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	01. Guideline for Initial Protocol Submission	

ANNEX 1
 AF 1.2-01-002.2012-02

Guideline for

INITIAL PROTOCOL SUBMISSION

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 prepare protocols for initial submission and how the Ethics Committee will process the Protocols.


The preparation of this guideline was based on SOP 3.1-007.2012-02 (Management of Protocol Submission), SOP 3.2-008.2012-02 (Submission of Protocol for Initial Review), SOP 3.4-010.2012-02 (Use of Study Assessment Forms), and SOP 3.6-028.2012-02 (Assessment of Research Involving Animal).

This document is completed with several forms to be used to complete initial protocol submission.

2. DETAILED DESCRIPTION

Preparation of the study protocols:

- Submit at least 3 hard copies and a soft copy of the study protocol and related documents, however, when the need arise, i.e. the study had to reviewed by more than two reviewers or the study needs to go to full board review, The Ethics Committee may require more than three copies.
- Preparation of the protocol should include the version number submitted (with or without date) written in the footer of the page of the protocol.
- The following documents should be included and bundled with the study protocol:
 - Information for subjects (when applicable)
 - Informed consent form (when applicable)
 - Case report form/ questionnaire/ interview guide (when applicable)
 - CV of the investigator(s)
 - Study budget (when applicable)
 - Study related brochure (when applicable)
 - Other necessary documents (when applicable)
- Abstract of the proposed study (in soft copy)


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Submission of the study protocols:

- The protocols should be sent 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).
- The protocols should be sent with a cover letter from:
 - The director of the study program (for students)
 - The Head of the Department/ Faculty/ University of the Principle
Investigator.
- The submission should be completed with submission of filled forms:
 - AF 3.2.01-008.2012-02: Initial Review Submission Form
 - AF 3.2.02-008.2012-02: Summary Sheet of the Study Protocol
 - AF 3.6.01-028.2012-02: Ethics Application Form for Research Involving
Animals (when applicable)
- The Investigator pays administrative fee to the account of Faculty of Medicine,
UGM in BNI Bank account name: UGM FKU PENUNJANG, No. 179402424
- Only completed documents will be processed. Investigator is highly
recommended to submit the documents him/ herself.

Process of protocol review:

- Upon completion of documents, the investigator(s) will receive a copy of AF
3.1.02-007.2012-02: Documents Receipt Form.
- The study protocol will then sent to the secretary for assignment of reviewers. The
reviewers will review the protocol using Study Assessment Form (AF 3.4.01-
010.2012-02)

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- The investigator is welcomed to monitor the stage of review at anytime by contacting the secretariat.
- The study protocol can be exempted, i.e. no review is necessary; expedited or regular review. For regular review, the investigator(s) may be expected to present their study in a full board review.

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 "***Approved with recommendation***", the investigator will get the summary of the recommendation showing the actions to be taken by the investigator. This means the investigator have to follow the recommendation before getting an approval.
- For the decision "***Resubmission***", the investigator will also get the copy of the summary of the recommendation showing the actions to be taken by the investigator. He/ she then has to resubmit the protocol by following the guideline for protocol resubmission.
- 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

All the forms are available in the website: (<http://fk.ugm.ac.id/2012/06/13/komisi-etik/>) and the Secretariat Office

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This guideline is completed with:

- Flow chart/ Bagan Alir (only available in Bahasa Indonesia)
- Guidance for preparation of Information for subjects and Informed consent form (petunjuk penyusunan lembar penjelasan kepada calon subyek) with their examples (only available in Bahasa Indonesia)
- Tariff for protocol review (only available in Bahasa Indonesia)