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	03. Guideline for Protocol Amendments	

ANNEX 1
AF 1.2-01-002.2012-02

Guideline for

PROTOCOL AMENDMENTS

Version No. 1.1

**MEDICAL AND HEALTH RESEARCH ETHICS
COMMITTEE
FACULTY OF MEDICINE
UNIVERSITAS GADJAH MADA**

Address:

Jl. Farmako, Sekip Utara Yogyakarta 55281
Phone: +62-274-560300, +62-274-7134955, 9017225 (from within
UGM), FAX: +62-274-581876
Email: mhrec_fmugm@ugm.ac.id

October 2012



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1. INTRODUCTION

The purpose of this guideline is to show investigator(s) how to submit amendment of protocols or other documents to be reviewed and how the Ethics Committee will process the submission of protocol amendments.

The preparation of this guideline was based on SOP 4.2-013.2012-02 (Review of Protocol Amendments).

This document is completed with form AF 4.2.01-013.2012-02 (Protocol Amendments Submission Form) to be used to complete the submission of protocol amendments.


2. DETAILED DESCRIPTION

Preparation for protocol amendments:

- Prepare the amended documents **with its version/edition number** along with the filled in form AF 4.2.01-013.2012-02 (Protocol Amendments Submission Form).
- **Please indicate the amendments in the new documents by putting post-fix and highlights the relevant pages and sentences**

Submission of the amended protocols:

- The amended protocol should be submitted to the Secretariat of the Ethics Committee/ Institutional Review Board::
 Gedung Radiopoetro Lt. 2 Sayap Barat, phone: 9017225 (dari lingkungan UGM), 0274-7134955, email: mhrec_fmugm@ugm.ac.id (for the time being, we only receive submission in person).
- Upon completion of the documents, the investigator(s) will receive a copy of AF 3.1.02-007.2012-02: Documents Receipt Form.

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Process of review of amended documents:

- The secretary of the Committee decided whether the amendments can be expedited (minor changes) or have to go to full review. For full review, the investigator(s) may be expected to present their study in a full board review.
- The secretary of the committee also assigns reviewers, which by custom will be the reviewers who have previously review the particular protocol.
- The amended documents and the filled form of AF 4.2.01-013.2012-02 (Protocol Amendments Submission Form) will then sent to the reviewers
- The investigator is welcomed to monitor the stage of the review at anytime by contacting the secretariat.

Information to the Investigator on the Decision of the Ethics Committee:

- The secretariat inform the investigator about the Committee’s decision by phone or sms (short message service)
- For the decision “*Approved*”, the investigator will directly get the Approval Letter that may be picked up at the Secretariat of the Committee.
- For the decision “*Suspend*”, the investigator has to suspend the study until further information is obtained.
- For the decision “*Further information required, continue with approved protocol*”, the investigator can only continue with previous protocol until more information to justify the amendment is obtained.
- For the decision “*Disapproved*”, the investigator has to continue with the approved protocols.

3. APPENDICES

Form AF 4.2.01-013.2012-02: Protocol Amendments Submission Form is available in the website and the Secretariat Office.