Human Subjects Research Training
Effective 01/15/2005
Revised 09/20/2007, 9/16/2011
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Purpose:

To establish policy and procedures for the training of all individuals involved in human subjects research.

Definitions:

None

Policy:

1. To meet federal requirements on investigator training for those conducting human subjects research and the desire of NSU to insure that our research meets the highest ethical standards in the protection of human subjects, NSU requires all individuals involved in human subjects research to satisfactorily complete (with at least a 90% passing score) the CITI (Cooperative IRB Training Initiative) program on human subjects research. This includes all studies that involve human subjects in any manner as well as research on medical, psychological, educational, or other records derived from individuals.

   The principal investigator and all co-investigators must have documented CITI course completion before their IRB proposal will be reviewed. All members of the research team involved in human subjects testing (e.g. staff, students, volunteers) must achieve CITI certification before participating in the research project. Individuals participating in the research who will not have any contact with human subjects or subject identifiable data are exempt from this policy.

   The IRB will make training available to everyone at NSU at no cost to individuals.

   Individuals conducting research must maintain their CITI training certification which expires every three years.

2. Colleges and centers will identify the modules appropriate for researchers in their disciplines.

3. All individuals who are members of the university’s IRB also complete all training modules (for all disciplines) and maintain their training certification which expires every three years.
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References:
Federal Wide Assurance
National Institutes of Health
FDA IRB Checklist

Procedures:

1. The IRB Director will ensure that the CITI training is available to researchers.

2. The PI is encouraged to include evidence of CITI completion for members of the research team, including research assistants, when submitting the research proposal to the IRB. The Center Representative may require inclusion of the CITI completion report.

3. The IRB office will verify CITI completion at the time exempt protocols are submitted to the IRB log. At the time of expedited or full review submission, the IRB office will verify CITI training for all individuals listed, and that the training has been completed within the last 3 years.

4. If the research protocol identifies individuals involved in the research who are not investigators, the principal investigator will submit evidence of their having completed CITI training before they participate in the research study.