

Creighton University Institutional Review Board
Quality Improvement (QI) & Not Human Subjects Research (NHSR)
Training, Documentation, and Disclosure Requirements
 Biomedical (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
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	Biomedical QI/NHSR Core Requirements		Additional Requirements		
	CITI Program Courses	Curriculum Vitae, Resume, & Professional Licenses	Additional CITI Program Courses	National Institutes of Health Financial Conflicts of Interest Tutorial	CU Financial Conflicts of Interest Disclosure
Applies To	<i>Quality Improvement Projects</i>	<i>Quality Improvement Projects AND/OR Not Human Subjects Research</i>	<i>Individuals with a CU FCOI Management Plan</i>	<i>Individuals Conducting Federally Funded Work</i>	<i>Individuals Conducting Funded Work</i>
CU-Affiliated Study Personnel	<ul style="list-style-type: none"> Group 1: Biomedical Research Responsible Conduct of Research (RCR) Health Information Privacy and Security (HIPS) 	<ul style="list-style-type: none"> 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	<u>Attestation</u> that the Personnel meets the HSR training requirements of their <i>home</i> IRB.	<ul style="list-style-type: none"> Signed, Dated, PDF-format Curriculum Vitae (CV) or Resume Professional Licenses (if held) 	<u>Verification</u> that the Personnel meets the HSR training requirements of their <i>home</i> 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	<ul style="list-style-type: none"> Group 2: Social Behavioral Research Responsible Conduct of Research (RCR) Health Information Privacy and Security (HIPS) 	<ul style="list-style-type: none"> 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 work 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 QI/NHSR Requirements							
Group 1: Biomedical Research	Responsible Conduct of Research (RCR)	Health Information Privacy and Security (HIPS)	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	Prof. Licenses
Renewal Course every 3 years	Renewal Course every 4 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	Renewed 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.

Please visit the [Training, Documentation, and Disclosure Requirements](#) page for guides on completing these requirements.