McLaren HEALTH CARE		Policy Title:	Expedited and Administrative Review of Human Subject Research
Effective Date:	February 17, 2012	Policy Number:	MHC_RP0106
Review Date:	June 5, 2020	Section:	Research Integrity
Revised Date:	March 22, 2024	Oversight Level:	Corporate
Administrative Responsibility:	Corporate Manager of Research Institutional Official		

1. Purpose

1.1. The purpose of this policy is to establish guidelines for recognizing and reviewing human subjects research that meet the federal criteria for expedited review. The policy also describes the types of research applications that qualify for administrative review.

2. Scope

2.1. The MHC Research Integrity department applies this policy to all proposed activities that meet the Common Rule definitions of “research” and “human subject” or the Food and Drug Administration (FDA) definitions of “clinical investigation” and “human subject” and when:

2.1.1. The research is conducted by or under the direction of an MHC investigator in connection with his/her assignment.

2.1.2. The research is conducted by an investigator employed by an MHC or its subsidiary hospitals.

2.1.3. The research engages MHC in the activity and is conducted using any property, patient population, or facility of the MHC or its subsidiary hospitals.

2.2. This policy applies to principal investigators, research staff, IRB chair or designee and IRB staff and administrators.

2.3. This policy does not apply the expedited review procedure may not be used for:

2.3.1. Research where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability, or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal risk.

2.3.2. Research that is classified.

3. Definitions

3.1. Refer to Appendix I “Definitions”

4. Policy

Expedited Review

4.1. An expedited review procedure consists of a review of research involving human subjects by the IRB chair or by one or more experienced reviewers designated by the IRB chair from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110 without convening a meeting of the full IRB.

4.2. In order to be eligible for expedited review, all aspects of the research must include activities that:

4.2.1. present no more than minimal risk to human subjects, and
4.2.2. involves only procedures included in one or more of the specific categories listed in the regulations at Federal Register Volume 63, No 216 (see Appendix A)

4.3. Expedited review procedures may be used when:

4.3.1. Expedited reviewers only approve research that meets the federal criteria for approval as specified in 45 CFR 46.111 and 21 CFR 56.111

4.3.2. Expedited reviewers ensure that the study’s informed consent process and documentation meet the requirements as specified in 45 CFR 46.116 and 21 CFR 50.25 unless the IRB waives the requirements in accordance with federal regulations.

4.3.3. Review of proposed human research activities including *Initial Review, Modifications and Continuing Review*, unless the reviewer determines and documents the rationale for the determination that the research involves more than minimal risk.

4.3.4. Review of certain research for which limited IRB review is a condition of exemption (see MHC_RP0105_Exempt Review of Human Subject Research)

4.3.5. Review of minor revisions of human subject research have been previously approved by the convened IRB and

4.3.6. Revisions to currently approved studies must be submitted as a modification. The following are examples of when the IRB may review and approve changes utilizing expedited mechanisms without subsequent review by the fully convened IRB. Minor changes which would qualify for expedited review that include but not limited to:

4.3.6.1. Changes that involve logistical, administrative, and/or editorial aspects of the research project.

4.3.6.2. Addition of research activities that would be considered expedited if considered independent from the main research protocol.

4.3.6.3. Increase or decrease in proposed human research participant enrollment where subjects are not placed at increased risk; (no greater than 10% increase of the total requested).

4.3.6.4. Narrowing the range of inclusion criteria.

4.3.6.5. Broadening the range of exclusion criteria.

4.3.6.6. Alterations in drug administration (e.g., tablet to capsule, capsule to liquid) provided the dose and route of administration remain constant and subjects are not placed at increased risk.

4.3.6.7. Decreasing the number or volume of biological sample collection provided that such a change does not affect the collection of information related to safety evaluations.

4.3.6.8. An increase in the length of participation or number of study visits for the purpose of increased participant safety monitoring.

4.3.6.9. Alteration or liberalization of payment schedule with proper justification.

4.3.6.10. Improvement in wording or language or to correct typographical errors in the consent document.

4.3.6.11. Deletions of qualified key personnel if the responsibilities of the study team member(s) are appropriately shifted to other personnel.

4.3.6.12. Addition of qualified key personnel.

4.3.6.13. Deletion of study sites.

4.3.6.14. Addition of a study site (which may require a Federal Wide Assurance (FWA) or other agreement between sites) with applicable off-site letters of approval.

4.3.6.15. Minor changes requested by other compliance committees.

4.3.6.16. Changes that do not alter the overall risk/benefit ratio of the study.

4.3.6.17. Change in the principal investigator (PI), provided the new PI has similar credentials to the previously approved PI. The IRB chair may elect to send the proposed change to the fully convened board for review.

4.4. Continuing review is not required for research described in 4.3.3 and 4.3.4 above unless the research is FDA regulation, or the IRB determines that it is required and documents the rationale within the expedited reviewer checklist.

4.5. The IRB is not required to review research proposals through the expedited review process, even if it appears to qualify under the federal regulations for such review. The decision to review an application through the expedited review process or to refer to the fully convened IRB for review is made by IRB staff or IRB administration upon consultation with the IRB chair or designee. An IRB reviewer

conducting an expedited review can also determine that the activity is greater than minimal risk, with documented justification, even though it fits an expedited category. The study would then be reviewed by the convened IRB.

4.6. When the IRB requires continuing review for a study that otherwise qualifies for expedited review procedures, the rationale for such a decision will be documented in the expedited reviewer checklist.

4.7. Expedited reviewers exercise all the authority of the IRB except suspensions, terminations, or disapprovals cannot be determined by expedited review. These actions can only be taken after review by the fully convened IRB in accordance with full board procedures and however, immediate actions can be taken by the MHC IRB chair, vice chair or IO for the imminent protection of human subjects (see policy MHC RP0111_Suspenison, Terminations and Investigator Hold).

Research Eligible for Administrative Review

4.8. Select submissions to the IRB can be reviewed by designated IRB staff by administrative review procedures. Those include:

4.8.1. Processing Annual Status Report

Under certain conditions, the requirements for continuing IRB review can be satisfied through the completion of a brief annual status report application confirmed by a designated IRB staff member through an administrative review, unless the IRB requires that a study undergo continuing review via expedited procedure. *Note: Annual status reports may not contain personnel changes.* See policy MHC_RP0112 Continuing Review of Human Subject Research.

4.8.1.1. Research initially approved under the pre-2018 Rule must meet all the following criteria to be eligible for the annual status report option:

4.8.1.1.1. The research is considered minimal risk and qualifies for expedited review even if the study initially received convened review.

4.8.1.1.2. The research has not been supported by a federal agency nor received federal funding at any time during the research, including through a sub-award from another institution and

4.8.1.1.3. The research is not FDA-regulated (including studies involving drugs, devices, and data submission)

4.8.2. Administrative Review of investigator request to use External IRB – See MHC_RP0128_Relying on External IRB.

5. Procedure

Expedited Review and Processing

Submissions

5.1. The PI can make a preliminary determination that a protocol is eligible for expedited review based on the criteria in the IRB electronic application system. However, the IRB makes the final determination regarding whether a protocol is eligible for expedited review.

5.2. Investigators submit the same materials for expedited review as they would for research subject to convened board review as follows:

5.2.1. Initial application, modifications, reportable events, continuing review, and annual status report (if applicable).

5.2.2. Progress Report for continuing review (e.g., sponsor provided report).

5.2.3. Information reports on minor changes in currently approved research.

5.2.4. Applicable supporting documents.

IRB Staff Pre-Review

5.3. Upon receipt of the expedited application for review in electronic IRB application system, IRB analyst will conduct a pre-review of the application and:

5.3.1. IRB staff checks for completeness and accuracy (e.g., appropriate documents attached).

5.3.2. IRB staff submit concerns to the study team for incomplete submissions, clarifications, or minor changes to allow for review by the fully convened IRB.

5.3.3. Confirm expedited category, as outlined in this policy, proposed for application is appropriate.

5.3.4. Confirm that the change(s) in currently approved research meet the criteria for expedited review and request revisions as appropriate.

5.3.5. Confirm that the reportable event meets the criteria for expedited review and request revisions or additional information as appropriate.

5.3.6. Request revisions and additional information from investigators as required by the IRB chair or designee.

5.4. IRB staff evaluates the protocol to determine whether a consultant is needed and notifies the IRB chair or the Corporate Manager of Research Integrity.

5.4.1. Guidelines on “Use of Consultants” is in policy MHC_RP0108 Full Board of Human Subject Research

Assigning Expedited Reviewers

5.5. On an annual basis, the IRB chair along with the Corporate Manager of Research Integrity will designate a list of IRB members experienced in conducting expedited reviews.

5.6. IRB Staff will assign expedited reviews to one or more IRB members from the pool of experienced reviewers designated by the IRB Chair (which may also include the IRB Chair).

5.7. The designees must qualify as "experienced" - Members who have completed IRB member orientation training, attended at least one convened meeting, received expedited review training, complete expedited reviews, and a voting member of the IRB.

5.8. IRB members who serve as designees to the IRB chair for expedited review will be matched as closely as possible with their field of expertise to the study. When making expedited reviewer assignments, the IRB staff member also considers the following:

5.8.1. Reviewer's scientific and/or scholarly expertise

5.8.2. Reviewer experience

5.8.3. Reviewer's status as scientist or nonscientist

5.8.4. Reviewer workload

5.8.5. The need for special representation (e.g., vulnerable populations)

5.8.6. Knowledge in the content of the protocol to be reviewed.

5.8.7. Knowledge of the requirements to approve research under expedited review.

5.9. IRB staff members may consult with the IRB Chair or Corporate Manager of Research Integrity as necessary when making reviewer assignments.

5.10. If a request is made for a waiver of HIPAA authorization or alteration of HIPAA authorization, a privacy officer, who is also a member of the MHC IRB, will be assigned.

5.11. Expedited reviewers notify IRB staff if they are unable to conduct an expedited review during the assigned time or have a conflict of interest on any protocol as outlined in the policy MHC_RP126 "Conflict of Interest: IRB Members. Another reviewer is selected by IRB staff.

5.12. The IRB Chair, based on their specific expertise may ask a consultant to review the research, if the Chair/Designee feels that the research activities involve issues that necessitate the additional consultation of someone with relevant expertise outside the realm of the IRB members. It is important to note that a consultant does not have authority to vote or take action on a research study.

5.13. IRB members with a conflict of interest in the research will not be selected.

5.14. IRB staff will ensure assigned reviewer(s) will receive all information that the convened IRB would have received and will initially review the materials submitted to confirm that the research meets the applicability criteria and one or more categories of research eligible for expedited review. This includes the complete application/submission and all supporting materials (e.g., the, study instruments, letters of support).

IRB Expedited Review Process

5.15. The IRB chair or other assigned reviewers are responsible procedures described in:

5.15.1. Policy MHC_RP109 Criteria for IRB Approval of Research and Possible IRB Actions

5.15.2. Policy MHC_RP111 Study Suspension, Termination and Investigator Hold

5.15.3. Policy MHC_RP0110 Additional Consideration During IRB Review

5.16. Expedited reviewers may exercise all the authorities of the IRB except, expedited reviewers cannot disapprove research. The research proposal may be disapproved only after review by the fully convened IRB in accordance with full board procedures.

5.17. If the research meets the criteria allowing review using the expedited procedure, the reviewer(s) will complete the appropriate reviewer checklist (Initial, Continuing or Modification Review) to determine whether the research meets the regulatory criteria for approval.

5.17.1. Ensuring that all protocol specific findings (Subpart Determinations, Consent waiver criteria) are documented.

5.17.2. If approving, ensuring that all the federal criteria at 45 CFR 46.111, 21 CFR 56.111 are met or

5.17.3. Reviewers will indicate approval, required modifications or requirement for convened board review on the appropriate checklist in electronic IRB

submission system and return to the MHC IRB office. If modifications are required, the IRB staff will inform the investigator via electronic IRB submission system.

5.17.4. If modifications are required, the IRB staff will inform the investigator via electronic IRB submission system.

5.18. In the event that expedited review is carried out by more than one IRB member and the expedited reviewers disagree, the IRB chair may make a final determination. Upon the discretion of the IRB chair, the protocol will be submitted to the IRB for review.

5.19. Modifications or clarifications requested by the reviewers are communicated to researchers in writing via the electronic IRB submission system. If a reviewer has any questions or concerns or is requesting modifications to the research study, s/he should draft a reviewer comment and submit it to the IRB office via electronic IRB submission system.

5.19.1. The IRB staff posts the reviewer comment(s) to the researchers in electronic IRB submission system.

5.19.2. Researchers are notified via e-mail automatically generated from electronic IRB submission system.

5.19.3. Once the researcher responds, the reviewer is notified. If the reviewer is satisfied with the response, the reviewer may issue his/her approval through the IRB submission system. If the reviewer has additional questions or concerns, another reviewer comment is submitted to the IRB office and the same process as above is followed.

5.19.4. If the reviewer and the researcher are unable to come to resolution over the issue raised, the IRB chair will mediate such discussions. If a resolution cannot be reached, the IRB will discuss the research study at its next convened meeting.

5.19.5. Refer applications to the convened board when uncertain whether the research qualifies for expedited review, when considering disapproval, or for any other reason that warrants convened board review.

5.20. If the research does not meet the criteria for expedited review or fits into an expedited category but is determined to be more than minimal risk then the reviewer will document his/her justification and indicate that the research requires full review by the IRB on the expedited reviewer sheet, and the protocol will be placed on the agenda for the next fully convened IRB meeting.

5.21. Note: Expedited IRB actions regarding noncompliance and event reporting are described in HRPP policies [Noncompliance] and [Event Reporting – Unanticipated

Problems Involving Risks to Subjects or Others, Adverse Events, and Other Problems], respectively.

Actions and Communication of Actions for Expedited Review:

5.22. IRB Staff will execute, and issue expedited approvals letters after all criteria necessary for approval have been met and approved by the IRB chair or designees.

5.23. Expedited approvals do not require convened IRB review. A standard approval letter will be used to communicate such approval to researchers in writing. The approved version of the consent form and the approval letter will be available through the electronic IRB system.

5.24. Initial Applications: All assigned reviewer(s) must issue an approval before the research study is given IRB approval. If there are multiple reviewers and they do not issue their approval on the same day, the date of approval will be the later of the dates of reviewer approval. The approval period is 364 days, unless otherwise noted.

5.25. Continuing Review Application:

5.25.1. Continuing review is not required for studies that qualify for expedited review unless the research is FDA-regulated, or the IRB requires continuing review.

5.25.2. Continuing Review -The continuing review approval date is the date the assigned reviewer issues approval. The revision approval date does not change the approval period.

5.26. IRB staff will list all studies approved using expedited review procedures on the agenda distributed at the next convened IRB meeting as informational items only and do not require any actions at the convened IRB meeting.

5.27. IRB records document the justification for determinations and expedited category.

6. References

6.1. 21 CFR 56

6.2. 45 CFR 46

6.3. Federal Register (Source: 63 FR 60364-60367, November 9, 1998

6.4. MHC_RP109 “Criteria for IRB Approval of Research and Possible IRB Actions”

6.5. MHC_RP111 “Study Suspension, Termination and Investigator Hold”

6.6. MHC_RP126 “Conflict of Interest: IRB Members”

6.7. Appendix I "Definitions"

7. Previous Revisions: 8/6/12, 3/18/13, supplement - MHC_0500 SOP Transition and IRB Review of Research Subject to Revised 2018 Common Rule For those studies receiving approval prior to the implementation of the Revised Common Rule (approved prior to January 21, 2019), the previous regulations apply. For more information regarding the regulations applicable to these studies, please see 11/6/15 version., 12/14/21, 1/12/23

8. Supersedes Policy: MHC_PR0112_Expedited Review of Human Subject Research

9. Approvals:

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

MHC /Institutional Review Board acknowledgment: 12/21/12, 8/21/15, 1/18/19

Signature on File *3/22/2024*

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

Appendix A Expedited Categories

The activities listed below should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

• The categories in this list apply regardless of the age of subjects, except as noted.

• The standard requirements for informed consent apply regardless of the type of review--expedited or convened--utilized by the IRB.

• Categories one (1) through seven (7) pertain to both initial and continuing IRB review. Categories eight (8) and nine (9) pertain to continuing studies only.

COMMON RULE 45 CFR 46.110 Expedited Categories

1. **Clinical studies of drugs and medical devices only when condition (a) or (b) is met.**

   a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

   b) Research on medical devices for which

      i. an investigational device exemption application (21 CFR 812) is not required; or

      ii. The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

   a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week

period and collection may not occur more frequently than 2 times per week; or

b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

3. **Prospective collection of biological specimens for research purposes by noninvasive means.**

Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization. Expedited Review Procedure 20 October 2021 OHRA-SOP-2019-007 5 ©2021 Albert Einstein College of Medicine

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications). Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. **Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).** (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

6. **Collection of data from voice, video, digital, or image recordings made for research purposes.**

7. **Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.** (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.) Note: The Following applies to Continuing review of research only.

8. **Continuing review of research previously approved by the convened IRB as follows:**

a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

b) where no subjects have been enrolled and no additional risks have been identified; or

c) where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified