McLaren HEALTH CARE		**Policy Title:**	Complaints, Concerns, Questions, and Suggestions in Human Subject Research
Effective Date:	December 15, 2021	**Policy Number:**	MHC_RP0129
Review Date:		**Section:**	Research Integrity
Revised Date:	January 22, 2023	**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Manager of Research Integrity Institutional Official, HRPP		

1. Purpose

1.1. The purpose of this policy is to provide guidance in handling concerns, complaints, or questions received regarding research involving human subjects.

2. Scope

2.1.1. Research participants and the research community involved in human subject research at McLaren Health Care hospitals and subsidiaries.

2.1.2. IRB chairs and IRB members who need to report that they have been subjected to attempts of undue influence on their decisions.

2.1.3. Investigators and research staff members

3. Definitions

3.1. Refer to Appendix I “Definitions”

4. Policy

4.1. It is the policy of the Research Integrity Department – Office of Research Compliance will establish and maintain a safe, confidential, and reliable channel for current, prospective, or past research participants or their designated representatives and research staff members to ask questions, make suggestions, or raise complaints and concerns about research in general, a specific research study, or an investigator or research staff member with an informed individual who is unaffiliated with the research. All complaints and concerns will then be investigated. This policy also applies to IRB chairs and members who report that they have been subjected to attempts at undue influence on their decisions and to investigators who believe that the IRB has acted contrary to provisions of 45 CFR 46 or 21 CFR 50 and 56.

4.2. As part of its commitment to protecting the rights and welfare of human subjects in research, McLaren Health Care (MHC) HRPP reviews all complaints and takes any necessary action to ensure the ethical conduct of research.

4.3. The right of research subjects or designated legal authorized representatives to lodge a concern (e.g., allegation), complaint, ask a question, or provide suggestions and to be assured that the matter will be taken seriously and resolved in a timely manner is of prime importance.

4.4. The Corporate Research Integrity Manager or designee in the Research Integrity Department is responsible for investigating concerns, complaints, and questions from subjects and any improprieties involving investigators or their staff including formulating corrective actions for serious complaints.

4.5. The Corporate Research Integrity Manager or designee handles these issues in a timely manner, assuring protection of human subjects, and the IRB holds any violators accountable to the applicable regulation.

4.6. A research subject (past, current, or prospective), a designated spokesperson, family member, or anyone with a concern about research may raise concerns, complaints, or questions, or offer suggestions, by telephone, in writing, or in person to the McLaren IRB.

4.7. Each IRB approved informed consent document that includes a telephone number to reach the MHC IRB the telephone number is also listed on the Research Integrity website.

4.8. Investigators must encourage participants to ask questions and provide them with contact information for themselves and IRB on consent documents or study information sheet. (See Template for Informed Consent and policy MHC_RP0125 Investigator Responsibility).

4.9. The Research Integrity Department website shall describe how subjects or others can ask questions, make suggestions, or raise complaints or concern about a research study.

4.10. Questions, suggestions, complaints, and concerns may be raised anonymously.

4.11. If contributors identify themselves, their issues shall be treated with maximum possible confidentiality.

4.12. Research Integrity website Participant Corner shall describe the McLaren's commitment to the protection of research participants and provide information about how to ask a question, make a suggestion, or raise a complaint or concern. A dedicated phone number will be provided but participant communications will be accepted by any medium.

4.13. Orientations of IRB chairs and members shall include their obligation and right to report attempts at undue influence upon their decisions and how to do so.

4.14. The Corporate Research Integrity Manager or designee will prepare an annual summary of the number, nature, and resolution of questions, complaints, and concerns raised by research subjects/community. This report shall be used for quality improvement of the Human Research Protection Program.

4.15. Research that has been disapproved by the IRB (45 CFR 46.112) cannot be approved by any other individual and/or committee.

4.16. Investigators who believe that the IRB has acted contrary to provisions of 45 CFR 46 or 21 CFR 50 and 56 may contact either the Corporate Manager Research Integrity, VP of Clinical Excellence and Research, or the Institutional Official. The contacted party will ensure that the issue is investigated, and, if determined valid, that appropriate corrective actions are taken.

5. Procedure

5.1. Questions, suggestions, complaints, and concerns may be received by any medium and may contain identifiers or be anonymous.

5.2. Each day Research Compliance Officer/Research Integrity Manager or designee and the VP of Clinical Excellence and Research will check their own telephone messages, e-mail, and U.S. mail for questions, suggestions, concerns, or complaints and will meet with any person who visits the Research Administration Office to ask questions or make suggestions.

5.3. *Complaints and Concerns*

5.3.1. The Chair of the MHC IRB will promptly handle (or delegate staff to handle), and, if necessary, investigate all complaints, concerns, and appeals received by the MHC IRB. This includes complaints, concerns, and appeals from investigators, research participants, and others.

5.3.2. All complaints, written or verbal (including telephone complaints), regardless of point of origin, are recorded in writing and forwarded to the IRB Chair and Corporate Manager of Research Integrity.

5.3.2.1. When a concern or complaint involves a study under the oversight of an external IRB, the concern or complaint will be investigated and managed in accordance with the terms of the reliance agreement/procedures.

5.3.3. Upon receipt of the complaint, the Chair in consultation with the Corporate Manager of Research Integrity will make a preliminary assessment whether the complaint warrants immediate suspension of the research project. If a suspension is warranted, policy MHC_RP0111_Study Suspension, Termination, Investigator Hold will be followed.

5.3.4. Corporate Manager will send complaint to Compliance, QI, and Education Specialist to enter it on the FORM: Log of Complaints and Concerns and assign it a consecutive number.

5.3.5. Receipt and review of audit reports, or other reviews, which suggest evidence of serious or continuing non-compliance if the complaint meets the definition of non-compliance, it will be handles according to MHC_RP0123_Non-Compliance in Human Subject Research.

5.3.6. If the complaint meets the definition of an unanticipated problem involving risk to subjects or others, it will be handled according to Policy MHC_RP0121_ Reporting Events and Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO).

5.3.7. If the complaint is a query from a subject regarding study procedures, payments not received, etc., it will be forwarded to the investigator/study team for handling. The investigator/study team will be required to inform the IRB when the matter is closed (and the subject is satisfied with the answer).

5.3.8. Within 3 business days of receipt of the complaint, the IRB Chair and/or Corporate Manager of Research Integrity will generate a letter to acknowledge that the complaint has been received and is being investigated, providing a follow-up contact name.

5.3.9. Response to Complain or Concern About a Research Study and update it as the investigation proceeds. Be sure to indicate date on which complaint is considered resolved. If complainant's contact information is available, notify him/her of the resolution of the complaint and determine degree of satisfaction if possible.

5.4. Corporate Manager will send response to Compliance, QI, and Education Specialist to enter it on the FORM: Log of Complaints and Concerns and assign it a consecutive number.

5.5. *Questions and Suggestions to HRPP/IRB*

5.5.1. If the question or suggestion cannot be answered by the Corporate Research Integrity Manager or designee, they will refer it to the VP of Clinical Excellence and Research, if that person was not the original recipient. Similarly, if the Corporate Research Integrity Manager or designee feels that a personal telephone call, meeting or email would best be handled by the VP of Clinical Excellence and Research, s/he will arrange for that method of communication.

5.5.2. The recipient of the question or suggestion will forward the issue to the Compliance, QI and Education Specialist who will enter it on the computer file "Log of Questions and Suggestions", assigning it a consecutive number and recording the date.

5.5.3. Determine whether the question or suggestion raises an issue of noncompliance or unanticipated events that qualify it as a complaint or concern. If so, process under Section 5.2 of this procedure.

5.5.4. If the contributor of a question is identified, thank him/her for the question. If the answer is known, please answer it or inform the contributor that an answer will be sought and provided within three working days.

5.5.5. If the contributor of a suggestion is identified, acknowledge the suggestion and state that it will be relayed to the appropriate person. If possible, ascertain whether the person wishes to know if the suggestion is adopted.

5.5.6. Update the FORM: Log of Questions, and Suggestions with the date when a question was answered, or a suggestion was presented to the appropriate people and if it was acted upon.

5.6. *Quality Improvement of HRPP/IRB*

5.6.1. The Corporate Manager of Research Integrity may bring any question, suggestion, or complaint or concern to the attention of the Vice President for Research, the IRB Chairs and members, or the Research Compliance staff for review and action at any time if it appears that a change would improve the functioning of the HRPP or IRB.

5.6.2. The Corporate Manager of Research Integrity will prepare an annual summary of the number, nature, and resolution of questions, complaints, and concerns raised by research participants or others and present this report to the Vice President for Research, who may approve its distribution to others. This report shall be used for quality improvement of the Human Research Protections Program/IRB.

6. Responsibility

6.1. The Vice President of Clinical Excellence and Research is ultimately responsible for this policy. Enabling parties include Corporate Research Integrity Manager, Research Compliance Office, IRB Chair, Principal Investigator/Study Personnel.

7. References

7.1. 45 CFR 46.116(a)

7.2. 21 CFR 50.25(a)

7.3. MHC_RP0125 Investigator Responsibility Policy

7.4. MHC_RP0123 Non-Compliance Policy

7.5. MHC_RP0111_Study Suspension, Termination, Investigator Hold

7.6. Report of Complaint or Concern About a Research Study FORM

7.7. Report of Attempt to Exert Undue Influence FORM

7.8. Log of Questions, Complaints, Concerns and Suggestions by Participants

7.9. Log of Questions, Complaints, Concerns and Suggestions by Research Community

Previous Revisions: Not Applicable

Supersedes Policy: MHC_RP0123 Complaints and Non-Compliance was divided into two policies: MHC_RP0123 Non-Compliance and MHC_RP0129 Concerns, Questions, and Complaints About Human Research Studies.

Approvals:

MHC Institutional Review Board acknowledgment: Insert Committee Date

Signature on File *1/31/23*

_____ _____

Justin Klamerus, MD, MMM Date
Executive President/Chief Medical Officer
Institutional Official of Research