

IRBNet Instructions for Central Michigan University

www.irbnet.org

VII. What does your electronic signature mean?

If you are the Principal Investigator, your electronic signature that is associated with a given study means that the research described in the application and supporting materials will be conducted in full compliance with Central Michigan University's Policies and Federal regulations governing human subject research. Furthermore, you will:

- Conduct all aspects of the project as approved by CMU's IRB,
- Promptly report any revisions or amendments to the research activity for review and approval by CMU's IRB prior to commencement of the revised protocols, with the only exception to this policy being those situations where changes in protocol are required to eliminate apparent, immediate hazards to the subject,
- Promptly report any unanticipated problems or serious adverse events affecting risk to subjects or others,
- Assume full responsibility for selecting subjects in strict accordance with the inclusion/exclusion criteria outlined in the application materials,
- Use only CMU's IRB-approved consent/assent forms for studies in which consent form(s) have been approved for the research activity, and
- Ensure that all personnel involved with human subjects, or human data and/or biological specimens during the course of this research activity are trained in the Protection of Human Subjects and HIPAA in Research, in full accordance with CMU on this matter.

If you are a co-investigator, your electronic signature that is associated with a given study means that:

- You are fully cognizant to the details of the protocol, and will conduct all aspects of the study as approved by CMU's IRB,
- You will promptly report to the Principal Investigator any unanticipated problems or serious adverse events affecting risk to subjects or other,
- You will not be involved in any aspect of the study for which you have not been trained, or conduct any procedure in which you are not certified/licensed.