

Detailed requirements*:

You must take UMDNJ's CITI educational program prior to engaging in human subjects research **IF**:

- **a human subjects research project is going to be performed in whole or in part on UMDNJ premises.** Those study personnel engaged in the research to be conducted on UMDNJ premises must take the CITI program. It doesn't matter whether these individuals are affiliated with UMDNJ or with another institution and it doesn't matter which IRB or IRBs have reviewed and approved the study.
- **a UMDNJ IRB is the sole IRB reviewing and approving a human subjects research project.** All study personnel engaged in research for that project must take the CITI program. It doesn't matter where the research is being performed and it doesn't matter whether the individuals engaged in the research are UMDNJ-affiliated or affiliated with another institution.
- **a UMDNJ-affiliated individual is going to engage in human subjects research** (faculty, non-faculty staff, house staff officer, student, volunteer or other agent, acting in connection with his or her UMDNJ responsibilities or educational program). An individual must take the CITI program, regardless of where the research is being performed, or which IRB or IRBs will review and approve the research.
- **a research project will make use of UMDNJ private, identifiable information** about human subjects or potential subjects. Study personnel using this information must take the CITI program, regardless of where the research is being performed, which IRB or IRBs will review the research, or whether the study personnel are affiliated with UMDNJ.

Individuals not "engaged in research," as defined by federal Guidance on this topic, need not take the CITI program under any circumstances. Consultation with UMDNJ IRB staff should be sought prior to determining whether certain activities for a human subjects research project constitute "engagement in research." Guidance posted by the Office of Human Research Protections (OHRP) @ <http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html> provides useful information.

* Exceptions to these requirements will be considered on a case-by-case basis.

If you have any questions regarding the requirements detailed above, you may contact Shelia Evans @ (973) 972-1149 or your Campus IRB office for assistance.