For research funded by the National Institute on Disability and Rehabilitation Research

When the IRB reviews research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research subjects, the IRB must include at least one person primarily concerned with the welfare of these research subjects.

Alternate Members

The appointment and function of alternate members is the same for primary IRB members. The alternates' expertise and perspective are comparable to those of the primary member. The role of the alternate member is to serve as a voting member of the IRB when the regular member is unavailable to attend a convened meeting. When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member would have received.

The IRB roster identifies the primary member(s) for whom each alternate member may substitute. The alternate member will not be counted as a voting member unless the primary member is absent. The IRB meeting minutes will document when an alternate member replaces a primary member.

Use of Consultants

- When necessary, the IRB Chair or the HRPP Director may solicit individuals from MCW, FH, Versiti, CW or the community with competence in special areas to assist in the review of issues or protocols, which require scientific or scholarly expertise beyond that available on the IRB.
- The need for a consultant is determined in advance of the meeting by the HRPP
 Director or the IRB Chair by reviewing the projects and submissions scheduled to
 be reviewed at the meeting. The HRPP Office will ensure that all relevant
 materials are provided to the consultant prior to the meeting.
- 3. If the need for a consultant is determined during the review in the meeting, a motion will be made to defer the submission to a future convened meeting until a consultant can be identified and their review provided to the IRB.
- 4. Written statements of consultants will be kept in IRB records. Key information

SUPPORTING DOCUMENTS:

MCW Corporate SOP: Research Involving Human Subjects and/or their Private Identifiable Information (RS.HS.010)

IRB Member SOP: Conflicts of Interest – IRB Committee Members

IRB Consultant Confidentiality Agreement and Conflict of Interest Certification Form

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Approved By

HRPP Authorized Official: Ryan Spellecy, PhD, Director, HRPP

Human Research Protections Program (HRPP)

Office of Research

Medical College of Wisconsin