Creighton University Institutional Review Board

Human Subjects Research (HSR) Training, Documentation, and Disclosure Requirements

Biomedical Research (IRB-01)

IRB, Research Compliance
Dr. C.C. and Mabel L. Criss
Health Sciences Complex I, Room 111
2500 California Plaza, Omaha, NE 68178
Phone: 402-280-2126
Email: IRB@creighton.edu

	Biomedical Research Core Education Requirements		**Additional Documentation and Disclosure Requirements for All Human Subjects Research**			
	CITI Program Courses		Curriculum Vitae & Professional Licenses	Additional CITI Program Courses	National Institutes of Health Financial Conflicts of Interest Tutorial	CU Financial Conflicts of Interest Disclosure
Applies To	*All Biomedical Research*	*FDA-Regulated Research*	*All Research Types*	*Individuals with a CU FCOI Mgmt. Plan* ***OR*** *Conducting Greater than Minimal Risk Research*	*Individuals Conducing Federally Funded Research*	*Individuals Conducting Funded* ***AND/OR*** *Greater than Minimal Risk* ***AND/OR*** *FDA-Regulated Research*
CU-Affiliated Study Personnel	• Group 1: Biomedical Research • Responsible Conduct of Research (RCR) • Health Information Privacy and Security (HIPS)	• CITI Conflicts of Interest (Basic) • Good Clinical Practice and ICH (GCP)	• Signed, Dated, PDF-format Curriculum Vitae (CV) or Resume • Professional Licenses (if held)	CITI Conflicts of Interest (Basic) †	National Institutes of Health Financial Conflicts of Interest Tutorial (NIH FCOI)	Creighton University's Conflicts of Interest Disclosure
Non-CU-Affiliated Study Personnel from an institution with an IRB	Attestation that the Personnel meets the HSR training requirements of their *home* IRB.	Verification that the Personnel meets the HSR training requirements of their *home* IRB.	• Signed, Dated, PDF-format Curriculum Vitae (CV) or Resume • Professional Licenses (if held)	Verification that the Personnel meets the HSR training requirements of their *home* IRB.	National Institutes of Health Financial Conflicts of Interest Tutorial (NIH FCOI)	Creighton University's Conflicts of Interest Disclosure
Non-CU-Affiliated Study Personnel from an institution without an IRB	• Group 1: Biomedical Research • Responsible Conduct of Research (RCR) • Health Information Privacy and Security (HIPS)	• CITI Conflicts of Interest (Basic) • Good Clinical Practice and ICH (GCP)	• Signed, Dated, PDF-format Curriculum Vitae (CV) or Resume • Professional Licenses (if held)	CITI Conflicts of Interest (Basic) †	National Institutes of Health Financial Conflicts of Interest Tutorial (NIH FCOI)	Creighton University's Conflicts of Interest Disclosure

† If conducting FDA-regulated or federally funded research and have completed NIH FCOI you may use the NIH FCOI in place of CITI COI.

Please see page 2 for renewal periods, definitions, examples, and guidance on the requirements above.

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Renewal Period of HSR Requirements								
Group 1: Biomedical Research	Responsible Conduct of Research (RCR)	Health Information Privacy and Security (HIPS)	Good Clinical Practice and ICH (GCP)	CITI Conflicts of Interest (COI)	National Institutes of Health Financial Conflicts of Interest Tutorial (NIH FCOI)	Creighton University Financial Conflicts of Interest Disclosure (FCOI Disclosure)	Curriculum Vitae (CV) or Resume	Professional Licenses
Renewal Course every 3 years	Renewal Course every 4 years	Renewal Course every 3 years	Renewal Course every 3 years	Renewal Course every 4 years	Initial Completion Only (Does not Expire)	Renewed Annually (July 1 – June 30); Updated as Necessary	Renewal 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.).

- **Attestation:** For HSR approved by CU IRB and not FDA-regulated, outside study personnel from an institution with an IRB (for example, faculty or students from another university) may satisfy CU HSR training requirements by providing a signed and dated statement to the CU IRB attesting that he/she/they are compliant with the HSR training requirements imposed by their home IRB. External personnel from institutions without an IRB (such as local medical practices) are required to complete all CU IRB HSR training requirements.
- **Verification:** For HSR approved by CU IRB that is FDA-regulated, outside study personnel from an institution with an IRB (for example, faculty or students from another university) may satisfy CU HSR training requirements by providing CU IRB with verification from their home IRB that he/she/they are compliant with the HSR training requirements of their home IRB. Verification may take the form of either:
  - A signed, dated letter or email from the home IRB stating the individual is current and compliant with all HSR training requirements; or
  - Documentation of the HSR training requirements of the home IRB (ex: screenshots) plus documentation of completion of those requirements (ex: CITI Course Completion Certificates).

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

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

Do These Requirements Apply to Me?

CU'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

Please visit the Training, Documentation, and Disclosure Requirements page for guides on completing these requirements.