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| | 02. Guideline for Protocol Resubmission | |

ANNEX 1
AF 1.2-01-002.2012-02

Guideline for

PROTOCOL RESUBMISSION

Version No. 1.1

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

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October 2012



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1. INTRODUCTION

The purpose of this guideline is to show investigator(s) how to resubmit protocols or other documents to be re-reviewed and how the Ethics Committee will process the protocol resubmission.

The preparation of this guideline was based on SOP 4.1-012.2012-02 (Review of Resubmitted Protocols).

This document is completed with form AF 4.1.01-012.2012-02 (Memorandum Addressing Correction) to be used to complete resubmission of protocol.


2. DETAILED DESCRIPTION

Preparation for resubmission of the study protocol:

- Get the letter showing the reviewers' recommendation from the secretariat of the Committee.
- Respond to each recommendation:
 - Fill in form AF 4.1.01-012.2012-02 (Memorandum Addressing Correction)
 - **If the suggestion is to add more information or to modify the protocol/ the informed consent document or other documents, please resubmit a new relevant document with its version/ edition number. Please indicate where in the new document you addressed the recommendation by putting post-fix and highlights on the relevant pages and sentences.**

Re-submission of the study protocols:

- The protocol should be resubmitted to the Secretariat of the Ethics Committee/ Institutional Review Board:
 Gedung Radiopoetro Lt. 2 Sayap Barat, phone: 9017225 (dari lingkungan UGM),

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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.

Process of review of resubmitted protocol:

- The resubmitted study protocol or other documents and the filled form of AF 4.1.01-012.2012-02 (Memorandum Addressing Correction) will be sent to the reviewers who have previously review the proposal. The resubmitted protocol can be reviewed in a full board or in an expedited manner.
- 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.
- However, the reviewer may ask for further modification, that can be:
 - "***Approved with recommendation***", the investigator will get a letter showing further actions to be taken by the investigator. This means the investigator have to further follow the recommendation before getting an approval.
 - "***Resubmission***", the investigator will also get a letter showing further actions to be taken by the investigator. He/ she then has to, again, resubmit the protocol by following the guideline for protocol re-submission.
 - The reviewer(s) may also decide to discuss the proposal or other documents in a full board meeting with or without the presence of the investigator.

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- For the decision “*Disapproved*”, a notifying letter to the investigator or the project manager should state the followings: “If you wish to appeal to this decision, please contact the MHREC FM UGM and submit your appeal in writing, addressed to the MHREC FM UGM Chairperson with justification as to why the appeal should be granted.”

3. APPENDICES

Form AF 4.1.01-012.2012-02: Memorandum Addressing Correction, is available in the website and the Secretariat Office.