Mahidol University
Center of Ethical Reinforcement for Research

Instructions for the submission of research-project information to MUCIRB, from 1 August 2021

Do not submit a cover letter with a reference number issued by the office, signed by supervisors.

Submit only the completed, signed MUCIRB form. Acceptable signature can be effected using the following methods.

For Principal Investigator who is a Mahidol University staff

- Sign using an electronic signature, according to the Mahidol University announcement regarding Criteria and Methods in using Electronic Signatures for the Documents within Mahidol University, B.E. 2021.

or

- Sign the paper copy (hardcopy) and scan it into an electronic/portable data (.pdf) file.

For Principal Investigator who is a Mahidol University student

- Request an Advisor sign the form electronically or manually on a paper copy (hardcopy). The advisor permits the Project Head (student) sign in the space specified in the form signed by the advisor.
- Scan the completely signed form as an electronic/ portable data (.pdf) file.

The major supervisor of the PI of the research project/ advisor needs only to sign **the first submitted** IRB Submission Form. The major supervisor can sign a paper copy (hardcopy) electronically or manually.

Co-investigators should not sign the form. Once MUCIRB has received the research-project submission, our staff will send e-mails to all co-investigators to verify their identity by e-mail reply.

Report Forms: after the research project has been verified, only the PI of the research project can sign report forms submitted for correspondence with MUCIRB. If the PI is a student, the advisor must co-sign each time, using the signing methods described above.

All digital information must be submitted to mucirb@gmail.com

Instructions for the submission of research-project information to MUCIRB, from 1 August 2021

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.