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1. Purpose

The purpose of this sop section is to provide procedures for engaging the expertise of a professional as a consultant to the mrin ec.

2. Scope

If the chairperson or the mrin ec members determines that a study will involve procedures or information that is not within the area of expertise of the ec members, the chairperson / secretary of the ec may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to those available in the ec. The consultants will be of two types: independent and ad hoc consultants.

3. Responsibility

Upon the advice or recommendation of the secretary or any mrin ec/ members, it is the responsibility of the ec to nominate and approve the name of the independent/ad hoc consultants to be endorsed by the chairperson.


4. Flow chart

<u>No.</u>	<u>activity</u>	<u>Responsibility</u>
1	Selection of independent /ad hoc consultant ↓	ec members / secretary
2	Consultation services ↓	ec secretary / consultant
3	Termination of the services	Consultant / Secretary of mrin ec

5. Detailed instructions

5.1 Selection of Independent / Ad Hoc Consultant

- Identify the experts by the ec member and secretary based on expertise needed in protocols review
- nominate the consultants
- Conduct a qualification review of the prospective consultant
- Make decision based on expertise, availability and independence criteria

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- Get approval from chair person of the ec.
- Invite the consultant.
- The consultant provides:
 - A curriculum vitae
 - A signed confidentiality/conflict of interest agreement (AF/01-006/2020/01.3)
- Keep the documents in a consultant's file.
- Create a roster of consultants and the areas of their expertise.

5.2 Consultation Services

- mrin ec provides study protocol documents to the appropriate consultant for review
- the consultant must submit the report the mrin ec as per the agreement.
- the consultant may attend the ec meeting, present the report and participate in the discussion but cannot vote.
- the report becomes a permanent part of the study file.

5.3 Termination of the services

- consultation services may be terminated by either the consultants themselves or by the chairperson / secretary of ec
- upon termination of the consultant's services, a member of the secretariat ensures that all the qualifying documentation and the reason for discontinuation of the services are filed with the administrative documents.


6. Glossary

Independent Consultant An expert who gives advice, comments and suggestion upon review of the study protocols with no affiliation to the institutes or investigators proposing the research protocols.

Ad Hoc Consultant Ad hoc generally signifies a solution designed for a specific problem or task, non-generalizable, and not intended to be able to be adapted to other purpose. Ad hoc consultants have expertise or others unique discipline competencies, that not covered by independent consultant.


7. Annex

Annex 1 AF/01-006/2020/01.3 Document History

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8. Reference

- Operational guidelines for ethics committees that review biomedical research, world health organization, 2000, geneva.
- standards and operational guidance for ethics review of health-related research with human participants, 2011, world health organization
- Pedoman nasional etik penelitian kesehatan, komisi nasional etik penelitian kesehatan, 2011.

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Annex 1
Form AF /01-006/2020/01.3

Document History

Author	Version	Date	Description
Ec members	01.0	2 January 2013	Final version
Ivet, lia, mona	01.1	11 October 2014	<ol style="list-style-type: none"> 1. Synchronize the topic number and sop number 2. Format document history : Author, version, date and description of the main change 3. Section 5.1. Selection of independent consultants :the independent consultants will be appointed in protocols when needed
Dondin sajuthi, liliana kurniawan	01.2	1 April 2017	<ol style="list-style-type: none"> 1. Delete komisi etik penelitian kesehatan (kepk) on the header 2. Item 2 : replace long term to ad hoc consultant 3. Item 4 : flowchart to add adhoc 4. Item 5. 1. Box 2 : to add adhoc 5. Item 6 : glossary to add the adhoc consultant
Is,lsh,mw,ge	01.3	02 January 2020	<ol style="list-style-type: none"> 1. 5.1,box 1 : add the sentences of “ based on expertise needed in protocols review” 2. 5.1,box 6 : replace the word of “contact” with “invite” 3. References : <ul style="list-style-type: none"> • Delete link who • Delete fercap sop