Creighton UNIVERSITY
Institutional Review Board

Social/Behavioral Human Subjects Research
Training, Documentation, and Disclosure Requirements

	Social/Behavioral 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	*All Social/Behavioral research*	*All research types*	*Individuals with a CU FCOI management plan **AND/OR** conducting Greater than Minimal Risk research*	*Individuals conducting federally funded research*	*Individuals conducting funded **AND/OR** Greater than Minimal Risk research*
CU-affiliated study personnel	• Group 2: Social & Behavioral Research • CITI Responsible Conduct of Research Course	• Dated, PDF-format curriculum vitae or resume • Professional license (if held)	• Conflicts of Interest*	• National Institutes of Health Financial Conflicts of Interest (NIH FCOI) Tutorial	• Creighton University's Financial Conflict of Interest Disclosure
CU-affiliated undergraduate students	• Group 2: Social & Behavioral Research • CITI Responsible Conduct of Research Course	• Dated, PDF-format curriculum vitae or resume	• Conflicts of Interest*	• National Institutes of Health Financial Conflicts of Interest (NIH FCOI) Tutorial	• Creighton University's Financial Conflict of Interest Disclosure
Non-CU-affiliated study personnel from an institution with an IRB**	• 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	• Dated, PDF-format curriculum vitae or resume • Professional license (if held)		• National Institutes of Health Financial Conflicts of Interest (NIH FCOI) Tutorial	
Non-CU-affiliated study personnel from an institution without an IRB**	• Group 2: Social & Behavioral Research • CITI Responsible Conduct of Research Course	• Dated, PDF-format curriculum vitae or resume • Professional license (if held)	• Conflicts of Interest*	• National Institutes of Health Financial Conflicts of Interest (NIH FCOI) Tutorial	• 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.

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Renewal Period of Human Subjects Research Requirements						
Group 2: Social & Behavioral Research	**CITI Responsible Conduct of Research Course**	**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	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