McLaren HEALTH CARE		Policy Title:	Expedited Review of Human Subject Research
Effective Date:	February 17, 2012	Policy Number:	MHC_RP0106
Review Date:	August 21, 2015	Section:	Research Integrity
Revised Date:	June 2, 2020	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.

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

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

2.1.2. The research is conducted by an investigator employed by a 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; or

2.3.2. Research that is classified.

3. Definitions

3.1. Refer to Appendix I “Definitions”

4. Policy

4.1. Expedited review procedures may be used for:

4.1.1. Initial review of proposed human research activities appearing on the federal register list (Source: 63 FR 60364-60367, November 9, 1998) detailed in Section 5.1 below, unless the reviewer determines, and documents the rationale for the determination, that the research involves more than minimal risk;

4.1.1.1. For studies that are FDA-regulated or DoJ funded, the reviewer must specify that the activity described in the expedited category(ies) constitute minimal risk

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

4.1.3. Review of minor revisions of human subject research previously approved by the convened IRB.

4.2. Continuing review is not required for research described in 4.1.1 and 4.1.2 above unless the IRB determines that it is required and documents the rationale within the expedited reviewer checklist.

4.3. 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.

4.4. All requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review (e.g. expedited or convened IRB) utilized by the IRB.

4.5. Federal Register List of Categories of Research eligible for expedited review:

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

4.5.1.1. (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)

4.5.1.2. (b) Research on medical devices for which an investigational device exemption application (21 CFR Part 812) is not required; or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

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

4.5.2.1. From healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, 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

4.5.2.2. From other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, 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.

4.5.3. Category 3: Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

4.5.3.1. Hair and nail clippings in a non-disfiguring manner;

4.5.3.2. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;

4.5.3.3. Permanent teeth if routine patient care indicates a need for extraction;

4.5.3.4. Excreta and external secretions (including sweat);

4.5.3.5. 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;

4.5.3.6. Placenta removed at delivery;

4.5.3.7. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

4.5.3.8. Supra- and sub gingival 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;

4.5.3.9. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

4.5.3.10. Sputum collected after saline mist nebulization.

4.5.3.11. Vaginal swabs that do not go beyond he cervical

4.5.3.12. Rectal swabs that do not go beyond the rectum

4.5.3.13. Nasal swabs that do not go beyond the nerves

4.5.4. Category 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:

4.5.4.1. 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 participant or an invasion of the participant's privacy;

4.5.4.2. Weighing or testing sensory acuity;

4.5.4.3. Magnetic resonance imaging;

4.5.4.4. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography;

4.5.4.5. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

4.5.5. Category 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 participants. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.) Category 5 can also include research involving existing information or specimens that were previously collected for research purposes, provided they were not collected for the currently proposed research.

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

4.5.7. Category 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 participants. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

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

4.5.8.1. Where the research is permanently closed to the enrollment of new participants; where all participants have completed all research-related interventions; and where the research remains active only for long-term follow-up of participants; or

4.5.8.2. Where no participants have been enrolled and no additional risks have been identified; or

4.5.8.3. Where the remaining research activities are limited to data analysis.

4.5.9. Category 9: Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories 4.1.6.1.2 through 4.1.6.8 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.

4.6. 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.

4.7. Examples of minor changes which would qualify for expedited review:

4.7.1. Revisions to currently approved studies must be submitted as an amendment. The following are examples of when the IRB may review and approve changes utilizing expedited mechanisms without subsequent review by the fully convened IRB:

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

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

4.7.4. Increase or decrease in proposed human research participant enrollment where subjects are not placed at increased risk;

4.7.5. Narrowing the range of inclusion criteria;

4.7.6. Broadening the range of exclusion criteria;

4.7.7. 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;

4.7.8. 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;

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

4.7.10. Alteration or liberalization of payment schedule with proper justification;

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

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

4.7.13. Addition of qualified key personnel;

4.7.14. Deletion of study sites.

4.7.15. 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;

4.7.16. Minor changes requested by other compliance committees;

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

4.7.18. 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.

4.8. 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 listed in section 5.2 above; The study would then be reviewed by the convened IRB.

4.9. 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.

5. Procedure

5.1. Under an expedited review procedure, the review may be carried out by the IRB chair or by one or more designated reviewers.

5.1.1. 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.

5.2. If 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.

5.3. On an annual basis, the IRB chair along with the Corporate Manager of Research Integrity will designate a list of IRB members experienced to conduct reviews.

5.1.2. The designees must be experienced (having completed appropriate training for IRB members as well as specifics on how to a conduct review using expedited procedure) voting members of the IRB.

5.1.3. The IRB staff will select expedited reviewers from this list. Selected reviewers will have the qualifications, experience and knowledge in the content of the protocol to be reviewed, as well as be knowledgeable of the requirements to approve research under expedited review.

5.1.4. IRB members with a conflict of interest in the research (see Policy *MHC_RP126 "Conflict of Interest: IRB Members*") will not be selected.

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

5.5. 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.

5.6. In reviewing the research, the reviewers will follow the review procedures described in Policy MHC_RP109 "Criteria for IRB Approval of Research and Possible IRB Actions" and Policy MHC_RP111 "Study Suspension, Termination and Investigator Hold" and may exercise all of the authorities of the IRB except to suspend, terminate and/ or to not approve a study.

5.7. 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.

5.8. 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.

5.9. 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.

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

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

5.9.3. 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 44 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.

5.9.4. 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.

5.10. Actions and Communication of Actions for Expedited Review: Expedited approvals are issued after all criteria necessary for approval have been met. 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 e-protocol online system.

5.10.1. 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.

5.10.2. Renewals: Continuing review of studies that qualify for expedited review is not required, however, an Institutional Annual Status Report form must be submitted.

5.10.3. Revisions - Minor Changes: The revision approval date is the date the assigned reviewer issues approval. The revision approval date does not change the approval period

5.11. Research studies approved using expedited review procedures will be listed on the agenda distributed at the convened IRB meeting as informational items only and do not require any actions at the convened IRB meeting.

5.12. All members of the IRB will be apprised of all expedited review approvals by means of a list in the agenda for the next scheduled meeting.

5.13. IRB records document the justification for determinations.

6. Responsibilities

6.1. PIs: Responsible for completion and submission of the appropriate IRB application(s) for review as follows:

6.1.1. Initial application, modifications, reportable events via e-protocol, and continuing review (if applicable per Section 4.2.1) ;

6.1.2. 6.1.2 Progress Report for continuing review (e.g. sponsor provided report);

6.1.3. Modification request and information reports for minor changes in currently approved research;

6.2. IRB Staff: Upon submission of the expedited application for review in e-protocol, IRB analyst will conduct a pre-review of the application and:

6.2.1. Confirm expedited category, as outlined in this policy, proposed for all applications as appropriate;

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

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

6.2.4. Assign the application to the IRB chair or designee for review and approval of all proposed research;

6.2.5 Ensure all assigned reviewers receive the same materials. This includes the complete application/submission and all supporting materials (e.g., the protocol/research plan, and all applicable informed consent documents, addendums, recruitment materials, study instruments, letters of support).

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

6.2.6. Issue approval letters once the application has been approved by the IRB chair or designee;

6.2.7. Assign all applications for expedited review to an agenda of the fully convened IRB as an information item once approved.

6.3. The IRB chair or other assigned reviewers are responsible for:

6.3.1 Receiving the required IRB application/submission and supporting materials for review;

6.3.3 Determining if a research activity meets the criteria for an expedited review process Federal Register and criteria for expedited review;

6.3.4. Approving or requesting revisions/additional information;

6.3.5 Completing the expedited reviewer checklist:

6.3.6 Ensuring that all of the federal criteria at 45 CFR 46.111, 21 CFR 56.111 are met

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

6.3.5. Sending applications to the fully convened board if the reviewer is not satisfied with the research as presented. 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.

7. References

7.1 21 CFR 56

7.2 45 CFR 46

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

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

7.6 MHC_RP111 “Study Suspension, Termination and Investigator Hold”

7.7. MHC_RP126 “Conflict of Interest: IRB Members”

7.8. Appendix I “Definitions”

8. Previous Revisions: August 6, 2012, March 18, 2013, 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 November 6, 2015 version.

9.

10. Supersedes Policy: MHC_PR0112_Expedited Review of Human Subject Research

11. Approvals:

12. MHC Institutional Review Board initial review: February 17, 2012MHC
Institutional Review Board acknowledgment: December 21, 2012

August 21, 2015

January 18, 2019

13. _____ _____

14. Michael McKenna, MD Date

Executive Vice President/ Chief Medical Officer

15. Institutional Official of Research

16.