October 30, 2009

Subject: Ethics Guidelines for Research Thesis Involving Human Beings by Students of Faculty of Graduate Studies (Additional)

Attn: Program Chairs of Master’s and Doctoral Programs

Attachment: A flow chart of the research submission process for Mahidol graduate students seeking approval from the Institutional Review Board (IRB) regarding ethics in human research

Dear Program Chairs of Master’s and Doctoral Programs,

The announcement of Ref. No. 0517.02 / 5984, dated 9 September 2008, stated that a graduate student, whose year of enrollment is from 2008 onwards and conducts research involving human subjects must submit his/her research and seek approval from the committee of the Institutional Review Board (IRB). The student must also complete a course, approved by MU-IRB and announced on the Faculty of Graduate Studies’ website that introduces the students to the ethics in human subject research.

The Faculty of Graduate Studies maintains additional guidelines on Ethics in Human Research for the Faculty of Graduate Studies’ students as follows.

1. For an international student whose research is conducted by international investigator(s) and international co-investigator(s) and has taken place in his/her country under an established Institutional Review Board (IRB), Mahidol University Institutional Review Board (MU-IRB) will confer responsibility for the Ethics in Human Research to the IRB of that country. The student must complete the form, prepared by the Faculty of Graduate studies, notify the Faculty of Graduate studies, and send a copy of the Board-approved consent document received from the IRB of that country to the Faculty of Graduate Studies.
In a country where the Certificate of Approval (COA) of the Mahidol University Institutional Review Board (MU-IRB) is accepted, the student can submit his/her research and seek approval from MU-IRB under the stated guidelines.

2. An international student who conducts research in his/her country where no IRB committee is established can submit his/her research and seek approval from the IRB at the same time as when the thematic paper proposal is submitted for the thematic paper proposal examination.

A student who passes the thesis proposal examination must send the examination report to the IRB, which will accordingly issue a COA allowing the student to conduct his/her research in the country lacking an IRB. If the student passes the examination with conditions or fails, conditions must be satisfied so that the COA can be issued.

If the result of the examination alters any aspects of thematic paper proposal, a student must proceed with the protocol amendment to the IRB.

The research must commence only when a COA is issued by the IRB.

3. Any graduate students whose research involving human subjects can submit their research and seek approval from the MU-IRB at the same time when they submit the thematic paper proposal for the thematic paper examination, using the same process from #2.

Please inform all instructors and all graduate students in your programs and follow the guidelines. Your cooperation is very much appreciated.

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Procedure for Receiving an Approval from the Institutional Review Board (IRB) for Mahidol University Graduate Students

Graduate student

International graduate student

Wishes to conduct research in a country with an IRB committee other than Thailand

Completes a form requesting an authorized responsibility for the Ethics in Human Research to confer to the IRB of that country and notifies the Faculty of Graduate Studies (FGS)

Seeks approval from a local IRB

Sends a copy of COA to FGS

Once approval is obtained

Notifies MU-IRB

Letter of Deferment for Oversight of Human Research to be issued to the researcher

Thai graduate student

Wishes to conduct research in Thailand OR in a country without a local IRB OR in a country with a local IRB, but seeking MU-IRB acceptance and approval

Proceed with related IRBs

Exemption

Expeditied

Full board Review

Result

Thematic Paper Proposal Examination

Proceeds with the examination

1*

2**

3***

COA

Adjustment

Proceeds

Fails

Proposal Amendment

Begin conducting research

Remarks

* If the result of the examination alters any aspects of thematic paper proposal certified by the IRB, the student must proceed with the protocol amendment to the IRB.

** 1. Approval granted

** 2. Approved in principle with suggestions of adjustment

*** 3. Must be adjusted and re-submitted to the committee before granting approval