McLaren HEALTH CARE		Policy Title:	The Federalwide Assurance and Institutional Review Board Registration
Effective Date:	January 16, 2012	**Policy Number:**	MHC_RP102
Review Date:	August 2, 2020	**Section:**	Research Integrity
Revised Date:	January 11, 2023	**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Manager of Research Integrity Institutional Office, HRPP		

1. Purpose

1.1. The purpose of this policy is:

1.1.1. To establish guidelines to ensure 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 the MHC Institutional Review Board (MHC IRB) is appropriately registered with the Office for Human Research Protection (OHRP) and Food and Drug Administration (FDA).

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 Health Care established one institutional review board (MHC IRB) to review all human subject research conducted at McLaren.

MHC's Federal Registration Numbers	
IORG	0007199
IRB Registration	00008640

4.2. McLaren Health Care Corporation holds a single corporate-level FWA and lists each subsidiary hospital as a component on its FWA.

MHC's Federal Registration Numbers	
FWA	00021944

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

4.4. The IO is also the official responsible for the McLaren 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. The Research Integrity Office will track the expiration date of the FWA to ensure it is renewed in accordance with timelines established by OHRP and FDA;

5.3. The Research Integrity Office will determine on a quarterly basis whether any revisions are required. If so, revisions will be made according to processes established by OHRP and FDA for making revisions to the FWA found on their website;

5.4. The institution must update its FWA within 90 days after changes occur regarding the legal name of the institution, the Human Protections Administrator, or the Signatory Official.

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

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

5.7. Each subsidiary hospital entered into an IRB Authorization Agreement whereby the hospital relies on the MHC IRB for the review and approval of human subject's research.

5.8. MHC IRB FWA expiration date can be confirmed at http://ohrp.cit.nih.gov/search/ and search by our FWA number.

5.9. HRPP/IRB staff will track the FWA expiration date.

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 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 ensure 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 and FDA.

6.5. The Corporate Manager of Research Integrity 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 Manager of Research Integrity ensures that MHC IRB is listed on the institution's FWA and ensuring that MHC IRB maintains current registration with OHRP and FDA.

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: 10/29/12, 8/3/21, 12/14/21

9. Supersedes Policy: MHC_RP0100_The Federalwide Assurance and IRB Registration

10. Approvals:

MHC Institutional Review Board initial review: 2/17/12

MHC Institutional Review Board acknowledgment: 8/21/15

Signature on File *1/31/23*

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Institutional Official of Research