Design for Implementing Recommendations from the Engaging Research Participants work group

June 17, 2016

Engaging Research Participants Committee Members:
Milton “Mickey” Eder (University of Minnesota, Clinical and Translational Science Institute); Sue Abderholden (NAMI Minnesota); Linnea Anderson (University of Minnesota, Human Research Protection Program); Jennifer Ball (University of Minnesota, School of Journalism and Mass Communication); Michelle Biros (University of Minnesota, Department of Emergency Medicine); Jill Cordes (Fairview Research Administration); Bethany Hansen (University of Minnesota, Human Research Protection Program); Megan Hoffman (University of Minnesota, Clinical and Translational Science Institute); Courtney Jarboe (University of Minnesota, Human Research Protection Program); Shannon Pergament (Somali, Latino and Hmong Partnership for Health and Wellness)
The Engaging Research Participants work group is one among many groups working to realize the vision of the Implementation Work Plan – to make the University a national model or leader in [clinical] research ethics. Over the past year, the Engaging Research Participants work group sought to develop a system to foster the co-creation and evaluation of knowledge about research conduct. The workgroup set out to foster the co-creation of knowledge by articulating clear expectations of researcher conduct when engaging participants. The workgroup developed a survey to assess the experience of research participants and those involved in the informed consent process. We have also been charged with recommending an approach to evaluate participant and public experience of research conducted by the University. The systems approach adopted by the work group identifies new standards and modes of conduct and also mechanisms for obtaining feedback to facilitate the continued improvement in the culture of research ethics at the University of Minnesota.

The formative work to conceptualize a system included defining engagement as an exchange relationship or a dialogue in which project specific information moves back and forth through a series of events and interactions that begins with researcher and staff training, includes participant recruitment and informed consent, and concludes with an expression of appreciation and dissemination of results to participants and a broader public. The workgroup further recognized a system for improving the engagement of research participants had to 1) inform, 2) monitor/assess, and 3) respond to feedback. The system’s engagement characteristics are illustrated as follows.

Our approach to developing a system has included a commitment to building upon existing structures and to identify effective engagement strategies that require minimal novel action or expense. The recommendations in this report recognize that research involves individuals, which both limits the capacity of compliance functions to fully police the system and emphasizes the importance of the organizational culture to establish and maintain normative standards.
The report is organized according to the engagement model. We begin with recommendations pertaining to the Engagement of Research Participants “before the study begins;” proceed to study participation followed by the individual’s completion of a specific research study. The work group remains cognizant of the importance of ongoing evaluation of 1) the implementation of these recommendations, and 2) the outcomes produced. In addition to HRPP monitoring, the evaluation of engagement practices is projected to require the support of the Community Liaison Officer and the assessment of the Community Oversight Board.

Work Group Background and Purpose

Charged by University of Minnesota’s (UMN) President Kaler, the Engaging Research Participant work area formed in September, 2015 under leadership of Milton “Mickey” Eder. On September 2, 2015 Mickey Eder submitted a proposed work plan to the Office of the Vice President for Research. The work plan was approved and charged the work area to:

- Put a system in place that fosters the co-creation and evaluation of knowledge about the conduct of research among researchers, collaborators, participants and the broader community to inform the education, administration and oversight of research;
- a) Revise the IRB application process and related documents to ensure researchers provide and implement plans for engagement of participants, for responding to participant feedback, and for sharing results with research participants;
- b) Establish a process to support ongoing interactions among community and research representatives to facilitate and respond to community priorities and areas of community concern about the conduct of UMN research;
- c) Enhance the process for obtaining, assessing and responding to feedback about recruitment and the conduct of research in real time;
- d) Identify opportunities for consistent community input in appropriate advisory capacities within the administration of the research and human subjects protection program;
- e) Develop a schedule and format for activities focused on disseminating both the results of the management of research activities and research findings to both the academic and broader community.

To address the charge over the next ten months, the following members were recruited into the work group: Mickey Eder (University of Minnesota, CTSI); Sue Abderholden (NAMI Minnesota); Linnea Anderson (University of Minnesota, Human Research Protection Program), Jennifer Ball (University of Minnesota, School of Journalism and Mass Communication); Michelle Biros (University of Minnesota, Dept of Emergency Medicine); Jill Cordes (Fairview Research Administration); Bethany Hansen (University of Minnesota, Human Research Protection Program); Megan Hoffman (University of Minnesota, CTSI); Courtney Jarboe (University of Minnesota, Human Research Protection Program); Shannon Pergament (Somali, Latino and Hmong Partnership for Health and Wellness)

Additional community leaders were reached out to for specific questions and recommendations.

Representatives of the work group are to be commended for their reliable participation and conscientious contributions to the recommendations in this Engaging Research Participants
workgroup Report. A special recognition is due the Human Research Protection Program representatives who responded in real time to recommendations advanced by the group. Responses indicative of changes already instituted include:

- Placing a link to an online readability tool to reinforce current institutional expectations of informed consent documents approximating an eighth grade reading level.
- Forwarding for IRB consideration the recommendation regarding the informed consent document adhering to publicly announced institutional guidelines on the reading level of the text.
- Development of the wallet card with contact information clearly indicated (see appendix A).

**Recommendations pertaining to the Engagement of Research Participants before Study Participation**

The following recommendations involve changes in the information researchers are to include on the Institutional Review Board application or protocol and related documents. These recommendations focus on activities prior to the recruitment of research participants and establish expectations of research conduct with a focus on engaging participants in research through informed consent.

**Recommendation 1**

Recommend the consent form foster participant engagement by clearly identifying contact information regarding the research study question or problems encountered due to research participation (PI), participant research appointments (project team), and feedback or concerns regarding experience as a research participant (IRB Subject Advocate line). Contact information should also be regularly provided on a small card to all participants, Legally Authorized Representatives and family members (i.e., for Psychiatry Department and other studies involving individuals with diminished, impaired or fluctuating capacity) participating in non-exempt studies when informed consent is obtained and at subsequent study visits. Cards should be provided to all people approached for consent. Ideally, the language used on the card will parallel that contained in the informed consent documents.

To reduce confusion, the ERP work group recommends consolidating the phone numbers to call with questions and concerns from two numbers (Fairview Research Administration and the Research Participants’ Advocate line) to one number (Research Participants’ Advocate line). This is reflected on the contact card and should also be consistent on informed consent documents.

We acknowledge the contact card and its information must be accessible to be used. The work group calls for the training of research staff to explain the card and its purpose to individuals providing informed consent, particularly for studies where the possibility of diminished capacity among participants exists. When real or potential issues of diminished, impaired or fluctuating capacity exist, the research team will provide family members and friends with a card and an explanation that they are also welcome to provide feedback as indicated on the card.
The contact card template, included in appendix A, is to be made available on the IRB forms page of the website. The IRB research study protocol should also link the research team to appropriate contact card template. The ERP work group recommends that the card be translated into Spanish, Somali and Hmong languages, and used as a companion card when Short Forms are used in accordance to IRB Policy 706. Printing costs as well as costs associated with translating the card into languages other than Spanish, Somali and Hmong are the responsibility of the study. Researchers should budget accordingly.

Comment: The Education Advisory Committee will need to include training on the contact cards for PIs and Coordinators. The Post Approval Review Group will continue to collect metrics about questions and concerns related to research (via the Research Participants’ Advocate Line and HRPP feedback form). These metrics will be shared with the Community Oversight Board (COB), and trends will be shared with the Education Advisory Committee.

Owner(s): HRPP owns contact card; Education and Advisory Committee owns training on the card; Post Approval Review Group owns the Research Participants’ Advocate Line and HRPP feedback form.

Recommendation 2
All researchers must evaluate the readability and accessibility of all materials used in support of obtaining informed consent. The IRB’s new protocol template includes prompts to facilitate this requirement. The HRPP website should serve as a repository of examples of easily understood phrases and the translation of often used research concepts into other languages. Eventually the site should identify preferred wording in multiple languages for concepts that regularly recur in the informed consent process. Web content will be updated to include links to readability tools and a lay language medical thesaurus. Information about readability tools has been provided to researchers, IRB members and IRB staff. Researchers will be directed to these tools when readability concerns are noted.

The informed consent document should indicate that research participants may be asked to complete a survey about their experience as a research participant. The document should further indicate that the surveys are identified by research project, that individual responses are voluntary and anonymous.

Owner: HRPP

Recommendation 3
When appropriate, HRPP will require researchers to submit 3 questions as part of the IRB protocol in order to prepare to approach informed consent as an ongoing process. These questions will enable the research staff to do an informal assessment and prompt brief discussion about topics like the specific research question, subject study activities, the voluntary nature of participation or other research participant rights; one or more questions should be posed when a participant returns for subsequent research visits.

Comment: The Research Education Advisory Committee will need to include this recommendation into PI and coordinator training programs.
Recommendation 4
The training curriculum for the research workforce should initially identify key differentiators from current practice and highlight the differences until new norms are established. The curriculum should also highlight best practices in engagement, such as conformity to The AHRQ Informed Consent and Authorization Toolkit for Minimal Risk Research Publication #09-0089-EF [http://www.ahrq.gov/funding/policies/informedconsent/index.html]; oral communication strategies (i.e. teach back method); diversity awareness such as would be involved in cultural and community norms; capacity and comprehension assessments relative to individuals with diminished capacity; and awareness of research subject rights as defined in the Belmont Report.

The work group recognizes that the training curriculum will evolve as recommendations for improvement are incorporated into practice as well as to address issues identified through research participant feedback.

Comment: The Research Education Advisory Committee will need to integrate this recommendation into PI and coordinator training and education programs that is being developed by the education and training of Investigators work group.

Recommendation 5
The IRB protocol should include a dissemination plan that describes the information to be shared by the research team with research participants and the public and a schedule for sharing the information. Researchers should include dissemination costs in their study budgets whenever possible. University offices such as the Office of Public Engagement or the CTSI’s Office of Community Engagement to Advance Research and Community Health, the Department of Family Medicine and Community Health’s Program in Health Disparities Research, etc., provide additional opportunities for the dissemination into community contexts as appropriate. Resources to assist researchers and community-academic research teams in preparing a research plan include

2) [https://ctsacorus.org/resources/252/download/CARE_Dissemination_Strategies_FINAL_eversion_2.pdf](https://ctsacorus.org/resources/252/download/CARE_Dissemination_Strategies_FINAL_eversion_2.pdf)

Research dissemination plans should be provided the Office of Public Engagement for support and/or to monitor follow-through. In this regard, it is important to recognize that, in addition to direct contact with research participants (e.g., letter, newsletter, websites, appreciation note, reports at COB meeting), the University has an existing infrastructure to disseminate research to the public (i.e., meetings, sponsored talks, conferences, collaborations with local schools and organizations).
The IRB will review the dissemination plan to evaluate it against the criteria for approval and privacy/confidentiality requirements.

Comment: Researchers specifying a community-engaged project will have the option to report on their dissemination activities through the Society of Translational Scholars and Fellows. The Society is being organized collaboratively with the Office for Public Engagement and the CTSI Office of Community Engagement to Advance Research and Community Health (CEARCH). A key goal of The Society is to provide the University Academic Leadership with reliable information on collaborative research activities for use in shaping performance expectations for evaluating community-engaged scholarship.

Owner(s); HRPP owns the implementation and review; Office for Public Engagement owns monitoring

**Recommendation about research participant feedback on their experience during and after their participation in research**

In addition to existing avenues for participants to provide feedback on their experience as research participants, a survey focused on obtaining feedback on the experience of individuals involved in University of Minnesota research was prepared by the group with leadership from Jennifer Ball. The survey on participant experience is reproduced in Appendix B. While the Implementation Work Plan called for the development of a sampling strategy with the assistance of a statistician, this goal was determined to be unrealistic. The work group shares the following recommendations regarding the survey and the development of a sampling strategy.

**Recommendation 6**

The ERP recommends outsourcing the implementation and administration of the survey to an objective third party. The survey should be administered bi-annually with summary of results and trends provided to the Post Approval Review Group, the COB, the Fairview University Research Oversight Committee (FUROC), and the Education and Training Committee.

Owner(s): TBN third party provider, Post Approval Review Group, COB, Fairview University Research Oversight Committee (FUROC), and Education and Training Committee.

**Recommendations regarding the Expression of Appreciation and Dissemination of Research Results or Findings**

The Implementation Work Plan report stipulated the need to develop a list of best practices for expressing appreciation for research participation and for sharing final results with research participants (e.g., letter, newsletter, research website, departmental website, etc.). However, the work group failed to identify in the scholarly literature or within current institutional practices nationally the evidence of accepted best practices for expressing appreciation or for sharing research results with participants across the range of methods and questions that encompasses research involving human subjects at the University of Minnesota.
The work group recognizes two distinct audiences for establishing dissemination standards for sharing research results – the unique individual research participant where there is possibility of benefit from research participation and the general public for which research may possess a future value. The work group recognizes that the sharing of research results for the potential benefit of individuals resides in the research protocol and reviewed by the IRB. The work group advances the following recommendations:

**Recommendation 7**

*Regarding the Expression of Appreciation* We recommend each research participant (and Legally Authorized Representative) who completes a multi-visit research study receive a personalized note of appreciation from the researcher team for their contribution to advancing scientific knowledge.

Comment: The ERP work group will work with U Relations, the Advancing Human Research Protections communication work group, and the Creating a Culture Ethics work group to develop a template postcard that study teams can personalize. HRPP will host the postcard template with IRB-approved language on their website.

Owner(s): U Relations and HRPP

**Recommendation 8**

*Regarding the Dissemination of Research Results* A lay language summary of results for all research studies should be made publically available to both research participants and the general public. Information about the availability of a summary can be provided research participants in the note of appreciation sent at the conclusion of a study. Recognizing an opportunity to contribute to the public understanding of research and science, these summaries should be written at the same reading level as that required of informed consent documents. The summaries should clearly and simply explain research findings in relation to the research question.

Comment: Researchers should include where and how the summary will be shared with participants in the dissemination plan. Summaries should be run through a readability tool to conform to the readability requirements set by the IRB.

Owner(s): HRPP to insure inclusion in dissemination plan; Research Compliance Office and/or the Office of Public Engagement to monitor compliance.

**Recommendation 9**

The work group further recommends ongoing involvement of the Community Oversight Board in evaluating participant and community responses to research participation and dissemination activities and in identifying best practices for expressing appreciation and sharing research results. Involving the Community Oversight Board in this way will provide the Board opportunities to organize and assess public input, to shape the culture of ethics at the University as well as shape the public perception of University research.

The Community Oversight Board has an essential role to play in providing recommendations to the University and in reporting to the public on research participant experience. To the fullest
extent possible, the Board should be provided with the information they request in fulfilling their oversight role. Specifically, we recommend that the COB receive information on the number of active protocols involving human subjects; the number of participants enrolled for the reporting period. THE COB should also receive information on the number of problems reported to the Research Participant Advocate; the number of Unanticipated Problem Involving Risks to Subjects or Others (UIPRSOs); any other adverse events (i.e., research integrity issues). The COB should also receive information on the timeliness of institutional responses to all reported problems in order to assess how well the system for responding to complaints and inquiries functions. In addition, the COB should be provided information on the timely posting of summaries at the conclusion of projects and on the extent and timeliness of research teams in expressing appreciation to participants. The various forms of information and reports will support the COB in performing its essential role of providing oversight and in reporting to the public about how well the University of Minnesota is managing ethical issues connected to research that involves human subjects/participants.

Owner: COB

Recommendation 10
The Engaging Research Participants work group will present these recommendations to the COB.

Owner: Engaging Research Participants work group
Appendix A

Research Participant Contact Information Card Template

Front

[Blank]

For questions about research appointments, research study, research results, or other concerns, call the study team at:

[Blank]

You will receive a response within 1 business day.

IRB Study:______________________________

Back

To share feedback privately about your research experience, call the Research Participants’ Advocate Line at:

612-625-1650

Or go to www.irb.umn.edu/report.html

You will receive a response within 1 business day.

UMN Research Participants’ Bill of Rights:

www.irb.umn.edu/xxxxxxx
Research Participant Experience Survey

The Human Research Protection Program office at the University of Minnesota thanks you for participating in a research study at the University. The purpose of this survey is to gather responses from research participants like you to help us improve how we do research. We ask you to spend about five minutes to complete this survey. We the feedback you can provide about your experience as a research participant.

You participated in [Name of Study], which was led by [Name of PI]. We plan to gather responses from participants about many research projects. Please do not put your name on this survey. This will protect your privacy.

You do not have to complete this survey; however, we appreciate as much feedback as you choose to provide. You can complete the survey without answering all the questions.

If you would like to talk with someone about this survey or tell someone about your experience, please call the Research Participants’ Advocate Line at (612) 625-1650 or send an email to http://www.irb.umn.edu/report.html.

Thank you!

<< END OF INSTRUCTIONS >>
1. Why did you want to be in the research study? (Check as many boxes as apply.)

☐ The topic is important to me
☐ To improve what we know about the topic
☐ To help improve the lives of others
☐ To help improve my life
☐ To earn extra money
☐ I wanted to learn something new
☐ Other (*please write your reasons in the box below):  

   

2. Please tell us how you felt *when you were deciding if you wanted to be in the study.*

   For each statement, check the box that fits how much you agree or disagree with that statement.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Disagree</th>
<th>Somewhat Disagree</th>
<th>Somewhat Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>I felt rushed to make a decision about being in the study</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>I was given enough information to decide if I wanted to be in the study</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>I felt pressured to be in the study</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>I felt comfortable being in this study</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
3. Please tell us what it was like to be in the study.

For each statement, check the box that fits how much you agree or disagree with that statement.

| Statement                                                                 | Strongly Disagree | Somewhat Disagree | Somewhat Agree   | Strongly Agree 
<table>
<thead>
<tr>
<th></th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>I knew why I was asked to do the things I did in the study</td>
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<tr>
<td>I was clearly informed about all the activities I would be asked to do as a research participant</td>
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<tr>
<td>I felt it was okay to leave the study at any time if I wanted to</td>
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<tr>
<td>It was easy to get answers when I had a question</td>
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<td></td>
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</tr>
<tr>
<td>I felt the researcher(s) cared about me</td>
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</table>

4. There are many types of research studies. Different information from a study may be shared with participants based on the type of study.

Please tell us about the information the research team provided to you by checking the appropriate box for each question.

<table>
<thead>
<tr>
<th>Information provided</th>
<th>Yes</th>
<th>No</th>
<th>Not Sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information about you (for example, your health or abilities)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>An update about the research study</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A final report with study results</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information about how to find the final study results</td>
<td></td>
<td></td>
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</tbody>
</table>

5. The research team thanked me for participating in their study.

☐ Yes    ☐ No    ☐ Not Sure
6. Would you participate in another research study at the University of Minnesota?

☐ Yes  ☐ No  ☐ Not Sure

6. Would you tell others to be in research studies at the University of Minnesota?

☐ Yes  ☐ No  ☐ Not Sure

7. Please feel free to share anything else about being in the research study in the box below.

Thank you for taking our survey and helping us improve how we do research!
Please tell us a little about yourself so that we know who is completing the survey: Are you ....

1)  Female ______  Male ______  Prefer not to answer ______

2)  American Indian/Alaska Native ______  Prefer not to answer ______
    Asian ______
    Native Hawaiian or Other Pacific Islander ______
    Black or African American ______
    White ______
    Multi-racial ______

3)  Hispanic/Latino  Yes ______  No ______  Prefer not to answer ______

4)  Age  12 – 18 years old ______  Prefer not to answer ______
    19 – 39 years old ______
    40 – 65 years old ______
    More than 65 years old ______