IN AUGURAL AHRP ACCOUNTABILITY METRICS
RESEARCH COMPLIANCE OFFICE

Abstract
A description of the baseline set of accountability metrics for the human participant enhancements proposed by the Advancing Human Research Protection workgroups and adopted by the Vice President for Research in November 2016. Implementation of these metrics is expected to occur in FY17 and FY18 as data becomes available with the rollout of updated electronic systems and business processes.

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The Research Compliance Office would like to take this opportunity to thank the Human Subjects Protection Program and the AHRP Workgroups for their valuable contributions and review of these metrics.
EXECUTIVE SUMMARY – INAUGURAL AHRP ACCOUNTABILITY METRICS

In August 2016, the Research Compliance Office (RCO) was asked to review the final reports of all the Advancing Human Research Protection (AHRP) workgroups to extract metrics they identified as important for the periodic evaluation of progress in their topical area. In addition, RCO was tasked with comparing those metrics with those contemplated in the original AHRP implementation report to identify any gaps or any discrepancies. In a number of cases, RCO contacted the work groups to clarify requirements or to resolve metric overlap.

The following metrics are planned for implementation in FY17 and FY18 as data becomes available, except one item noted as being on hold. If future enhancements were identified by a work group, those plans are noted in the individual metric.

<table>
<thead>
<tr>
<th>ACCOUNTABILITY METRICS SUMMARY</th>
<th>Page(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. For-Cause Investigations</td>
<td>3</td>
</tr>
<tr>
<td>Statistical data about the volume, types, sources, and outcomes of for-cause investigations conducted by RCO under the University’s For-Cause Investigations policy, as well as recommendations arising from those results that have received attention or require future attention.</td>
<td></td>
</tr>
<tr>
<td>2. Conflict of Interest Exceptions – Human Participant Studies [On Hold]</td>
<td>4</td>
</tr>
<tr>
<td>The report will include statistical data about the number of exceptions granted by the Conflict of Interest Program to the planned new COI policy to allow an investigator who participates in an open human participant research study to have personal remuneration from or equity in the same company. This metric will evaluate both the volume, type and the circumstances under which exceptions are sought and granted, existence of any current or potential external sales agreements, as well as any instances of non-compliance. <strong>NOTE: This metric cannot be implemented until the new COI Policy is approved; and that approval is currently on hold due to the Status Quo Order.</strong></td>
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<tr>
<td>3. Education and Training of Investigators involved in Human Participant Studies</td>
<td>5</td>
</tr>
<tr>
<td>Statistical data about the CTSI courses offered, training requirements by role, and the completion records by individual and role. Additional data collected by HRPP will include automatic and self-reporting of class completion, IRB training sessions offered, and the number of attendees. This metric will also identify targeted training and education needs that are determined based on PAR findings. The number and type of education and outreach activities (newsletters, presentations, webinars, website enhancements, online courses, participation in or attendance at annual UMN conference) will be captured. Feedback will be collected for outreach activity (newsletter) and trainings.</td>
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<tr>
<td>4. IRB Membership</td>
<td>6</td>
</tr>
<tr>
<td>Statistical data about IRB member meeting attendance, IRB member departmental and specialty representation, as well as the member and chair compensation model and compensation practice for a given year.</td>
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</tr>
<tr>
<td>5. IRB Protocol Review Process</td>
<td>7-8</td>
</tr>
<tr>
<td>Statistical data about the protocol review process including the numbers and type of submissions, types of reviews, turnaround times, committee member workloads, and IRB Final Approval survey results.</td>
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<tr>
<td>6. Scientific Review of</td>
<td>9</td>
</tr>
<tr>
<td>Statistical data related to scientific reviews conducted via HRPP’s</td>
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<tr>
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<tr>
<td><strong>Studies</strong></td>
<td></td>
</tr>
<tr>
<td><strong>7</strong></td>
<td>Monitoring of Studies</td>
</tr>
<tr>
<td><strong>8</strong></td>
<td>Research with Vulnerable Populations</td>
</tr>
<tr>
<td><strong>9</strong></td>
<td>Monitoring of Department of Psychiatry Studies</td>
</tr>
<tr>
<td><strong>10</strong></td>
<td>Engaging Research Participants</td>
</tr>
<tr>
<td><strong>11</strong></td>
<td>SOuRCE Survey</td>
</tr>
</tbody>
</table>
### METRIC #1: FOR-CAUSE INVESTIGATIONS

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<td>Related AHRP Group(s):</td>
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#### Summary

The report will include both statistical data about the volume, types, sources, and outcomes of for-cause investigations conducted under the University's For-Cause Investigations policy as well as recommendations arising from those results that AHRP Work Groups, Compliance Committees, or RCO note have already received attention or require future attention.

#### Details

1.1. Statistical data to be captured include:
   1.1.1. Total # of research compliance cases reported, by type (e.g., human, animal, biosafety, sponsored/financial\(^1\)); by origin (e.g., compliance committee, individual reporter, assigned by VPR); by campus; by department
   1.1.2. Actions taken on those cases (remanded to another office, accepted for investigation, declined for review and why)
   1.1.3. Whether or not each case required use of an investigative committee
   1.1.4. Outcomes of each case, including the # of allegations made, # of findings, # of findings resolved
   1.1.5. Timeliness of reviews and followup on findings

1.2. Analysis will include:
   1.2.1. Observations on trends identified
   1.2.2. After the first year, observations on upward or downward trends
   1.2.3. Itemization of actions already taken by compliance units
   1.2.4. Recommendations for any potential future action that the Research Compliance office or a compliance unit believes should be taken

#### Satisfies Metrics Contained in AHRP Report?

Yes, except for “# of individuals required to complete an investigation.” This was not seen as a useful number to track.

\(^1\) This metric includes both human participant cases and cases involving the other research compliance areas noted above.
Summary
The report will include statistical data about the number of exceptions granted by the Conflict of Interest Program to the planned new COI policy to allow an investigator who participates in an open human participant research study to have personal remuneration from or equity in the same company. This metric will evaluate both the volume, type and the circumstances under which exceptions are sought and granted, existence of any current or potential external sales agreements, as well as any instances of non-compliance.

NOTE: This metric cannot be implemented until the new COI Policy is approved; and that approval is currently on hold due to the Status Quo Order.

Details
2.1. Statistical data to be captured include:
   2.1.1. Total # of external sales agreements and exceptions approved by the Conflict Review Panel
   2.1.2. Documentation for circumstances leading to exceptions
   2.1.3. Total # of instances of non-compliance found
   2.1.4. Number of exceptions requested
   2.1.5. Direct or current payment
   2.1.6. Stock options or other forms of future or potential income
   2.1.7. Industry involvement (derives funding from related business interests)
   2.1.8. Actions taken on those cases to include actions taken by OIC and the College involved
   2.1.9. Timeliness and type of corrective action

2.2. Analysis will include:
   2.2.1. Observations on trends identified
   2.2.2. After the first year, observations on upward or downward trends
   2.2.3. Recommendations for any potential future action that the Office of Institutional Compliance believes should be taken

Satisfies Metrics Contained in AHRP Report?
Not applicable, as no specific metrics were identified. The tracking and addressing of non-compliance has not been implemented yet, since the updated policy is pending. Further discussions will need to take place to confirm how the reporting would be disseminated for exceptions and external sales as well as a timeline for implementation and reporting on instances of non-compliance.
METRIC #3: EDUCATION AND TRAINING OF INVESTIGATORS INVOLVED IN HUMAN PARTICIPANT STUDIES*

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<td>Related AHRP Group(s):</td>
<td>Education &amp; Training of Investigators, HRPP, Department of Psychiatry</td>
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Summary
The report will include statistical data about the courses offered, training requirements by role, and the completion records by individual and role (CTSI). This report will also include training completions including types of training and attendee numbers, education and outreach activities (such as participation in and/or attendance at annual conference), PAR directed training and feedback on outreach and training (HRPP).

Details
3.1. Statistical data to be captured by CTSI for their courses include:
   3.1.1. Training opportunities and requirements by role
   3.1.2. Training completion records including date of completion and scores of competency-based training modules
   3.1.3. Number of people who tested out of some training with a score above 90%; number of people who require additional one-on-one mentoring for those who score below 60%*

3.2. Statistical data to be captured by HRPP report, dashboard or website include:
   3.2.1. Data are collected by automatic reporting to the U of M upon completion of a class or by self-reporting (HRPP Metric #124)
   3.2.2. IRB training sessions delivered and number of attendees (HRPP Metric #13)
   3.2.3. Education & outreach activities and estimated audience (e.g., newsletters, presentations, webinars, website enhancements, online courses) (HRPP Metric #14)
   3.2.4. Research Community Newsletter open-rates (HRPP Metric #15)
   3.2.5. Feedback received on HRPP newsletter and trainings (HRPP Metric #16)
   3.2.6. Summarize PAR review findings to identify targeted training and education needs (HRPP Metric #46)
   3.2.7. # of researchers that have completed required human subjects training (HRPP Metric # 125)

3.3. Analysis will include:
   3.3.1. Tracking of fulfilled training requirements and unfulfilled requirements by role
   3.3.2. Trending of PAR directed training
   3.3.3. Feedback for education and outreach as well as training

Satisfies Metrics Contained in AHRP Report?
Yes as this identifies training requirements and offers training for investigators as well as other staff.

*This metric is about training for investigators, but data about staff training will also be included where available.
METRIC #4: IRB MEMBERSHIP

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<td>IRB Membership</td>
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Summary
This report will include data about IRB member meeting attendance, information about IRB departmental and specialty representation, as well as the compensation model in place for a given year, and compensation practices.

Details
4.1. Statistical data to be captured include:
   4.1.1. Identify IRB member department affiliation and specialty represented (HRPP Metric #100)
   4.1.2. IRB member compensation model (compensation type for IRB chairs, vice chairs, affiliated, and non-affiliated members) (HRPP Metric #28, 102)
   4.1.3. IRB member compensation actually provided (confirmation of adherence to plan)
   4.1.4. IRB meeting attendance (beginning in September 2016) (HRPP Metric #101)

4.2. Analysis will include:
   4.2.1. Assessment of representation at meetings
   4.2.2. Confirmation that each IRB member is meeting expectations of membership commitment
   4.2.3. Observations on trends identified
   4.2.4. After the first year, observations on upward or downward trends

Data Availability
Some of the data for this metric will be available from the University’s OHRP and AAHRPP reports and from OVPR-Finance records.

Satisfies Metrics Contained in AHRP Report?
Yes
**METRIC #5: IRB PROTOCOL REVIEW PROCESS**

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<tr>
<td>Related AHRP Group(s):</td>
<td>IRB Protocol Review Process, HRPP</td>
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**Summary**

The report will include statistical data about the protocol review process including data documenting the numbers and type of submissions, types of reviews, turnaround times, committee member workloads, and IRB Final Approval survey results.

**Details**

5.1 Statistical data to be captured by HRPP’s internal processes include:

5.1.1 # of active studies (HRPP Metric 11)
5.1.2 % of active studies by IRB review type: Full Committee and Non-Committee (HRPP Metric 12)
5.1.3 IRB submission volumes by study type (HRPP Metric 4)
5.1.4 IRB submission volumes by submission type (HRPP Metric 5)
5.1.5 # of new studies approved by study type (HRPP Metric 2)
5.1.6 # of IRB Minutes sets audited (HRPP Metric 7)
5.1.7 Committee Member and panel workload: # of expedited + full committee items assigned (HRPP Metric 1)
5.1.8 # of submissions by department/division for biomedical IRB compared to biomedical IRB composition.
5.1.9 Median turnaround time for new studies: # of days to review, results sent, and approved (HRPP Metric 9)
5.1.10 Average # of days from submission to first IRB review and response, by study type (HRPP Metric 10)
5.1.11 Survey response rate on IRB Final Approval Survey (HRPP Metric 3)

5.2 Statistical data to be captured by HRPP for annual AAHRPP reporting (can be re-used for internal use) include:

5.2.1 Total number of active protocols & review procedure: # reviewed by convened IRB/EC, Expedited Review, Activities determined exempt in past 12 months (HRPP Metric 17)
5.2.2 Location of organization’s research activities: State/Province/Region - mine and/or other, and Country - mine and/or other (HRPP Metric 18)
5.2.3 Percentage of types of research conducted, reviewed, or managed at organization: Social/behavioral/educational or Biomedical [IND, IDE, Other] (HRPP Metric 19)
5.2.4 Types of research involving vulnerable participant populations that are allowed or reviewed: children, pregnant women, prisoners, students, employees, adults unable to consent, other (HRPP Metric 20)
5.2.5 # of of IRB/EC meetings per month (HRPP Metric 21)
5.2.6 Percentage of protocols that rely on an external IRB/EC (HRPP Metric 22)
5.2.7 Percentage of studies reviewed by non-AAHRPP accredited IRB’s (HRPP Metric 23)
5.2.8 Regulations/guidance pertaining to human research that apply to active protocols (DOD, DOE, ED, HHS, DOJ, VA, EPA, FDA, state & local laws, ICH GCP, etc.) (HRPP Metric 24)
5.2.9 Sources of sponsorship research - % governmentally/federally sponsored, % industry sponsored, % externally sponsored, % internally sponsored (HRPP Metric 25)
5.2.10 Total number of FTE’s dedicated to HRPP (other than IRB/EC) and IRB/EC (HRPP Metric 26)
5.2.11 US dollars budgeted in the most recent 12 months or last fiscal year for HRPP (other than IRB/EC) and IRB/EC (HRPP Metric 27)
5.2.12 # of researchers (HRPP Metric 29)
5.2.13 # of research coordinators and research staff (HRPP Metric 30)
5.2.14 Median number of calendar days from complete submission to review and approval for new protocols reviewed in the most recent 12 months by the convened IRB/EC (HRPP Metric 31)
5.2.15 Median number of calendar days from complete submission to review and approval for new protocols reviewed in the most recent 12 months by the expedited procedure (HRPP Metric 32)
5.2.16 Median number of calendar days from protocol submission to exempt determination in the most recent 12 months (HRPP Metric 33)
5.2.17 # of protocols disapproved by the IRB/EC in the most recent 12 months (HRPP Metric 34)

5.3 Analysis will include:
   5.3.1 IRB Final Approval Survey feedback themes from written comments
   5.3.2 IRB Final Approval Survey feedback (critical, positive, neutral)

Satisfies Metrics Contained in AHRP Report?
Mostly, except for the number and role of members at convened meetings, the tracking of expert consultation to inform review (full and expedited) and the expedited reviews by member to whom they were distributed (will be available with Click IRB). The latter two are a part of planned future enhancements.

Future Enhancements:
5.4 Include:
   5.4.1 Reviews will be tracked by the member to whom they were distributed (will be available with Click IRB) (HRPP Metric 105)
   5.4.2 Document and track use of expert consultation to inform full and expedited review (TBD) (HRPP Metric 106)
   5.4.3 Determine if there is a need for a more formal review of consent forms in new IRB applications (beyond what is currently undertaken by IRB analysts) to assess use of technical jargon and complexity of lay language.
**METRIC #6: SCIENTIFIC REVIEW OF STUDIES**

<table>
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<td>Related AHRP Group(s):</td>
<td>Scientific Review</td>
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**Summary**

This metric will include statistical data related to scientific reviews conducted via HRPP’s mechanism. Other methods of scientific review (for all biomedical applications determined to be greater than minimal risk) will be inferred from the funding source documented in study records.

**Details**

6.1 HRPP will maintain a data collection tool to allow aggregation of the method of scientific review as documented in the individual protocol record.

6.2 HRPP will maintain a Google Sheet to include the data recommended in the Plan, as follows:
   - 6.2.1. Type of protocol defined by specialty and funding (HRPP Metric 109)
   - 6.2.2. # of individuals that complete the review (HRPP Metric 109)
   - 6.2.3. Specialty of the reviewers (HRPP Metric 109)
   - 6.2.4. # that recuse themselves from review (HRPP Metric 109)
   - 6.2.5. Outcome of the reviews (approved or not approved) (HRPP Metric 109)

6.3 Analysis will include:
   - 6.3.1. Trending to identify specific patterns of recusal (individual, subject matter, type of project, etc.)
   - 6.3.2. Issues related to recusals
   - 6.3.3. Delays due to scientific limitations or special challenges encountered

**Satisfies Metrics Contained in AHRP Report?**

Yes; HRPP will provide the metrics as listed on this mark up and can commit to doing these prior to implementation of Click.
**METRIC #7: MONITORING OF STUDIES**

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<td>Related AHRP Group(s):</td>
<td>Monitoring of Studies, HRPP</td>
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**Summary**

Reporting on number of non-compliance findings (to include serious and continuing), number of for cause and random audits of investigator protocols, number of for cause and random audits of IRB/EC records and number of regulatory agency inspections (AAHRP Annual Report). Additional reporting on number and percent of report forms received by college and department in relation to active studies.

**Details**

7.1 Statistical data to be captured in AAHRP Annual Report include:

7.1.1. # of new cases of alleged non-compliance investigated in the most recent 12 months (HRPP Metric 36)

7.1.2. # of determinations of serious non-compliance in the most recent 12 months (HRPP Metric 37)

7.1.3. # of determinations of continuing non-compliance in the most recent 12 months (HRPP Metric 38)

7.1.4. # of determinations of unanticipated problems involving risks to participants or others in the most recent 12 months (HRPP Metric 39)

7.1.5. # of internal and Sponsor “for cause” audits of investigator protocols conducted in the most recent 12 months (HRPP Metric 40)

7.1.6. # of internal and Sponsor random audits of investigator protocols conducted in the most recent 12 months (HRPP Metric 41)

7.1.7. # of internal “for cause” audits of IRB/EC records conducted in the most recent 12 months (HRPP Metric 42)

7.1.8. # of internal random audits of IRB/EC records conducted in the most recent 12 months (HRPP Metric 43)

7.1.9. # of US FDA, other US regulatory agencies, or other country regulatory agencies (e.g., EMA) inspections of investigators conducted at UMN in the most recent 12 months (HRPP Metric 44)

7.1.10. # of US FDA, other US regulatory agencies, or other country regulatory agencies (e.g., EMA) inspections of IRB/ECs conducted at UMN in the most recent 12 months (HRPP Metric 45)

7.2 Statistical data to be captured by internal HRPP report, dashboard or website include:

7.2.1. # and % of report forms received by college and department; compared with % of active studies by department

7.2.2. Track number of staff required for review (HRPP Metric 110)

7.2.3. Number of reviews and reason for reviews, for-cause or random reviews (HRPP Metric 111)

7.2.4. Comprehensive communication of findings (HRPP Metric 112)

7.3 Analysis will include:

7.3.1. College and department profiles for report forms related to active studies

7.3.2. College, department and PI trends for non-compliance

**Satisfies Metrics Contained in AHRP Report:**

Yes.
### METRIC #8: RESEARCH WITH VULNERABLE POPULATIONS

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<td>Related AHRP Group(s):</td>
<td>HRPP</td>
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**Summary**

Reports will contain data related to research with vulnerable populations to include identification of the person obtaining the consent, who is actually signing the consent, presence and role of an advocate in the process, number of new protocols targeting adults with diminished or fluctuating capacity to consent.

**Details**

HRPP will collect data related to the number of new protocols targeting adults with diminished or fluctuating capacity to consent and provide it for review and analysis. RCO will perform annual sampling to obtain data to review areas 8.1.1 through 8.1.3 below.

8.1 Statistical data to be captured include:

8.1.1. Person performing the consent: research coordinator or investigator - only available from PI (HRPP Metric 115)

8.1.2. Person signing the consent: research participant, single parent, both parents, guardian, LAR - only available from PI (HRPP Metric 116)

8.1.3. Data regarding whether an advocate participated in the consent process and signed the document - only available from PI (HRPP Metric 117)

8.1.4. The number of new protocols targeting adults with diminished or fluctuating capacity (HRPP Metric 20)

8.2 Analysis will include:

8.2.1 Identification and trending related to role of person(s) performing consent

8.2.2 Percentage and role of person(s) signing consent

8.2.3 Percentage and trends related to advocate participation in the consent process and signing

8.2.4 All above to be related to number of new protocols targeting adults with diminished or fluctuating capacity

**Satisfies Metrics Contained in AHRP Report?**

Yes, the AHRP report requires who performed the consent, who signed the consent, if an advocate participated in the consent process and signed the document and tracking the inclusion of adults with diminished or fluctuating capacity as part of the application process.
**METRIC #9: MONITORING OF DEPARTMENT OF PSYCHIATRY STUDIES**

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### Summary

This metric will contain statistical data on the degree of adherence to the CTSI Study Monitoring Plan scheduled, the volume of items which require “Prompt Attention”, and adherence of study personnel (researchers and staff) to mandatory and study-specific training requirements.

### Details

9.1 Statistical data to be captured include:

9.1.1. Degree of adherence to CTSI Study Monitoring Plan visit schedule

9.1.2. Volume of items needing “Prompt Attention” (per the plan)

9.1.3. Adherence of all study-involved personnel to mandatory training requirements (as these are established) which is overseen by the IRB

9.1.4. Reports on the currency of study specific training which will be provided by CTSI from their Monitoring Reports

9.1.5. Reports on the topics and attendance of investigators at the monthly Psychiatry Research Council brown bag education offerings

9.1.6. Reports on attendance at sessions specifically devoted to revisions of departmental policy or procedures or related to regulatory changes

9.2 Analysis will include:

9.2.1. Identification of trends or patterns that may require attention

9.2.2. Identification and reporting of revisions to departmental policies and procedures

9.2.3. Patterns of non-participation in educational sessions by investigators and research staff

### Satisfies Metrics Contained in AHRP Report?

No, intentionally. The AHRP report called for metrics related to the timing of presentation of protocols to FUROC (protocols aren’t being presented to FUROC); the number of revisions to protocols (this was seen as not being a meaningful thing to count); and the number of findings. The For-Cause Investigation report will include information on the department(s) associated with each of their cases, and HRPP will be providing PAR data and data on research compliance concerns, so these items were seen as adequately covered via other mechanisms.
METRIC #10: ENGAGING RESEARCH PARTICIPANTS

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<td>10.1, 10.2 and 10.3 by HRPP; all others by RCO</td>
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<td>Delivered to:</td>
<td>Vice President for Research, Vice President for Health Sciences and Medical School Dean, Medical School Executive Vice Dean, HRPP, RCO, COB, FUROC, RCAC, other as directed</td>
</tr>
<tr>
<td>Related AHRP Group(s):</td>
<td>Engaging Research Participants</td>
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Summary
This metric will track research participant satisfaction data, the degree of active participation of investigators in ensuring the appropriateness of consent documents and ongoing trial comprehension by participants, the degree of use of targeted materials to help research participants to know their avenues for having questions or concerns addressed, and the degree to which participants are thanked and/or notified of trial results.

Details
10.1 Statistical data to be captured in AAHRP Annual Report include:
10.1.1. # of complaints from research participants received by the IRB/EC in the most recent 12 months (HRPP Metric 35)
10.1.2. # and type of other concerns/questions received by HRPP from research participants or their families (HRPP Metric 6)

10.2 While the above are required measures, the work group recognized uncertainty that subjects make direct contact to discuss satisfactory research experience in a way that will lead to improvements in participant experience or the institutional culture of ethics. As a result, the work group recommends including the following measures that will ultimately support the reliability of feedback received by calls and letters.

Statistical data to be captured by HRPP includes:
10.2.1. Test degree of use of contact cards by academic unit and by type of study (e.g., Phase III or IV) by asking about use of contact cards during the previous year as a mandatory data element in the annual IRB renewal process and testing for their actual use during PAR reviews. (HRPP Metric 120)

10.3 HRPP will undertake a participant sampling survey as proposed in the AHRP report (representative statistical sampling of all human participants).
10.3.1. Include a question about whether the participants received a contact card (during study)
10.3.2. Include a question about whether the participant received an appreciation card (at the end of the study)
10.3.3. Include a question about whether the participant received trial results/outcomes.

10.4 RCO should analyze the number of closed studies that post/disseminate a lay statement of (even preliminary) results on a UMN or other website (e.g., CT.Gov) designed to support result dissemination.

10.5 Analysis will include:
10.5.1. Use of contact cards to determine if additional educational efforts about use and value of cards is needed
10.5.2. Trend analysis of complaints to determine if there are themes that may require attention
10.5.3. Determination if data from research participant satisfaction survey indicates themes that may require attention
10.5.4. Determination if trial results are being posted/disseminated timely.

**Satisfies Metrics Contained in AHRP Report?**
Yes. The AHRP report requires (1) monitoring of the creation and broad publicity of policy and procedures for handling concerns about research from potential, current, and past research participants, family members, legally-authorized representatives, research personnel, and clinical staff to provide confidential feedback and/or report concerns; (2) creation and use of the card will be monitored and quantified; (3) feedback from research participant survey will be analyzed. There is a final metric in the AHRP plan that is not clear: “(4) materials will be distributed related to research participant reporting and implementation of plans to express research appreciation in IRB and final reports.” We believe that this is intended to refer to appreciation cards and delivery of results when a study is ended, and if so, the metrics listed above and in future enhancements, below would satisfy this requirement.

**Future Enhancement (HRPP)**
10.6 Statistical data to be captured include:
   10.6.1. Current policy along with changes made during review period (HRPP Metric 120)
   10.6.2. Survey implementation expected by 12/31/16, after which time results will be available to analyze
   10.6.3. Evaluation of whether each study included a dissemination plan (HRPP Metric 123)
### METRIC #11: SOuRCE SURVEY

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<th>Cycle</th>
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<td>Research Compliance Office / University of Illinois</td>
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<tr>
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</tr>
<tr>
<td>Related AHRP Group(s):</td>
<td>Cultivating a Culture of Ethics</td>
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**Summary**

This point-in-time metric will be based on the results of the Fall 2016 Survey of Organizational Research Climate (SOuRCE) administered to 12,694 researchers and research-engaged staff across all five campuses. This externally-validated instrument assesses the environment for responsible research practices. The metric will analyze the survey results to determine areas both where strength exists and where improvements toward fulfilling the institution’s commitment to establishing and sustaining an ethics-based culture are needed. Follow-up actions may be scheduled and if so, this metric will be used to track adherence to the established timetables and action steps.

**Details**

11.1 Summary statistical data at the institution-wide, campus-wide, and departmental levels will be provided to the University and analyzed for trends

11.2 Analysis will include

11.2.1. Areas of opportunity will be identified and follow-up actions plans established as needed

11.2.2. Areas of strength will be identified and good/best practices identified where possible

**Satisfies Metrics Contained in AHRP Report?**

Not applicable, as no metrics in this area were identified in the AHRP report