



Manila Doctors Hospital INSTITUTIONAL REVIEW BOARD

MDH IRB SOP
003/06-0-2021
Effective Date:
08December2021

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III. POST-APPROVAL REVIEW

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.

4.3.1.2. The frequency of continuing review 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.

4.3.1.3. For ethical clearance or approval approaching the expiry date and requiring a renewal or extension, PI shall submit a hard copy and electronic copy of a letter requesting such and **MDH IRB FORM 3(K) 2021: Continuing Review** on or before thirty (30) days before the expiry date.

4.3.1.4. The Secretariat looks through the Study Protocol Database for the titles of study protocols that are due for continuing review at the end of the month.

4.3.1.5. The Secretariat informs the respective PI at least **30 days** in advance of the due date using **MDH IRB FORM 4(N)2021: REMINDER LETTER FOR CONTINUING REVIEW** and keeps a receiving copy of the communication.

4.3.1.6. 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(K) 2021: Continuing Review–Application Form**, to the PI or his/her representative stamped received by MDH IRB.



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4.3.2. Classification of Review by the IRB Chair

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

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

4.3.3. Review by IRB Chair and primary reviewers

4.3.3.1. The continuing review application package is uploaded together with a copy of the study protocol for review.

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

4.3.3.3. Continuing review application 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.

4.3.3.4. The Secretariat places the continuing review application on the agenda for the next IRB meeting.

4.3.3.5. The primary reviewers accomplish the review using **MDH IRB FORM 3(K) 2021: Continuing Review Application Form** within three (3) working days prior to the MDH IRB meeting.

4.3.4. Full board review of Continuing Review Application

4.3.4.1. The Secretariat uploads the following continuing review application package for IRB Members:

- a. **MDH IRB FORM 3(K) 2021: Continuing Review Form**
- b. Study protocol synopsis



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c. Current informed consent documents

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

- e. Approval
- f. Request information
- g. Recommend further action
- h. Disapproval

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(K) 2021: Continuing Review Form**

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