

คณะพยาบาลศาสตร์ มหาวิทยาลัยมพิดล (โรงเรียนหญิงแพทย์ผลุงครรภ์แลการพยาบาลไข้)

INSTRUCTION AFTER RECEIVING RESULT OF CONSIDERATION

Approve with condition

"Approve with minor condition" means the research protocol will be approved, if the researchers



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1) make specified changes to the researcher protocol or informed consent documents and/or

2) submit clarifications or additional documents, based on the assumption that the conditions are satisfied.

The researcher have to revise following the IRB-NS committee's comments and submit revised documents for consideration from committee.

Starting the process of data collection after receiving certificate of approval (COA).



- 1. Check the deadline for submission revised documents. The date is specified in "Guideline for submission for the research protocol with the result "Approve with minor condition".
- 2. Providing revised documents. Submit only documents that have been corrected following committee's comments, for example, the comments are only about the topic in protocol submission form and participant information sheet. The submission form and participant information sheet, which are corrected , should be resubmitted. Don't submit all kinds of documents
- 3. Process after receiving the result of consideration: Type 2 Approval with minor conditions following flowchart 2.

Preparation Documents (1)



Lists	Number	Actions
 Covered letter for submission the revision research protocol 	1 original copy	Contact to office of graduate studies, Faculty of Nursing, Mahidol University for preparing.
2) Revised document (with underline on the fonts the researcher makes change)	1 original copy and electronic file	Need the signature from entire investigators in the protocol submission form.
3) Revised document (without underline on the fonts the researcher makes change)	1 copy and electronic file	Need the signature page is copy of item 2.
4) Summary form	1 copy and electronic file	
5) CD	1 CD	Write all the corrected documents in form electronic files.

Preparation Documents (2)



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Revised document

Without underline, IRB-NS stamps IRB-NS symbol to entire documents specified in COA after approval and turns back to researcher to use for data collection.

With underline, IRB-NS office will collect.



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If the researchers have any troubles or do not understand any issues, should contact to the **IRB-NS** administrator by

- 1) At the **IRB-NS** office
- Call telephone no. 662 441 5333 ext. 2531,2532 or 093 124 2057
- 3) E-mail: ns.irbnursing@gmail.com, natta.won@mahidol.edu