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Members

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Institutional Review Board for the Protection of Human Participants

Annual Report for 2008 - 2009

Members

Dr. Karen Arscott
Dr. Estelle Campenni
Ms. Jean Deecki (Community Member – Resigned March 2009)
Dr. Uldarico Rex Dumdum (Chair)
Sr. Margaret Gannon
Dr. Christine Kessen
Sr. Joan McCusker
Rev. William Pickard (Prisoner Advocate)
Dr. Moses Prabu (Member at Large/ Community Member)
Dr. Robert Shivers (Community Member)

Administrative Staff throughout the academic year included Dr. Diane Keller, Ms. Courene M Loftus, Mrs. Tonya Renae McNair, and Mrs. Kristie Congdon

Meetings

Meetings were held monthly and there have been 8 meetings held between September 2008 and August 2009.

Accomplishments

New Application Review: N=63

- Full Review: N= 3
- Expedited Review: N=34
- Exempt Review: N=22
- Not Research with Human Participants: N= 4

Renewal Application Review: N=13

- Full Review: N=4
- Expedited Review: N= 4

- Exempt Review: N= 5

Review of Revisions to Previously Approved Research Protocols (Non-Clinical Trial): N= 15

- Full Review: N=4
- Expedited Review: N=3
- Exempt Review: N=8

Review of Clinical Trial or Biological Revisions, Safety/Adverse Reports and Deviation/Violation Reports: N=33

Completion of CITI training program in Human Participant Protection by researchers, sponsors, IRB members and staff: N=277

Implementation of online management and submission system through IRBNet.org

Ongoing training of IRB Members, sponsors and undergraduate, graduate and doctoral students on various aspects of the review process, regulations and IRBNet.

- Via Workshop or Classroom Presentation: N=97
- Via One-on-One Training: N=Unknown

Creation of IRBNet training instructions and website information

Revisions to IRB policies and procedures, including clarification of adverse event reporting, deviation/violation reporting, etc.

Attendance at the Center for Professional Innovation and Education's *Pediatric Clinical Trial Design – Ethics, Management and Regulatory Requirements* by Director and Human Physiology Lab Staff

Continued Certification as an IRB Professional (CIP) by the Director

Submitted by

Dr. Uldarico Rex Dumdum, Chair
September 17, 2009

MARYWOOD UNIVERSITY
UNIVERSITY STANDING COMMITTEES
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Dolores M. Filicko, IHM

Secretary of the University

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