June 29, 2016

TO: Brian Herman, Vice President for Research
FROM: Ann Aronson, Deputy Chief of Staff, University Relations
Susan Wolf, Professor and Chair, Consortium on Law and Values in Health, Environment & the Life Sciences
Lynn Zentner, Director, Office of Institutional Compliance

SUBJECT: Cultivation a Culture of Ethics Final Report

We are pleased to submit our final tracking and summary of the work completed by the Cultivating a Culture of Ethics work team. As you know our task was considerable. In order for real and lasting change to occur, the institution must remain vigilant, investing in our human research protection program, taking action to advance a culture of ethics, and reaffirming our core commitment to the ethical conduct of research. The final deliverables here are foundational, targeted, and most importantly meet the expectations created by the external review panel’s recommendations. These deliverables also build on principles contained in the Implementation Team’s June 2015 final report. As that report says,

“Culture is an attribute of a community, not an institution. Institutions’ policies, procedures, practices, and leadership creates and sustains the ethical culture for its activities. Sustaining an ethical culture for research with research participants will require institutional time and resources. More importantly, it will require personal commitments and an understanding that cultural reform is necessary if health research is to be able to keep its promise of creating better knowledge to serve human health.”

With this in mind, the attached summary provides necessary tools to promote the broad "forward looking "culture shift that was envisioned by the external review panel’s cover memo to President Kaler. That memo said, “The University has an opportunity to signal a change in its culture of human subjects research by creating an expectation of excellence, demanding accountability, and more effectively engaging the community.”

We are happy to meet with you and discuss any and all parts of our work. We appreciated the opportunity to work with our colleagues in the research community to define our values around a strong ethical culture, a component that is critical to a sound human research protection program.

Attachment
Cultivating A Culture of Ethics
Advancing Human Research Protections

“The University of Minnesota is dedicated to meeting, upholding and exceeding the highest ethical standards in research practices involving human participants. Clinical research is critical to discovering treatments and cures for many of society’s most vexing diseases, including cancer, diabetes and AIDS.” - Advancing Human Research Protections website

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Major Deliverables (expected and/or completed)</th>
<th>Owner</th>
<th>Date Complete</th>
<th>Status/Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorporate the University’s stated commitment to, and plans for strengthening research ethics and research participant protections in future strategic planning. (page 21)</td>
<td>► The incorporation of research ethics and human participant protections in the strategic planning documents of the University, AHC, Medical School, OVPR, Psychiatry, and other units.</td>
<td>Lisa Warren and Advancing HRP Comm Team</td>
<td>Dec 2015</td>
<td>FY2015 BOR presentations – U <a href="#">Accountability Report, Research Annual Report</a> See Ethics Campaign planned distribution.</td>
</tr>
<tr>
<td>Establish both formal and informal means of stimulating a university-wide conversation about the manner in which this newly endorsed culture of ethics can be most effectively realized. (page 90)</td>
<td>► Sponsored a Conference on Research with Human Participants: the National Debates, Dec. 2, 2015. Going forward, the identification of additional opportunities, including opportunities to engage the community of patients, potential research participants, and current participants.</td>
<td>Susan Wolf/ Consortium on Law and Values</td>
<td>Dec 2015</td>
<td><a href="#">12/2/15 National Debates Conference website includes videos</a>. Planning cmte has re-engaged since that Conference and is planning an annual conference and “Research Ethics Day” for Spring 2017.</td>
</tr>
<tr>
<td>Publicize unequivocal statements on the administration’s intention to create and nurture a culture of ethics in research; the OVPR must then animate these values to life by investing in their visibility and adoption at all levels of the</td>
<td>► Integrating acknowledgement of the primacy of research participant protections and ethical research into relevant University publications, materials, and web pages. The HRPP, IRB, OVPR, and AHC</td>
<td>Ann Aronson, Susan Wolf, Lynn Zentner, AdvancingHRP Comm Team</td>
<td>June 2016</td>
<td>Leadership adoption of “Core Commitments”. Faculty consultation March 1st through April 15th. Final language provided foundation for communications campaign. <a href="#">Developed Ethics Campaign and</a></td>
</tr>
</tbody>
</table>
**Cultivating A Culture of Ethics**  
**Advancing Human Research Protections**

**June 27, 2016**

<table>
<thead>
<tr>
<th>University’s research enterprise. (page 20)</th>
<th>websites as well as departments that are involved in research with research participants will incorporate clear statements, in prominent locations, about the University’s commitment to research participant protection. All departments engaged in clinical research should incorporate this acknowledgment into their materials and messaging.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Explore ways in which an acknowledgement of the primacy of research participant protections and ethical research could be integrated into relevant University publications, materials, and web pages and other messaging. (page 20)</td>
<td>Create a document that explains the University’s commitment to research participant protection, including the ethical conduct of research involving research participants. Statements and websites will be reviewed and discussed with the Community Oversight Board and the Research Compliance Advisory Committee (RCAC).</td>
</tr>
</tbody>
</table>
| Require all departments engaged in clinical research to acknowledge this refocusing of University research priorities and craft statements reflecting their own commitment to excellence and accountability in human participant protections. (page 21) | **toolkit** to include:  
- web content  
- talking points  
- posters  

See Ethics Campaign planned distribution.  

Reviewed Board Policy:  
**Code of Conduct**  
IRB policies linked to University Administrative Research policy library:  
**IRB Policies**  

Rework institutional messaging in policies and procedure to include unequivocal statements on the administration's intention to create and nurture a culture of ethics, and adopt communication strategies to bring these core values to life by investing in their visibility and adoption at all levels of the University community and beyond. (page 90)
Create a document that describes the U of M’s commitment to research participant protection, including the ethical conduct of research involving research participants. [WP]

The HRPP, IRB, OVPR, and AHC websites as well as departments that are involved in research with research participants, will incorporate clear statements, in a prominent location, about the U of M’s commitment to research participant protection, including the ethical conduct of research involving research participants. The statements will be written for audiences that include current and potential research participants and their families, investigators conducting research with research participants; U of M faculty; the general public and others who are concerned with the U of M’s maintaining the highest ethical standards.

In addition, there will be a one-stop web location that has easy-to-access consolidated information regarding IRB policies, educational materials and programs plus resources for getting advice and consultation on legal, regulatory, and ethics topics related to research participant protection.

| Create “a one-stop web location that has easy-to-access consolidated information regarding IRB policies, educational materials and programs plus resources for getting advice and consultation on legal, regulatory, and ethics topics related to research participant protection.” | AdvancingHRP Comm Team (Ethics Campaign) | June 2016 | IRBRenew (Spring 2017) | See Ethics Campaign. |
| AdvancingHRP Comm Team (Ethics Campaign) | IRBRenew (Spring 2017) | June 2016 | IRBRenew (Spring 2017) | See Ethics Campaign. |

HRPP is a key partner in the Ethics Campaign and the “one stop” website work will be done in partnership with the IRB Renew “Click” software implementation and where appropriate the Advancing HRP communications team.
### Define a hierarchy of accountability for human research ethics and thereby expand oversight responsibilities

**Department chairs** should be expected to review and approve the submission of IRB protocols, be engaged in follow-up compliance activities, develop department-specific educational programs, and share ultimate responsibility for human participant protections within their departments. (page 89)

<table>
<thead>
<tr>
<th>Create materials and a visual chart defining a hierarchy of accountability for human research ethics and thereby expand oversight responsibilities beyond the IRB.</th>
<th>Create materials and a visual chart defining a hierarchy of accountability for human research ethics and thereby expand oversight responsibilities beyond the IRB.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brian Herman (IO), Brooks Jackson HRPP, Steve Miles May 2016</td>
<td>Brian Herman (IO), Brooks Jackson HRPP, Steve Miles May 2016</td>
</tr>
</tbody>
</table>

Accountability chart presented to the Legislature March 2016.


Department specific education:

- **HRPP Advanced Training**
  - [http://www.research.umn.edu/irb/advanced.html](http://www.research.umn.edu/irb/advanced.html)

**Standards for Research with Human Participants**

Spring Semester, Jan 19 - May 6, 2016 (Fall 2016 coming)

### The U of M will regularly benchmark itself against its peers to ensure that our human research participant protection programs meet or exceed the norm.

For departments engaged in human participant research, the U of M will determine how to annually evaluate each department’s commitment to the safe and ethical conduct of human participant research. [WP]

<table>
<thead>
<tr>
<th>Identify and implement metrics to use to evaluate excellence in research ethics and the culture of ethics going forward.</th>
<th>Identify and implement metrics to use to evaluate excellence in research ethics and the culture of ethics going forward.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ann Aronson, Lynn Zentner, Susan Wolf, Brian Herman June 2016</td>
<td>Ann Aronson, Lynn Zentner, Susan Wolf, Brian Herman June 2016</td>
</tr>
</tbody>
</table>

U committee recommends adopting SOuRCe ethics survey. Survey planning to start September 2016.

http://ethicscenter.csl.illinois.edu/sorc/

Talked to experts:

- Mark Yarborough re: research integrity climate instrument
- Brian Martinson
- C.K. Gunzalus re: Survey of Organizational Research Climate (SOuRCe)
The University of Minnesota community strives to meet the highest ethical standards in the planning and conduct of research. The University holds each individual involved in research with human participants accountable for adherence to these standards. Essential to the research enterprise is preserving the trust of research participants. Each researcher has a duty to maintain that trust and to protect participant well-being. Individuals who make the gift of consenting to volunteer as research participants trust us to protect them from harm and to respect their freely given, informed consent to participate in research. Research participants retain the right to decline to continue participation in a research study for any reason, including as new data, side effects, or unexpected circumstances occur during the course of the study. We bear special responsibilities toward those persons whose capacity to consent to research is impaired or fluctuates during participation in a study.

All involved in conducting research must ensure that research is conducted ethically and in compliance with University policies and procedures. Any action that violates the trust of potential or enrolled research participants harms the entire research enterprise.

University leaders and all involved in research with human participants have the responsibility to:

• Ensure that all faculty, staff, and others who oversee and/or conduct University research on human beings have taken the appropriate ethics training.

• Protect and promote the rights and interests of all research participants, including those who are vulnerable, who may be susceptible to coerced consent, or who lack (or may come to lack) the capacity to consent to or decline continued participation in research.

• Comply with the letter and be committed to the spirit of the laws, regulations, and policies that pertain to the treatment of patients and of participants who are enrolled in research studies.

• Be transparent and accountable in all research activities. Anyone who observes a breach of the ethical rules, laws or regulations that govern the conduct of research involving human participants should report his or her observations. Individuals can report without fear of retaliation and with confidence that their concerns will be promptly considered and fully addressed.

• Ensure that identified individual and institutional conflicts of interest that potentially undermine the well-being of research participants will be effectively managed.

• Sustain a culture of respect and engagement at the U of M that recognizes the importance of integrity in University-based research. Sustaining that commitment requires respect for participants, their families, and community, as well as regard for cultural diversity, and attention to the societal implications of research.

• Effectively engage in a dialogue with the broader community which has a stake in benefitting from research involving human participants and an interest in protecting loved ones who may participate in these studies.