4.3.5. Communication of results

4.3.5.1. The PI is notified of the decision, referring to the board action, on the continuing review application through an action letter.

4.3.5.2. The PI may be requested to provide additional information or submit additional documents.

4.3.6. Files management

4.3.6.1. The IRB Chair shall sign the accomplished **MDH IRB FORM 3(A)2021: Continuing Review Application Form**

4.3.6.2. The Secretariat stores the signed continuing review application documents in the study protocol file folder.

4.4. Final Report

4.4.1. Management of the final report package upon submission

4.4.1.1. Upon completion of the study, the PI should provide the MDH IRB with a summary report of the study site.

4.4.1.2. The Secretariat looks through the Study Protocol Database for the titles of study protocols that are due for final report at the end of the month.

4.4.1.3. The Secretariat informs the respective PI of study protocols whose MDH IRB clearance is about to expire. The PI shall submit an accomplished **MDH IRB FORM 4(N) 2021: REMINDER LETTER FOR CONTINUING REVIEW and ANNUAL REPORT** one month in advance of the expiration date of MDH IRB clearance. The

Secretariat shall keep a receiving copy of the communication.

4.4.1.4. The end of study reporting is facilitated through the submission of an electronic copy and 1 hard copy of **MDH IRB FORM 3(C)2021: FINAL REPORT FORM,** together with documents deemed relevant by the investigator to clarify information indicated in the final report.

4.4.1.5. The Secretariat checks the submission for completeness, requests the PI or his representative to log details of submission in the submissions logbook, and gives a receiving copy of **MDH IRB FORM 3(C)2021: FINAL REPORT FORM** to the PI or his/her representative stamped received by MDH IRB.

4.4.2. Classification of Review by the IRB Chair

4.4.2.1. The IRB Chair classifies the submission as either full board or expedited review.

4.4.2.2. Generally, classification of review of final report as expedited or full board is based on the initial review unless otherwise indicated by the specificities of the submitted information.

4.4.3. Review by primary reviewers

4.4.3.1. The Secretariat uploads he final report package together with a copy of the study protocol. In the event that primary reviewers are no longer with IRB, the Chair assigns reviewers with the same expertise required by the protocol.

4.4.3.2. For submissions under expedited review, action is finalized at the level of the primary reviewers within **seven (7**) calendar days.

4.4.3.3. Final report packages subject to full board review received within the cut-off period of **fifteen (15)** days before the IRB meeting are **uploaded ten (10)** to **twelve (12)** calendar days before the meeting.

4.4.3.4. The Secretariat places the final report submission on the agenda for the next IRB

meeting.

4.4.3.5. The primary reviewers accomplish the review using **MDH IRB FORM 3(C)2021: FINAL REPORT FORM within three (3) working days prior to the MDH IRB meeting.**.

4.4.4. Full board review of Final report

4.4.4.1. The Secretariat uploads the following final report package in the MDH IRB OneDrive cloud storage

4.3.4.1.1. MDH IRB FORM 3(C)2021: FINAL REPORT FORM

4.3.4.1.2. Relevant documents or attachments

4.4.4.2. The documents are presented to IRB Members when final reports are deliberated on. For detailed information on the conduct of full board review of final reports, see **SOP II-5.8.2. .** The MDH IRB Chair calls on the members to deliberate on the summary of findings and related ethical issues, including post-study management of study participants, and decide on MDH IRB action such as:

a. Approved
b. Request information
c. Recommend further action

4.4.5. Communication of results

4.4.5.1. The PI is notified of the IRB decision referring to IRB action on the final report, through an action letter.

4.4.5.2. The PI may be requested to provide additional information or submit additional documents, in which case the final report may be accepted, but action regarding archiving may be deferred pending submission of results of the study.

4.4.5.3. If the final report is approved, the PI is informed of the following:

4.3.5.3.1. The study protocol is classified as INACTIVE.
4.3.5.3.2. Ethical clearance is expired effective on the day of the IRB meeting.
4.3.5.3.3. Study protocol records will be made available for three **(3) years in the archives.**

4.4.6. Files management

4.4.6.1. The IRB Chair shall sign **MDH IRB FORM 3(C)2021: FINAL REPORT FORM.**

4.4.6.2. The Secretariat stores the signed final report documents in the study protocol file folder, upon approval of the final report, when no further action is expected from the PI.

4.4.6.3. The Secretariat highlights in grey the study protocol data in the Study Protocol Database to signify the end of study and update relevant fields on the date of termination and status.

4.4.6.4. The Secretariat transfers the study protocol folder to the inactive files. See **SOP IV-8: Archived (Inactive/Completed/Terminated) Files** for management of inactive files.

4.5. Study Protocol Non-compliance (Deviation/Violation) Report

4.5.1. Management of the Study Protocol Non-compliance Reports upon submission

4.5.1.1. The investigator should document, explain and report to the MDH IRB any non-compliance from the approved protocol, whether major or minor, within 7 working days upon knowledge of the Protocol Deviation.

4.5.1.2. The investigator may implement a deviation from the protocol to eliminate an immediate hazard(s) to study subjects without prior MDH IRB approval, but must