

Biomedical Human Subjects Research Training, Documentation, and Disclosure Requirements

	Biomedical Research Core Education Requirements		Additional Requirements			
	CITI Program Courses		Curriculum Vitae (CV) & Professional Licenses	Additional CITI Program Courses	National Institutes of Health Financial Conflicts of Interest Tutorial	Creighton University Financial Conflict of Interest Disclosure
Applies to	<i>All Biomedical research</i>	<i>FDA-regulated AND/OR NIH funded research</i>	<i>All research types</i>	<i>Individuals with a CU FCOI management plan AND/OR conducting Greater than Minimal Risk research</i>	<i>Individuals conducting federally funded research</i>	<i>Individuals conducting funded AND/OR Greater than Minimal Risk AND/OR FDA-regulated research</i>
CU-affiliated study personnel	<ul style="list-style-type: none"> Group 1: Biomedical Research CITI Responsible Conduct of Research Course CITI Health Information Privacy and Security (HIPS) for Clinical Investigators 	<ul style="list-style-type: none"> Conflicts of Interest* Good Clinical Practice and ICH (GCP) 	<ul style="list-style-type: none"> Dated, PDF-format curriculum vitae or resume Professional license (if held) 	<ul style="list-style-type: none"> Conflicts of Interest* 	<ul style="list-style-type: none"> National Institutes of Health Financial Conflicts of Interest (NIH FCOI) Tutorial 	<ul style="list-style-type: none"> Creighton University's Financial Conflict of Interest Disclosure
Non-CU-affiliated study personnel from an institution with an IRB**	<ul style="list-style-type: none"> Verification letter/email from their home IRB that states the person is qualified to conduct the research, that there is no financial conflict of interest, and they meet the human subjects research training requirements of their home IRB 	<ul style="list-style-type: none"> Verification that the personnel meets the human subjects research training requirements of their home IRB. 	<ul style="list-style-type: none"> Dated, PDF-format curriculum vitae or resume Professional license (if held) 		<ul style="list-style-type: none"> National Institutes of Health Financial Conflicts of Interest (NIH FCOI) Tutorial 	
Non-CU-affiliated study personnel from an institution without an IRB**	<ul style="list-style-type: none"> Group 1: Biomedical Research CITI Responsible Conduct of Research Course CITI Health Information Privacy and Security (HIPS) for Clinical Investigators 	<ul style="list-style-type: none"> Conflicts of Interest* Good Clinical Practice and ICH (GCP) 	<ul style="list-style-type: none"> Dated, PDF-format curriculum vitae or resume Professional license (if held) 	<ul style="list-style-type: none"> Conflicts of Interest* 	<ul style="list-style-type: none"> National Institutes of Health Financial Conflicts of Interest (NIH FCOI) Tutorial 	<ul style="list-style-type: none"> Creighton University's Financial Conflict of Interest Disclosure

* If you have completed the NIH FCOI Tutorial, this can be used in place of CITI's Conflict of Interest Course.

** This only applies to reliance/collaborative studies. Please contact the IRB Office (irb@creighton.edu) for assistance with entering into a reliance agreement with an external institution.

Renewal Period of Human Subjects Research Requirements

Group 1: Biomedical Research	CITI Responsible Conduct of Research Course	CITI Health Information Privacy and Security (HIPS) for Clinical Investigators	CITI Conflicts of Interest	National Institutes of Health Financial Conflicts of Interest (NIH FCOI) Tutorial	Creighton University's Financial Conflict of Interest Disclosure	Curriculum vitae and/or resume	Professional License
Renewal every 3 years	Renewal every 4 years	Renewal every 3 years	Renewal every 3 years	Initial completion only, does not expire	Must be submitted annually for the academic year (July 1 – June 30), update as necessary	Renew every 2 years	As expire

DEFINITIONS:

CU-affiliated study personnel: Any Creighton University faculty, staff, undergraduate student, School of Medicine learner (i.e. medical student, resident, fellow), graduate or professional student, or any other agent of Creighton University regardless of geographical location (Omaha and Phoenix campuses, distance learners, etc.).

Non-CU-affiliated (“External”) study personnel: Any non-Creighton University study personnel (i.e. faculty or students from other institutions, physicians in local practice, etc.).

Funded research: Human subjects research funded through any source – commercial, federal or state funding, IDEA Grants, Creighton University grant and award programs, etc.

Professional license: Licensed professionals (therapists, counselors, lawyers, etc.); required to maintain a current copy of their professional license on file with the CU IRB.

Do These Requirements Apply to Me?

The CU IRB's training, documentation, and disclosure requirements apply to anyone conducting human subjects research under the oversight of CU IRB. The following activities qualify as human subjects research:

- Obtaining, using, or analyzing for research purposes identifiable information generated through intervention or interaction with a living individual
- Obtaining, using, or analyzing for research purposes identifiable biospecimens (or leftover de-identified biospecimens for FDA-regulated research)
- Conducting research procedures as a part of a clinical investigation
- Recruiting or consenting individuals for participation in human subjects research