PURPOSE:
The Medical College of Wisconsin and Froedtert Hospital (MCW/FH) HRPP office is committed to educating the research community about the IRB process by evaluating Community Outreach efforts that are designed to enhance the community's understanding of the human subject research process.

The MCW/FH HRPP office is responsible for enhancing the education of research subjects and the community about the IRB process and must assure that researchers employ a procedure that provides a venue for subjects to ask questions and voice concerns or complaints.

DEFINITIONS:
N/A

PROCEDURE:
I. COMMUNITY OUTREACH EDUCATION EFFORTS
Research Subjects
1. MCW HRPP Website
   The MCW HRPP website provides information to the research community and subjects about human subject research, the rights of a research subject, the IRB process, and who to contact with questions, concerns or complaints.

2. Office of Human Subject Research Protection (OHRP) Website
   The MCW HRPP website provides a link to the OHRP website, which is the federal agency charged with governing Institutional Review Boards.

3. Educational/Informational Brochures
   • MCW: “Is a Research Study for You”
     i. Describes Informed Consent Process
     ii. Identifies the Research and the Research Team
     iii. Describes Meeting the Research Team
     iv. Asking Questions
     v. Identifies Rights as a Volunteer
     vi. Identifies Other Resources
   • MCW: “Rights and Responsibilities of Participants”
   • OHRP: “Becoming a Research Volunteer”

4. Informed Consent
   The MCW HRPP requires each project to provide opportunities for subjects to ask questions and voice concerns or complaints. All Informed Consent documents must contain contact information for the Principal Investigator, in the event a subject has questions or concerns about the project. Additionally, the investigator must provide the contact information for the MCW/FH Research Subject Advocate, in the event a
subject has questions or concerns about the investigator or the study, and the investigator is not available or the subject is uncomfortable discussing their questions or concerns with the research team.

Investigators:
1. **MCW HRPP Website**
   The MCW HRPP website provides information to the research community and subjects about human subject research, the rights of a research subject, the IRB process, and who to contact with questions, concerns or complaints. The site provides the following educational links, including but not limited to:
   - OHRP and FDA (federal human subject research protection agencies),
   - Human Subject Research links for other federal agencies (i.e. DoD, DoEd, DoJ etc)
   - AAHRPP (Accrediting Organization),
   - NIH (National Institutes of Health)
   - MCW Office of Research

2. **OHRP Website**
   The MCW HRPP website provides a link to the Office of Human Subject Research Protection (OHRP), which is the federal agency charged with governing Institutional Review Boards.

3. **Informed Consent**
   The MCW HRPP requires each project to provide opportunities for subjects to ask questions and voice concerns or complaints. All Informed Consent documents must contain contact information for the Principal Investigator, in the event a subject has questions or concerns about the project. Additionally, the investigator must provide the contact information for the MCW/FH Research Subject Advocate, in the event a subject has questions or concerns about the investigator or the study, and the investigator is not available or the subject is uncomfortable discussing their question or concerns with the research team.

4. **Educational/Informational Brochures**
   - MCW "Is a Research Study for You"
     i. Describes Informed Consent Process
     ii. Identifies the Research and the Research Team
     iii. Describes Meeting the Research Team
     iv. Asking Questions
     v. Identifies Rights as a Volunteer
     vi. Identifies Other Resources
   - MCW "Rights and Responsibilities of Participants"
   - OHRP "Becoming a Research Volunteer"
   - DOE/NIH: Protecting Human Research Subjects
     i. Defines "Are you conducting research using Human Subjects?"
     ii. Requirements for conducting research involving human participants.
     iii. The Role of the IRB
     iv. Types of IRB Review
     v. Defines Informed Consent
     vi. Contact information for questions, concerns or complaints.
   - Human Subject Research Decision Charts

5. **IRB Education & Training**
   The MCW HRPP Office provides onsite live training sessions to the investigator/research community about human subject research activities and the IRB processes.
   - Human Research Professionals Monthly Meeting
   - Modules:
MCW/FH IRB MEMBERS & HRPP STAFF

1. MCW HRPP Website
   The MCW HRPP website provides information to the research community and subjects about human subject research, the rights of a research subject, the IRB process, and who to contact if you have questions, concerns or complaints. The site provides the following educational links, including but not limited to, OHRP (federal human subject research protection agencies), AAHRPP (Accrediting Organization), NIH (National Institutes of Health), and the MCW Office of Research.

2. OHRP Website
   The MCW HRPP Office provides a link to the Office of Human Subject Research Protection (OHRP), which is the federal agency charged with governing Institutional Review Boards.

3. MCW/FH IRB Member & HRPP Staff Training
   Members and Staff receive training on an ongoing basis regarding IRB regulations, interpretative guidelines, regulatory updates, AAHRPP accreditation standards, and MCW HRPP and/or MCW Corporate policy revisions. Training includes activities to enhance the education of the subjects and research community.

RESEARCH COMMUNITY

1. MCW HRPP Website
   The MCW HRPP website provides information to the research community and subjects about human subject research, the rights of a research subject, the IRB process, and who to contact with questions, concerns or complaints. The site contains sample TEMPLATES, IRB recommendations, IRB Decision Chart Templates, and FAQs to facilitate an understanding of the IRB process. The site provides the following educational links, including but not limited to, OHRP (federal human subject research protection agencies), AAHRPP (Accrediting Organization), and NIH (National Institutes of Health).

2. OHRP Website
   The MCW HRPP Office provides a link to the Office of Human Subject Research Protection (OHRP) website, which is the federal agency charged with governing Institutional Review Boards.

3. MCW/FH IRB & Staff Training
   Members and Staff receive training on an ongoing basis regarding IRB regulations, interpretative guidelines, regulatory updates, AAHRPP accreditation standards, and MCW HRPP and/or MCW Corporate policy revisions. Training includes activities to enhance the education of the subjects and research community.
   - IRB Chairs and co-Chairs serve as IRB educational ambassadors to the research community.
   - Staff members serve as IRB educational ambassadors to the research community.

4. Regulatory Agency/IRB Partnerships
   MCW is a recipient of Clinical and Translational Science Award from NIH and a member of Southeast Wisconsin Clinical and Translational Science Institute. Partner
institutions include: Marquette, UW-Milwaukee, Milwaukee School of Engineering, Children’s Hospital of Wisconsin and Zablocki VA Hospital. In addition is a member of the Wisconsin Institutional Review Board (IRB) Consortium (WIC) which fosters collaboration among local institutions (UW-Madison, Aurora Healthcare, and Marshfield Clinics) for review and research. The MCW HRPP office, MCW/FH IRB Members and IRB members of other institutions in addition to representatives from federal agencies may participate in community outreach activities such as conferences, public forums, and newsletters.

5. Cooperative Community Partnerships
MCW/FH HRPP Office works with MCW’s Advancing a Healthier Wisconsin Initiatives and community partners. With these initiatives MCW IRB and community representatives participate in community driven conferences to field questions about the IRB process. Organizations, agencies or departments serving the extended community and research subjects coordinate educational opportunities for potential research subjects with the IRB to enhance the communities understanding of human subject research and the IRB process.

II. EVALUATION OF COMMUNITY OUTREACH EFFORTS
1. Quarterly Reviews of Outreach and Educational Offerings
   The MCW HRPP office will assess the effectiveness of its outreach efforts on a quarterly basis using reviews of educational opportunities offered.
   - Training Evaluations
     Feedback forms evaluating the trainer of each “Live Training” session will be distributed and reviewed on an ongoing basis. The evaluation will be conducted by the HRPP Director, MCW/FH IRB Chair or MCW Quality Assurance Manager or designee.
   - Online Training
     Feedback forms evaluating the online MCW/FH CITI Human Subject Training module are submitted individually from investigators and research team members. All evaluations are dependent upon the participant’s submission, and will be reviewed on an ongoing basis. The evaluation will be conducted by the HRPP Director, MCW/FH IRB Chair or MCW Quality Assurance Manager or designee.
   - Subject Outreach Evaluations
     The MCWHRPP Office will assess the effectiveness of its Subject Outreach efforts on an ongoing basis. The participant, at their discretion, may submit the evaluation forms individually when accessing the website. All evaluations are dependent upon the participant’s submission, and will be reviewed on an ongoing basis. The evaluation will be conducted by the HRPP Director, MCW/FH IRB Chair or MCW Quality Assurance Manager or designee.

2. Organizational Periodic Evaluation of Outreach Activities
   The MCW HRPP Office, the Office of Research and CTSI leadership will annually evaluate the quality and effectiveness of community outreach activities. Improvements will be made as needed based on this evaluation to promote continual improvement of community outreach activities.

REFERENCES:
N/A

SUPPORTING DOCUMENTS:
OHRP website - http://www.hhs.gov/ohrp/humansubjectsguidance/45cfr46.htm#46.116
MCW HRPP website - http://www.mcw.edu/hrpp.htm