Reminders for Personnel Involved with IRB-Approved Research

(Any faculty, staff, or student engaged in a human subject research activity, whether funded or not)

- ONLY the IRB is authorized to approve research protocols, consent forms, and related documents. If alterations are necessary, notify the faculty responsible for oversight of the research and s/he can then contact the IRB and take the appropriate steps.

- All personnel (faculty, staff, students, or collaborators) engaged in human subject research must be listed on the IRB protocol and have up to date human subject training certification.

- Changes to any consent forms or tools used for research may be used **ONLY** after IRB approval.
  - If any approved documents need to be changed, an amendment form must be submitted with the reason for the request and the revised documents included.
  - ONLY Faculty PIs may request changes through the amendment approval process.
  - Data collected using unauthorized and unapproved consent documents must be discarded or participants re-consented using the appropriate form.
  - If data collection has started and you notice the wrong consent form has been used, STOP and contact the IRB immediately for guidance.

- Report to the IRB, as soon as possible, unanticipated events or problems that occur during the research.

- International research activities take more time to receive IRB approval. Documents are first submitted and approved in English and then translated and back-translated with a translation certification signed from two different translators. These should be submitted as an amendment after approval of the English documents. Consent forms as well as survey tools, recruitment flyers, etc. will all need to be translated and back-translated into the language(s) necessary to conduct the research. In addition, a person familiar with the local culture is typically asked to review the protocol, methods, and materials to ensure everything is consistent with the ethical considerations for the country or region.

- NO research may begin until IRB approval is granted. You will receive a formal 'approval memo' when all IRB requirements have been met. Data collected without approval must be destroyed.

- Refer to the website www.uml.edu/Research/OIC frequently for up-to-date forms, policies, etc.

- Research in schools where parents may have English as a second language or in international locations will likely need to be translated. Google Translator is not yet adequate for this. Allow time for English documents to be approved and then submit required translated materials and certifications through an amendment.

- NSF and NIH funded research now requires clear descriptions of **all** human subject research activities to be conducted for the term of the award for UML to accept it. If, for example, year one is to use existing data, the IRB protocols may be submitted and approved in a phased approach. While an exempt application may be approved for use of existing data, it should also outline the plan for proposed future research and IRB approvals. IRB approval will be for only specific activities or phases.

- Protocol categories are based on risk and collection of identifying data:
  - Exempt protocol applications typically are for low or minimal risk research with **no** identifiers and **ONLY** the IRB is authorized to approve exempt applications!
  - Expedited or full review applications allow for collection of identifiers and higher risk research. Check with the IRB if you are not sure what type of application to submit.