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Frequently Asked IRB Questions

Q: Does a student project involving humans require IRB review?

A: If the project meets both the definition of research and human subject IRB review is required. The definition of research is often key in determining if a student project needs IRB review. Research is defined as a systematic investigation **designed to develop or contribute to generalizable knowledge**. If a student project is not designed to develop or contribute to generalizable knowledge (e.g. it will be used only to satisfy a curricular requirement), it would not meet the definition of research. Master's or Doctoral proposals are typically designed to develop or contribute to generalizable knowledge so IRB review for such is typically required if the project also involves human subjects. IRB approval cannot be granted retrospectively. Students are therefore encouraged to discuss submitting an IRB protocol with their faculty advisor prior to starting any activity for which a question exists as to whether it constitutes human subject research.

When students at UML are involved in the conduct of human subjects research at an external institution, please consult the UML IRB prior to engaging in the external research activities.

Q. Who can serve as Principal Investigator (PI) on an IRB submission?

A: To be eligible to serve as a principal investigator, an individual must hold one of the following titles: professor, associate professor, assistant professor, or research professor. Although it is not common, other designated full-time, benefited professional positions *may* be granted PI Status at the discretion of the Vice Chancellor for Research, Innovation & Economic Development.

Full-time benefited individuals holding titles other than professor, associate professor, assistant professor, and research professor must obtain approval from the Vice Chancellor for Research, Innovation & Economic Development or his/her designee to submit an IRB protocol. Please contact IRB@uml.edu for a 'Request for PI Status Form".

Q: What training is required for Human Subjects Research?

A: Researchers who collect data/specimens from subjects through interactions or interventions, obtain informed consent, or receive or have access to identifiable private information are considered to be engaged in Human Subjects Research and must complete the human subjects CITI "Social & Behavioral Research" course. This course fulfills the IRB HSR training requirements. For instruction on how to register for CITI training, please visit CITI Program Information page.

Q: Does a pilot study have to be reviewed by the IRB?

A: Yes. Any study involving human subjects, regardless of the number of subjects to be involved, must be reviewed and approved by the IRB prior to initiation. Because the purpose of a pilot study is to test the feasibility of a design that is intended to be used on a

larger scale a pilot study is considered be "designed to develop or contribute to generalizable knowledge".

Q: If I want to make a change to my study after I've received approval, do I need IRB approval again?

A: Yes. Any change to a previously approved **non-exempt study** must be reviewed and approved by the IRB prior to implementation. This includes changes to any document related to the study (e.g. informed consent form, surveys, advertisements, recruitment letters, etc.) You will need to submit the form to request a modification / addendum to a previously approved study. The only exception to this is that a change can be implemented if it is needed to eliminate immediate harm to subjects or others. Such changes must be reported to the IRB within 5 business day. Investigators are encouraged to contact the IRB@uml.edu to seek guidance for any modification to an exempt study to ensure that the change does not invalidate the exempt status of the study.

Q: What type of IRB review is required for a research project using existing specimens?

A: It depends on whether the existing specimens are identifiable. If not, and if the investigator will make no effort to re-identify the specimens, the specimens do not meet the definition of human subject and IRB review would not be required. If the specimens are identifiable, or efforts will be made to re- identify the samples, IRB review is required. Research that only involves the use of existing identifiable samples may qualify for exemption if one of the following is true:

- the specimens are publicly available
- information is recorded in such a manner that the identity of the human subject cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subject and the investigator will not re-identify subjects.

Q: How does the mandate for single IRB review for multi-site federally supported research apply?

A: The NIH has published a list of frequently asked questions pertaining to the requirement for single IRB review. Please review this list. If your question is not addressed by this list, you may contact the IRB. IRB reliance agreements between UML and commercial IRBs that are willing to act as the single IRB can be executed, and additional IRB Reliance agreements can be entered into if needed. Please review the guidance document "Single IRB and Reliance Agreements".

Q: I will be doing research that will involve individuals who speak a foreign language, do I have to submit a translated version for approval?

A: Yes. The IRB must approve all translated documents that will be presented to subject, e.g. the informed consent form and surveys. Investigators may either use a professional translation service or the back translation process. The English version must be approved first before the document is translated. Translation are submitted via an Amend request in RES.

Questions Related to IRB Submissions:

Q: Once I submit my application, how long does the IRB review/approval process take?

A: Review of applications occur on a year-round basis. Screening of the application will generally occur within 2-3 business days of receipt. All concerns will be communicated to the investigator through RES. Once all pre-review concerns have been addressed the application will be forwarded for official review. If a study is determined to be Exempt an approval is typically issued within 2-3 business days, if Expedited 5-10 business days.

Studies requiring full board review and have already gone through the pre-review submission process must be submitted within two weeks of the meeting date. This allows sufficient time for the committee to review the application prior to the meeting. Full Board studies are typically approved in 2-3 months.

NOTE: you may not begin your research until you have received final approval from the IRB.

Q: Can I e-mail my new study materials to the IRB office?

A: No, all **new** IRB studies must be submitted through the online submission platform RES.

NOTE: If you an active IRB approved study, you will continue to submit modifications, continuing reviews and closure requests via email to IRB@uml.edu using the HRP forms below.

- HRP-212 FORM - Continuing Review Progress Report (docx)
- HRP-213 FORM - Modification of Approved Human Research (docx)
- HRP-214 FORM - Reportable New Information (docx)
- HRP-215 FORM - Closure Report (docx)

In certain situations, you may be requested to transfer the study to RES. This is determined on a case-by-case basis.

Q: I am not sure how to answer some questions in the Investigator Study Plan; can I leave them blank?

A: The IRB expects the investigator to respond to relevant items on the IRB Investigator Study Plan. Providing complete responses will make it less likely that the application will be returned for corrections. If you have a question as to how to respond you are encouraged to contact a the IRB@uml.edu for guidance.

Q: What documents do I need to submit to the IRB for review of my study?

A: The IRB will require all study materials, including but not limited to, recruitment materials, data collection materials, consent forms, assent forms, letters of support, etc.

Q: If my project will most likely qualify for exempt status do I still have to submit the entire Investigator Study Plan?

A: Yes. The IRB is the only office that can determine if a research project qualifies for exemption and must have sufficient information in order to make that determination.

Q: Do I have to submit every single protocol deviation (e.g. instance of non-compliance with the protocol) to the IRB?

A: Yes, however the timing of when you report the non-compliance may differ. If the non-compliance was within the control of the research team (e.g. a follow-up appointment was scheduled by the research team outside of the study window) it should be reported within 5 business days of becoming aware of it using the problem report form available in RES. All reports should contain a description of the deviation, why and when it occurred, and corrective action implemented, if any, to prevent future occurrence. If the non-compliance was not within the control of the research team it and it does not place a subject at risk (e.g. the subject canceled a scheduled appointment and had to be rescheduled outside of the study window) the event can be reported at the time of continuation. However, if the event was not within the control of the research team but has in impact on subject safety or data integrity it should still be reported within 5 business days of becoming aware of it.

Q: Who do I contact with questions?

A: Contact the IRB@uml.edu or call 978-934-4134 with questions.