

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." *Draft* guidance posted by the Office of Human Research Protections (OHRP) @ www.hhs.gov/ohrp/requests/engage.html provides useful information.

If you have any questions regarding the requirements detailed above, you may contact [Susan M. Torok-Rood](mailto:Susan.M.Torok-Rood@umdnj.edu) @ (732)235-2135 or your Campus IRB office for assistance.

Transition to CITI:

(April 02, 2007 through December 28, 2007)

- 1. If you never completed the old UMDNJ *WebCT* human subjects protection training**, the IRBs will not issue final approval of any submission until you complete the CITI Basic Course.
- 2. If you completed the old UMDNJ *WebCT* human subjects protection training module prior to April 02, 2007**, the IRBs will review your future IRB submissions but you must complete the required **CITI Basic Course** on or before December 28, 2007. You may access the CITI modules @ www.citiprogram.org .
- 3. If you completed the CITI Basic Course at any other institution within the last three years**, UMDNJ must verify that the modules you have completed meet the University's current HSP education requirements. Please follow instructions posted on HSP and Campus IRB websites under 'Completing the Course', number 4 (a) & (b).