Implementation Team  
April 8, 2015

The meeting began with introductions and a brief review of the charge. All members were present. Each member was asked to declare any potential conflicts of interest and there were no relevant conflicts.

The team discussed a proposed process for the work. The chair suggested that the recommendations of the external review be assigned to team members to develop action plans. These plans would then be discussed by the group and accepted, amended or rejected. No decisions, however, will be final until the end of the process. It was also suggested that a public comment period be added to the process at the end before full implementation begins.

The team discussed the importance of sharing the work in a clear and transparent way and agreed that the recommendations being considered by this team are not the only changes underway at the University. A new website http://research.umn.edu/advancehsr/index.html was created for the team to share their charge, progress and provide an opportunity for the research community to contact the team with feedback.

There were 11 recommendations assigned for consideration this week.

3.1.4 Incorporate the University’s stated commitment to and plans for strengthening research ethics and research subject protections in future strategic planning.

The action plan recommends incorporating statements into future strategic plans, consideration of a values statement on the University website, amending the statement on HRPP’s website, and adding a statement to OVPRs website and to the AHC website.

3.1.5 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 subjects protections.

The action plan recommends requiring departments and centers engaged in human subject research to develop and post statements and holding chairs and directors accountable for this work.

3.1.2 Convene a task force that would include research subjects, research ethicists, educators, researchers, and HRPP/IRB staff to consider ways in which ethics and ethics education on the topics of research subject protections will be integrated into practice.
The action plan recommends that in addition to two committees already formed, the Implementation Team and the Research Compliance Advisory Committee, that a Community Oversight Board will be named to monitor these areas.

3.1.1 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 University’s research enterprise.

The action plan recommends asking media relations to use all tactics – interviews, newspaper op-eds, web pages, internal newsletters, and town halls to publicize and communicate our commitment to ethics in research. It also suggests consulting with bioethicists and patient advocates on the statement. The commitment should also be discussed at the department and project level.

3.6.3 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.

The action plan recommends, in addition to the means of communication highlighted in earlier recommendations, HRPP/CTSI website forums, additional seminars or courses through the Center for Bioethics, and holding a Campus Conversation on the issue.

3.2.4 Revise the format of the convened IRB meeting minutes to include a meaningful summary of the study, any controverted issues that are discussed, their resolution, and documentation to support the IRB's rationale for requesting modifications to the study.

Implementation of this recommendation is in progress.

Meeting ended with 4 recommendations still yet to be reviewed. These will carry forward into the next meeting.