4.2. Progress Report

4.2.1. Receipt and management of the Progress Report package

4.2.1.1. After approval, a progress report is required at least once a year, depending on the risk assessment, number of subjects and feasibility issues of the study protocol, which is determined during the initial review. High risk studies should be reported every 3-6 months, moderate risk studies every 6-12 months and low risk studies annually). The Principal Investigator is reminded to report the progress of the study using **MDH IRB FORM 3(A)2021: Progress Report**.

4.2.1.2. The frequency of progress reports is indicated in **MDH IRB FORM 4(B) 2021: APPROVAL LETTER TO THE STUDY PROTOCOL,** which is provided to the PI upon approval of the study.

4.2.1.3. The Progress report is facilitated through the submission of **MDH IRB FORM 3(A)2021: Progress Report Form,** together with current informed consent documents. Electronic copy should be submitted as well as 1 hard copy. This comprises Progress report package. Any changes in the **IB** should be submitted using **MDH IRB FORM 3(B) 2021: Study Protocol Amendment Submission Form** for review and approval by the board.

4.2.1.4. 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(A) 2021: Progress Report Form,** to the PI or his/her representative stamped received by MDH IRB.

4.2.2. Classification of Review by the IRB Chair

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

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

4.2.3. Review by IRB Chair and primary reviewers

4.2.3.1. The progress report package is uploaded together with a copy of the study protocol for review.

4.2.3.2. For submissions under expedited review, action is finalized at the level of the IRB Chair within **seven (7)** calendar days.

4.2.3.3. Progress report packages subject to full board review received within the cut-off period which is every 15th day of the month are uploaded **ten (10) to twelve (12)** calendar days before the IRB meeting.

4.2.3.4. The Secretariat places the progress report on the agenda for the next IRB meeting.

4.2.3.5. The primary reviewers accomplish the review using **MDH IRB FORM 3(A) 2021: Progress Report Form** within three (3) working days prior to the MDH IRB meeting.

4.2.4. Full board review of Progress Report

4.2.4.1. The Secretariat uploads the following Progress report package for IRB Members:

a. MDH IRB FORM 3(A)2021: Progress Report Form
b. Study protocol synopsis
c. Current informed consent documents

4.2.4.2. The documents are presented to IRB Members when progress report are deliberated on. For detailed information on the conduct of full board review of progress reports, see **SOP II-5.8.1.** The MDH IRB Chair calls for any of the following actions:

a. Uphold Original Approval with no further action
b. Request information

c. Recommend further action
d. Disapproval

4.2.5. Communication of results

4.2.5.1. The PI is notified of the decision, referring to the board action, on the progress report through an action letter.

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

4.2.6. Files management

4.2.6.1. The IRB Chair shall sign the accomplished **MDH IRB FORM 3(A)2021: Progress Report Form**

4.2.6.2. The Secretariat stores the signed progress report documents in the study protocol file folder.

4.3. Continuing Review Application

4.3.1. Receipt and management of the Continuing Review Application package.

4.3.1.1. Ethical clearance or approval is granted for a period of one year usually but maybe semi-annually depending on risk assessment, number of subjects and feasibility issues of the study protocol, which is determined during the initial review. The Principal Investigator is reminded to report the **Continuing Review Application** of the study using **MDH IRB FORM 3K2021: Continuing Review Form**. The approval letter shall mention that failure to apply for a continuing review application for a study beyond the prescribed approval period constitutes an ethical violation.