>Gail Klatt</td>
</tr>
<tr>
<td>Internal Audits</td>
<td>Al Willie</td>
</tr>
<tr>
<td>Internal Audits</td>
<td>Kelly Kuhns</td>
</tr>
<tr>
<td>Human Research Protection Program</td>
<td>Debry Dykhuis</td>
</tr>
<tr>
<td>Human Research Protection Program</td>
<td>Linnea Anderson</td>
</tr>
<tr>
<td>Human Research Protection Program</td>
<td>Felicia Mroczkowski</td>
</tr>
<tr>
<td>Institutional Animal Care and Use Committee</td>
<td>Cory Goracke Postle</td>
</tr>
<tr>
<td>Institutional Animal Care and Use Committee</td>
<td>Kristin Pilon</td>
</tr>
<tr>
<td>Research Compliance Advisory Committee</td>
<td>John Wagner</td>
</tr>
<tr>
<td>Research Animal Resources</td>
<td>Mark Suckow</td>
</tr>
<tr>
<td>Vice President for Research</td>
<td>Frances Lawrenz</td>
</tr>
<tr>
<td>Institutional Compliance</td>
<td>Lynn Zentner</td>
</tr>
<tr>
<td>Office of General Counsel</td>
<td>Barb Shiels</td>
</tr>
<tr>
<td>Clinical &amp; Translational Science Institute</td>
<td>Jennifer Cieslak</td>
</tr>
<tr>
<td>Clinical &amp; Translational Science Institute</td>
<td>Lisa Johnson</td>
</tr>
<tr>
<td>Clinical &amp; Translational Science Institute</td>
<td>Kathy Mischke</td>
</tr>
<tr>
<td>Research Education and Oversight</td>
<td>Sue Richards</td>
</tr>
<tr>
<td>Fairview Research Administration</td>
<td>Jill Cordes, Director</td>
</tr>
<tr>
<td>Fairview Health Services</td>
<td>Carolyn Williams, CEO</td>
</tr>
</tbody>
</table>
SAMPLE JOB DESCRIPTION

The leadership qualities for this position include:

1. ability to build credibility with faculty
2. ability to manage complex processes and groups of people
3. ability to provide a conduit between the research business units and the Office of Institutional Compliance
4. broad knowledge of the research enterprise; extensive knowledge of research regulations

**Director of Research Compliance**

The Office of the Vice President for Research seeks a Director for its Research Compliance Office to provide independent oversight of its units and to collaborate with units across the system:

- to ensure that the University employees are educated in policies, procedures, and legal requirements relevant to research
- to aid in the development and enforcement of research related policies
- to provide oversight of OVPR research services
- to manage the processes and personnel involved in the research integrity and oversight functions
- to work with others to coordinate U wide research integrity and oversight functions
- to develop a culture where members of the University view research integrity and oversight as reinforcing their activities.

The successful candidate should have experience with University research environments; at least five years of experience with research compliance including familiarity with compliance regulations; exceptional management, interpersonal, verbal, and writing skills.

Preferred qualifications include:

- a post baccalaureate degree
- experience working with research compliance in higher education settings
- experience dealing with regulators
- experience developing and using data systems to inform management
- demonstrated ability to:
  - work effectively with others to achieve goals,
  - supervise employees,
  - adapt to changing environments and
  - prioritize among multiple demands.
Key Documents

The following documents are available on the Google Drive:
https://drive.google.com/a/umn.edu/folderview?id=0B2Ox93wkKsapb2xHZ0ExUkQyX0k&usp=sharing

RCO Matrix

Benchmarking - RCO and For Cause

Organizational Charts:

1. Harvard Medical School
2. University of Indiana
3. Case Western Reserve University
4. University of Maryland at College Park
5. Penn State University
6. Emory University
7. Duke University
8. University of Iowa
9. University of Michigan
10. University of Chicago
11. SUNY Stony Brook
12. University of Washington, St. Louis

Collins Review 2015 U of M Final

CTSI SOP 202.1 Monitoring Plans signed copy