McLaren HEALTH CARE		Policy Title:	The Federalwide Assurance and Institutional Review Board Registration
Effective Date:	January 16, 2012	**Policy Number:**	MHC_RP0102
Review Date:	August 21, 2015	**Section:**	Human Research Protections Program (HRPP)
Revised Date:	August 10, 2015	**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Director, HRPP Institutional Official, HRPP		

1. Purpose

1.1. The purpose of this policy is:

1.1.1. To establish guidelines for ensuring that all McLaren Health Care (MHC) subsidiary hospitals have on file a written Federalwide Assurance (FWA) of Compliance with the Department of Health and Human Services (DHHS) Regulations for Protection of Human Research Participants (45 CFR 46 Subpart E) and;

1.1.2. To ensure that MHC Institutional Review Board (IRB) is appropriately registered with the Office for Human Research Protection (OHRP).

2. Scope

2.1. McLaren Health Care Corporation and its subsidiaries

3. Definitions

3.1. Refer to Appendix I "Definitions"

4. Policy

4.1. McLaren's Health Care established one Institutional Review Board (MHC IRB) to review all human subject research conducted at McLaren

MHC IRB is registered as 00008640

4.2. McLaren Health Care Corporation holds a single corporate-level FWA and lists each subsidiary hospital as a component on its FWA. This is reflected in a Letter of Resolution for each hospital.

4.3. The President of McLaren Health Care has designated a senior level executive to serve as the Institutional Official (IO) for the protection of human research subjects.

4.4. The IO is also the official responsible for the McLaren's Human Research Protections Program (HRPP).

5. Procedure

5.1. The FWA applies to all human subject research which is conducted or supported by an agency under the Common Rule;

5.2. HRPP Office will track the expiration date of the FWA to ensure that it is renewed in accordance with timelines established by OHRP;

5.3. HRPP Office will determine on an annual basis whether any revisions are required. If so, revisions will be made according to processes established by OHRP for making revisions to the FWA found on their website;

5.4. Any proposed revisions to the FWA will also require evaluation of any inter-organizational agreements such as those establishing reliance on the MHC IRB (i.e. Letter of Resolution, IRB Authorization Agreement);

5.5. MHC IRB is registered with OHRP for the review and approval of biomedical and social and behavioral research conducted at all MHC subsidiary hospitals;

5.6. Each subsidiary hospital entered into IRB Authorization Agreements whereby each subsidiary hospital relies on the review and approval of human subjects research by the MHC IRB.

6. Responsibilities:

6.1. Although the ultimate responsibility for the protection of human subjects of research resides with the individual hospitals, the MHC HRPP coordinates and carries out review and oversight activities on behalf of each subsidiary hospital and reports directly to the Institutional Official (IO).

6.2. The IO is ultimately responsible for overseeing the protection of human subjects participating in research conducted at each hospital, by the MHC employees or agents, and research approved by the MHC IRB.

6.3. The IO is the signatory of the FWA for the McLaren Health Care Corporation and assumes the obligations of the Institution's FWA.

6.3.1. The IO understands the institution's responsibilities under the Federal-wide Assurance (FWA), assures the protection of human subjects of research, and assures that the MHC IRB is knowledgeable about the local research context and will comply with the terms of the FWA.

6.4. The IO ensures that MHC IRB maintains current registration with OHRP.

6.5. The Corporate Director of HRPP ensures compliance with the FWA, federal regulations, state statutes, local laws, IRB decisions, institutional policies and ethical principles for protecting human research participants.

6.6. The Corporate Director of HRPP ensures that MHC IRB is listed on Institution's FWA and ensuring that MHC IRB maintains current registration with OHRP.

7. References

7.1. FDA Guidance for Institutional Review Boards: Frequently Asked Questions – IRB Registration (July 2009)

7.2. Appendix I "Definitions"

8. Previous Revisions: October 29, 2012

9. Supersedes Policy: *MHC_RP0100_The Federalwide Assurance and IRB Registration*

10. Approvals:

MHC Institutional Review Board initial review: February 17, 2012

MHC Institutional Review Board acknowledgment: August 21, 2015

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