Mahidol University
Center of Ethical Reinforcement for Research

Guidelines for Submitting Research-Related Documents

to the Center of Ethical Reinforcement for Research, Mahidol University (MU-CIRB)

Refrain submit cover letters with official document numbers issued by your department, which require signatures from immediate supervisors.

Submit only the MU-CIRB form that has been fully completed and signed.
The signature must be provided using one of the following methods:

If the principal investigator is a university staff member,

- Sign the form using an electronic signature in accordance with Mahidol University's Announcement on Criteria and Guidelines for the Use of Electronic Signatures for the University's Internal Documents, B.E.2564 (2021).
- Sign on a tablet or other electronic devices.
- Sign a printed copy of the form and scan it as a PDF file

If the principal investigator is a student,

- Ask the supervisor to provide an electronic signature, sign using a tablet or other electronic devices, or sign a printed copy of the form. Once the supervisor has signed, the student principal investigator must sign the designated space on the form.
- Scan the completed form as a PDF file.

01 Initial submission for review and approval

For projects where the principal investigator is a university lecturer, researcher, or staff member,
the principal investigator, all co-investigators, and the immediate supervisor of the principal investigator must sign the IRB submission form using one of the methods specified above.

For projects where the principal investigator is a student,
the principal investigator, all co-investigators, and the main supervisor must sign the IRB submission form using one of the methods specified above.

02

Any reports submitted to the MU-CIRB **after project approval** should be signed only by the principal investigator.

However, **protocol amendments** must be signed by the principal investigator, all co-investigators, and the immediate supervisor of the principal investigator.

03

If the principal investigator is a student, the main supervisor must co-sign all submitted reports using one of the methods specified above.

Please submit all digital files to the MU-CIRB at
mucirb@gmail.com

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List of electronic data files to be submitted for further review

Proposal for Initial Review

* must be signed

Title of Document	File Name	File Type
0.Exemption Review Checklist, Expedited Review Checklist	0.Exemption Review Checklist/ 0.Expedited Review Checklist	PDF
1.Submission Form	1.Submission Form	PDF*, Word
2.Protocol/ Proposal	2.Proposal	PDF
3.Participant Information Sheet	3.PIS/ Self-PIS (If more than 1, list as 3.1, 3.2, etc.)	Word
4.Informed Consent Form	4.ICF	Word
5.**Principal Investigator**'s Curriculum Vitae (CV), Position, Affiliation, and Works, as well as those of all Co-investigators. If the project head is a student, the CV of the Major Advisor must be added.	5.CV (If more than 1, list as 5.1, 5.2, etc.)	PDF
6. Tools used for data collection such as questionnaires, interview forms, interview or observation guidelines, case-record form, case-report form for a research.	6.Questionnaire/Interview guide/ Case record form/ (If there are more than 1, mention as 6.1, 6.2,... respectively.)	PDF
7. Other documents or media used to publicize the research project (if any)	7.Poster/ Recruitment Material (If more than 1, list as 7.1, 7.2, etc.)	PDF
8. Other relevant documents, such as request for permission to utilize data for research, request for permission to conduct research on that research site (**A copy with evidence of approval from an authorized person must be submitted)**	8. Name the file based on the submitted title (If more than 1, list as 8.1, 8.2, etc.)	PDF
If the researcher is a student, the following documents must be attached		
9. Bor Thor 1, Order to approve the thesis title and appoint a Thesis Advisory Committee.	9. Bor Thor 1 Form	PDF
10. Documents confirming the training or registration for a research ethics course	10. Certificate (If more than 1, list as 10.1, 10.2, etc.)	PDF

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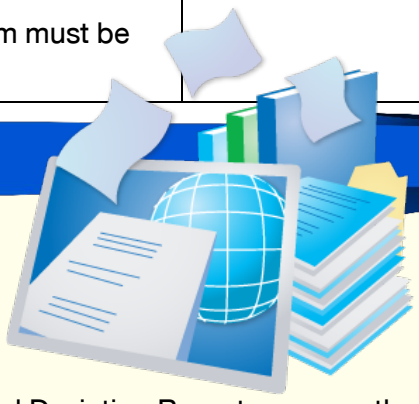
If it is a Clinical Drug Trial		
11. Information and description on the drug - If the drug is registered: the drug registration or drug documentation of the Food and Drug Administration, Ministry of Public Health shall be submitted. - If the drug is not registered: submit a document of Application to drug import into Thailand for clinical trial (Nor Yor Mor.1) along with the attachment of the form by clicking the link as well as the investigator brochure.	11. Name the file based on the submitted title	PDF
If the research project requires medical device		
12. Information and description about the medical device - If registered: Approval documentation, or medical device license must be submitted. - If not registered: ● state details of device description, specifications. ● state/attach documents indicating the safety of the medical equipment, such as laboratory quality test results, production process, and production quality system. ● Yor Por 1 Form must be attached by clicking the link.	12.Name the file based on the submitted title	PDF
If the research project requires food/ dietary supplements		
13. If using food/dietary supplements, - If registered, only the registration number of Food and Drug Department (Or Yor) must be submitted. - If not registered, if must be imported from abroad, the Or 12 form must be attached by clicking the link.	13.Name the file based on the submitted title	PDF

Follow-Up Review comprises:



1. Progress Report
2. Protocol Amendment
3. Closeout Report
4. Other Reports (if any), such as Adverse Event Report, Protocol Deviation Report, among others.

For every report, please fill in the MUCIRB form and have it signed using the above-mentioned signing methods.