Executive Summary

The University of Minnesota is dedicated to meeting, upholding and exceeding the highest ethical standards in research practices involving human participants. In 2015, the university launched a major initiative to enhance its human research protection program through specific program and policy reforms. As part of this work, the Human Research Protection Program (HRPP) is leading the development of educational resources for participants to enhance understanding of research and to encourage communication of questions, concerns, or complaints. These materials include:

- A Research Participant Bill of Rights
- A Research Participant Brochure (which contains the Bill of Rights)

Purpose

Research Participant Bill of Rights

The Bill of Rights states clearly the rights of research participants, thereby increasing awareness and understanding among: the public, the research community, and research participants and their friends and families.

Research Participant Brochure

The brochure is an educational tool, developed to provide research participants, across the broad range of U of M research, with key information including: questions to ask when considering participation, the Bill of Rights, the difference between research and treatment, and who to contact with questions or concerns.

Please note: the brochure that has been developed is designed for adult participants who speak English and who have the capacity to make decisions about research participation. The HRPP is developing additional materials related to legally authorized representatives, assent, parental consent, and participants who do not speak English.

Development Process

Benchmarking was done by HRPP staff through review of similar materials from numerous research institutions and organizations\(^1\). Examples were evaluated and compared for content, readability, grade level, and clarity of language and presentation.

\(^1\) National Institute of Health Clinical Center, Quorum (privately held IRB) – California Sites Version, University of California – Los Angeles, University of Iowa, University of Arizona, Duke University, Emory University, Tufts University, Harvard University, Western Michigan University, Louisiana State University, The Center for Information and Study on Clinical Research Participation, Fairview Research Administration, University of Utah, University of North Carolina, University of Michigan, Veterans Administration, Department of Health and Human Services, Huron Consulting Group.
Vetting Process

Following initial review by HRPP leadership, brochure drafts were vetted by key stakeholders as well as non-affiliated community members. During the course of the process, nearly 70 individuals, including representatives of numerous stakeholder groups, offered valuable feedback from a range of perspectives. Feedback related to:

- Language
- Tone
- Content
- Scope
- Flow
- Design
- Adoption
- Requests for additional materials for specific populations

Vetting Process Steps

1. Representatives from 14 stakeholder groups were invited to offer feedback on Draft One. Responses were received from 18 individuals.
2. Draft One was also presented at meetings of the Fairview University Research Oversight Committee and the UM - Public Engagement Network, during which members provided feedback.
3. Draft Two, incorporating feedback from steps 1 & 2 above, was developed.
4. Representatives from five stakeholder groups were invited to offer feedback on Draft Two. In addition, non-affiliated groups and individuals from the broader community were invited to offer feedback. Responses were received from 56 individuals.
5. Draft Three, incorporating feedback from step 4 above was developed.
6. Draft Three was submitted to Debbie Dykhuis, Executive Director of the Human Research Protection Program, and Brian Herman, Vice President for Research, for final review and approval.

Release and Use

Official release is planned for January of 2017. Prior to release, all who contributed feedback will receive a preview copy, along with a letter of appreciation.

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2 Academic Health Center, Center for Bioethics, Clinical and Translational Science Institute, Community Oversight Board, Consortium on Law and Values, Fairview Health, Gillette Children’s, Human Research Protection Program, Institutional Review Board Chairs, MHealth, Office of the General Counsel, Office of the Vice President for Research Communications, University of Minnesota Physicians, Urban Research and Outreach-Engagement Center

3 Academic Health Center, Campus – Community Coordinators Alliance, Clinical Nursing Staff, Fairview University Research Oversight Committee, UM – Public Engagement Network
Communication of Release

The dissemination of information about these materials will involve multiple communication channels including, but not limited to, the Research Community Newsletter (which reaches 10,000 researchers and study team members), the IRB Newsletter (which reaches IRB members, chairs, HRPP leadership/staff), and university-wide communications (Inquiry, Brief).

Digital Format

The participant Bill of Rights and brochure will be available digitally on the research participant webpage maintained by the HRPP. A link to these materials will be provided on other University websites, such as the CTSI Study Finder.

Print Format

These products will be developed for print, and will be ordered via the HRPP through the UMN Printing Services. An initial order of brochures will be purchased by the HRPP at no cost to departments/units. Future orders will be facilitated by the HRPP but the cost of the order will be the responsibility of departments/units.

Use

These products can be used by research teams, university departments, and healthcare components. The IRB may require the use of certain participant facing materials on a study-by-study basis. The HRPP recommends these materials be utilized whenever appropriate, aligning with the University's mission to foster a culture of ethics, representing our shared responsibility to protect research participants, uphold the highest ethical standards and improve our practice at every step:

- The Bill of Rights will be posted in research centers, clinics, or other spaces in poster format. It can also be printed as a hand-out to be shared with participants and participant representatives. In addition, it is included in the participant brochure and referenced on participant contact cards.
- Participant brochures will be printed and made available at research centers, clinics, or other spaces. The brochure can also be provided to participants and participant representatives during recruitment, consent meetings, or events.

Maintenance and Monitoring of Use

The Bill of Rights and Participant Brochure will be maintained by the HRPP. The HRPP will monitor the usage of participant facing materials and share this information with the HRPP Committee.