McLaren HEALTH CARE		**Policy Title:**	Michigan State University IRB(s) Approved Projects
Effective Date:	January 16, 2012	**Policy Number:**	Appendix II
Review Date:	December 4, 2015	**Section:**	Human Research Protections Program (HRPP)
Revised Date:	November 2, 2015	**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Director, HRPP Institutional Official, HRPP		

1. Purpose

1.1. The purpose of the policy is to establish guidelines for human subjects research projects that will undergo Institutional Review Board (IRB) review at either the MSU Biomedical and Health Science IRB (BIRB), or Social Science/Behavioral/Education IRB (SIRB) where the MSU IRB will become the IRB of record, or "lead IRB".

2. Scope

2.1. This Policy applies to certain human research projects which undergo IRB review at MSU's Biomedical BIRB and SIRB.

2.2. The categories of projects for such review, termed "Reliance" are:

2.2.1. Human Subjects Research Projects proposed to be initiated or continued by Investigators employed by MSU using MHC subsidiary hospitals and other facilities. NOTE: If the project's Principal Investigator (PI) is not a staff member of the MHC subsidiary hospital/facility, the initial review application must name a Co/Sub-Investigator who is a member of the MHC subsidiary hospital/facility where the project is being conducted

2.2.2. Human Research Projects which were reviewed and approved by BIRB and/or SIRB for MHC subsidiary hospitals prior to this policy.

3. Definitions

3.1. Appendix I "Definitions"

4. Policy

4.1. Most of MHC subsidiary hospitals are participating members of either BIRB or SIRB. Projects to be performed in some or all of the participating subsidiary hospitals and other facilities where the PI is an MSU employed staff member, may be reviewed and approved one of the MSU's IRBs mentioned in this document.

4.2. If the MSU PI does not have privileges at MHC subsidiary hospital/facility, the application must name Co/Sub-Investigator from the MHC subsidiary hospital/facility where the study will be conducted.

4.3. When an investigator plans to conduct human subject research at one or all of the MHC subsidiary hospitals or other facilities that is engaged in the research, communication with the impacted departments is important for the protection of human research subjects. Investigator must obtain permission to allow research to be conducted at each impacted department as appropriate (e.g., Project Impact Statements).

4.4. The investigator must provide completed Project Impact Statement(s) to the MHC IRB prior to initiating the study.

4.5. The BIRB and SIRB will be maintained and supported by MSU and included on the University's Federalwide Assurance (FWA) on human research protections.

4.6. The MHC IRB will be maintained and supported by McLaren Health Care which is a parent institution to all MHC subsidiary hospitals. The MHC IRB will be included on all MHC subsidiary hospitals' FWA on human research protections as an IRB of record.

4.7. MSU IRB(s) will review and monitor research involving human subjects according to regulations at 45 CFR 46, 21 CFR 50 and 21 CFR 56.

4.8. MHC IRB will provide at least one IRB consultant to serve on all or one MSU IRB to represent MHC, when applicable.

4.9. After a project has been approved by the applicable MSU IRB, each MHC subsidiary hospital/facility either will concur with the BIRB's or SIRB's approval or decline to serve as a performance site for the project. This will be done through the MHC IRB as MHC IRB is the IRB of record for the subsidiary hospitals/facilities by the execution of a reliance agreement between each hospital and the MHC IRB outlining the responsibilities of each entity.

4.10. Minutes of BIRB or SIRB meetings and individual project documentation shall be made available to MHC IRB according to this policy.

5. Procedure

5.1. Prior to MSU IRB approval:

5.1.1. Investigators conducting research at MHC subsidiary hospitals or other facilities are required to provide completed Project Impact Statement(s) to the MHC IRB Staff, when appropriate.

5.1.2. MSU IRB office will alert the PI of the need to communicate with MHC IRB in order to facilitate the review of projects conducted at one or all MHC subsidiary hospital(s).

5.1.3. MSU IRB staff will assign MHC IRB consultant(s) on studies where MHC is listed as a participating site.

5.1.4. If MHC IRB approves the project, continuing review and any changes in the project will be performed at MSU's applicable IRB.

5.2. Newly approved projects:

5.2.1. Once a new project receives BIRB or SIRB approval, MHC IRB Staff will be provided with the following documents electronically from the MSU IRB Office:

5.2.1.1. MSU IRB approval letter (including conditional approval, if applicable).

5.2.2. Minutes from the fully convened BIRB and/or SIRB meeting(s).

5.2.3. NOTE: Other items, including, but not limited to, the protocol document, Investigators Brochure, advertisement, recruiting tool(s), diaries/questionnaires, reviewer comments, etc, can be accessed. MSU online system by the MHC IRB reviewer.

5.2.4. The MHC IRB Staff will contact MSU IRB office, or the PI for any apparent missing forms, such as completed Project Impact Statement.

5.2.5. The MHC IRB Staff will create a file for the study, separate from the MHC IRB study files and will enter the study into the created BIRB/SIRB database.

5.3. Review Outcome:

5.3.1. The study will be placed on the agenda of the next fully convened MHC IRB meeting as an Information Only item.

5.3.1.1. MHC IRB Staff will include a brief summary of the purpose of the research.

5.3.2. Continuing Reviews and Changes to Previously Approved Protocols

5.3.2.1 MSU IRB will continue to make available to the MHC IRB (electronically):

5.3.2.1.1. Copies of all subsequent BIRB/SIRB approvals and/or correspondence for the study. Such notifications will then be placed on the next fully convened MHC IRB meeting agenda as Information Only, and filed in the MHC IRB study file as applicable.

5.3.3. Reportable Adverse Event (AE) or Unanticipated Problem Involving Risks to Subjects or Others (UPIRSO)

5.3.3.1. If a reportable AE or UPIRSO occurs in a one of MHC subsidiary hospital's subjects, the PI is required to report the event within the required time frame directly to MHC IRB in addition to CRIRB or BIRB

5.3.3.2. When reporting reportable AE or UPIRSO to MHC IRB, PI should follow MHC HRPP Policy MHC_RP121 "Reporting Adverse Events and Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO)".

5.3.3.3. Both IRBs will work together to investigate the event and plan responses accordingly.

6. Responsibilities:

6.1. Principal Investigator (PI)

6.1.1. Obtain appropriate IRB approval(s).

6.1.2. The investigator must provide a completed Project Impact Statement to the MHC IRB prior to initiating the study.

6.1.3. Ensure all investigators and research staff at all MHC sites has current required human subjects training and other training as needed.

6.1.4. When appropriate, develop a data safety monitoring plan.

6.1.5. If medical records are accessed at any MHC sites:

6.1.5.1. Develop an approved HIPAA Authorization Form or obtain Waiver of Authorization.

6.1.5.2. Work with performance sites to ensure authorization or waiver.

6.1.6. Develop plans for data security at all MHC sites (if applicable).

6.1.6.1. Physical materials – locked file cabinets, limited access, etc.

6.1.6.2. Electronic data – passwords, encryption, firewalls, access, etc.

6.1.7. Develop a plan for a secure central database (if applicable).

6.1.7.1. Secure data transmission or transportation.

6.1.7.2. Security parameters for central database.

6.1.7.3. Limited access to identifiable data.

6.1.7.4. Identify who has access to data for research purposes and in what form. (e.g., anonymous).

6.1.8. Develop a communication plan with all MHC research sites (if applicable).

6.1.8.1. Develop a mechanism of reporting and responding to, unanticipated problems, adverse events, and complaints from all sites.

6.1.8.2. Develop a mechanism of coordinating information and applications for all revision and continuing review applications at all involved IRBs.

6.1.9. Develop a management plan with all MHC research sites (if applicable)

6.1.9.1. Develop plan for management of information that is relevant to protection of subjects, such as interim results.

6.1.10. Report any reportable AEs or UPIRSO occurring at the MHC site(s) according to the MHC HRPP Policy MHC_RP0118 “Reporting Adverse Events and Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO)”.

6.2. MSU IRB

6.2.1. Fulfill requirements stipulated in the formal Individual Institutional Agreement (IIA) e.g., provide copies of relevant IRB determinations regarding approval, continuing review including protocol modifications, interim results, unanticipated problems involving risks to subjects or others, suspensions, terminations, closure, required modifications, reports to government agencies, etc.

6.2.2. Communicate with the MHC sites, investigators, and/or MHC IRB, in order to:

6.2.2.1. Obtain information regarding reports of unanticipated problems, noncompliance, termination or suspension, and emergency use of investigational drugs or devices.

6.2.2.2. Coordinate corrective action plans as necessary.

6.2.2.3. Fulfill any other activity necessary to protect research subjects.

6.2.3. Work together with the MHC IRB to investigate the event and plan responses accordingly.

6.3. MHC IRB

6.3.1. MHC IRB will provide at least one IRB member or consultant to serve on all or one MSU IRB to represent MHC, when applicable

6.3.2. Ensure that a completed Project Impact Statement is on file with the MHC IRB office for each Impacted Department

6.3.3. Inform MHC IRB Committee of the approval at the next convened MHC IRB Meeting

6.3.4. Work together with the MSU IRB to investigate any related AEs and/or UPIRSOs and plan responses accordingly.

7. Previous Revisions: December 3, 2012

8. Supersedes Policy: MHC_RP0121_*Michigan State University IRB(s) Approved Projects*

9. Approvals:

MHC Institutional Review Board initial approval: February 17, 2012

MHC Institutional Review Board acknowledgment: December 3, 2012
December 4, 2015

_____ _____

Michael McKenna, MD Date
Executive Vice President/Chief Medical Officer
Institutional Official