

TRAINING REQUIREMENTS FOR INVESTIGATORS AND KEY PERSONNEL:

Training	Who must take the training?	Location of Investigators (or Key Personnel):			
		Internal	External		
		SUNY Downstate Workforce (See Step 4 at IRB Electronics Submissions)	NYC H + H, Kings County (IRA in place with KC)	From an Institution with an IRB Reliance Agreement (IRA) with Downstate	Has an Individual Investigator Agreement (IIA) with Downstate
Human Research Protections training	<p>Anyone conducting human research.</p> <p>Recommended for all others.</p> <p><i>Note: Requirements do not apply to Clinicians named on an IRB application under Expanded Access for treatment use or for use of a Humanitarian Use Device (HUD) for clinical purposes or IRB Determination Requests.</i></p>	<p>1) Register online for Collaborative Institutional Training Initiative (CITI) training (use your Downstate e-mail address if you have one; if not affiliate your account with SUNY DOWNSTATE).</p> <p>2) Choose <u>either</u> Group 1 (Biomedical Investigators and Key Personnel, Basic Course) or Group 2 (Social / Behavioral Investigators and Key Personnel)</p> <p>3) Sign up for optional training as desired or required (e.g., GCP, IRB Member training, etc.).</p> <p>4) Refresher training is required every 4 years.</p> <p>For detailed help, see Create CITI Account.</p>	<p>Complete the same requirements as SUNY Downstate workforce by affiliating with Downstate on the CITI training website.</p>	<p>Provide copies of the Human Research Protections training required by the employee's institution or confirmation from the institution that all training requirements are met.</p> <p>-OR-</p> <p>Complete the same requirements as SUNY Downstate workforce by affiliating with Downstate on the CITI training website.</p>	<p>Complete the same requirements as SUNY Downstate workforce by affiliating with Downstate on the CITI training website.</p>
HIPAA Compliance Training	<p>1) Anyone conducting human research</p>	<p>For SUNY Downstate workforce (except for students as noted below):</p> <ul style="list-style-type: none"> Contact the Office of Compliance and Audit Services (OCAS) at 718-270-4033 	<p>Complete the Downstate workforce requirements if dual member of the Downstate workforce</p>	<p>Complete the Downstate workforce requirements if a dual member of the Downstate workforce</p>	<p>Same as Downstate workforce, after IRB notifies OCAS of executed IIA</p>

	<p>2) Anyone with access to PHI for non-human research projects, including applications for IRB Determinations, Expanded Access for treatment use, and an HUD for clinical use.</p>	<p>or email compliance@downstate.edu to obtain a User ID to gain access to the training.</p> <ul style="list-style-type: none"> For more information: https://www.downstate.edu/compliance/hipaa/bridge.html <p>For Students in a Downstate Academic Program:</p> <ul style="list-style-type: none"> Follow the instructions at: https://sls.downstate.edu/registrar/hipaa_training.html Medical Students complete HIPAA certification upon matriculation and again prior to beginning clinical years. <p>Downstate HIPAA training is valid for 2 years.</p> <p>The IRB will check the Downstate HIPAA training online; therefore, it is not necessary to upload the training certificate in the IRB application.</p>	<p>(e.g., KC Clinician with UHB credentials).</p> <p>-OR-</p> <p>If above does not apply, complete the <u>optional</u> CITI HIPAA training offered through affiliation with SUNY Downstate.</p> <p>-OR-</p> <p>Attending Clinicians at KC may provide copies of the HIPAA Compliance training module completed through People Soft.</p>	<p>(e.g., UPB Clinician with UHB credentials).</p> <p>-OR-</p> <p>If the investigator is from an institution, meeting the requirements for “Option 2” (see cover page of this guidance) to establish an IRA, provide copies of the HIPAA training required by the employee’s institution or confirmation from the institution that all training requirements are met.</p> <p>-OR-</p> <p>If above does not apply, complete the <u>optional</u> CITI HIPAA training offered through affiliation with SUNY Downstate.</p>	
Dangerous Goods Training	<p>Anyone who causes dangerous goods to be transported by a public carrier.</p>	<p>There are 2 options that the Downstate IRB will accept:</p> <p>Option 1:</p> <p>Complete CITI program training: Shipping and Transport of Regulated Biological Materials.</p> <p>-OR-</p> <p>Option 2:</p> <p>Take the free online training for Dangerous Goods Training Module provided by the Mayo Clinic Laboratories: Individuals must pass this quiz with a score of 80% or greater in order to</p>	<p>Same as Downstate workforce.</p>	<p>Complete the Downstate workforce requirements if dual appointment exists that meets the definition of Downstate workforce (e.g., UPB Clinician with UHB credentials).</p> <p>-OR-</p> <p>If the investigator is from an institution, meeting the requirements for “Option 2” (see cover page of this guidance) to</p>	<p>Same as Downstate workforce.</p>

		obtain a dangerous goods shipping certificate. Attach a copy of the certificate to the submission. The expiration date of the training is on the certificate.		establish an IRA, provide copies of the Dangerous Goods Training required by the employee's institution or confirmation from the institution that all training requirements are met. -OR- Complete Dangerous Goods Training required by the Downstate workforce.	
Good Clinical Practice (GCP) Training	<p>Investigators and key personnel for a trial that follows ICH-GCP standards.</p> <p>-OR-</p> <p>NIH-funded clinical investigators and clinical trial staff who are involved in the design, conduct, oversight, or management of clinical trials, including study coordination, data collection, and data management, as defined by NIH.</p> <p><i>Note: Requirements do not apply to Clinicians named on an IRB application under Expanded Access for treatment</i></p>	<p>Complete one of the following options:</p> <ul style="list-style-type: none"> • CITI GCP training module • GCP training listed at: https://grants.nih.gov/policy/clinical-trials/good-clinical-training.htm • Other GCP training or in-person GCP workshop. <p>The certificate must not be expired.</p> <p>A clinical trial is defined by NIH as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.</p> <p>For NIH guidance see:</p> <ul style="list-style-type: none"> • http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html • https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html <p>In collaboration with Sponsored Research Programs, the IRB confirms GCP training for</p>	Same as Downstate workforce.	<p>Complete the Downstate workforce requirements if dual appointment exists that meets the definition of Downstate workforce (e.g., UPB Clinician with UHB credentials).</p> <p>-OR-</p> <p>If the investigator is from an institution, meeting the requirements for "Option 2" (see cover page of this guidance) to establish an IRA, provide copies of the GCP Training required by the employee's institution or confirmation from the institution that all training requirements are met.</p> <p>-OR-</p>	Same as Downstate workforce.

	<i>use or for use of a Humanitarian Use Device (HUD) for clinical purposes or IRB Determination Requests.</i>	NIH funded studies that meet the NIH definition of a clinical trial. The investigators listed on an IRB application must either take the CITI training or provide a copy of their GCP certificates.		Complete GCP training required by the Downstate workforce.	
Department of Defense (DoD) Training	For DoD funded research, check with the DoD.	In general, the DoD confirms all training requirements after IRB approval. Submit copies of required training certificates with the IRB application, if the DoD sponsor requires IRB acknowledgement of such training.	Same as Downstate workforce	Same as Downstate workforce	Same as Downstate workforce
COI Training	Anyone who is required to submit COI disclosures (see next section) <i>Note: Requirements do not apply to Clinicians named on an IRB application under Expanded Access for treatment use or for use of a Humanitarian Use Device (HUD) for clinical purposes or IRB Determination Requests.</i>	Take “ Conflict of Interest (COI) and Research Misconduct Training. ” To register an investigator who is a member of the Downstate Workforce for COI training/disclosures, please refer to: https://www.downstate.edu/compliance/training/index.html Downstate COI and Research Misconduct is valid for 4 years. The IRB will check the Downstate COI training online, therefore it is not necessary to upload the training certificate in the IRB application.	Complete the Downstate requirements if dual member of the Downstate workforce (e.g., KC Clinician with UHB credentials). -OR- If research is funded, complete the <u>optional</u> CITI Conflict of Interest training module offered through affiliation with SUNY Downstate and follow any additional HHC requirements.	Complete the Downstate requirements if dual appointment exists that meets the definition of Downstate workforce (e.g., UPB Clinician with UHB credentials). -OR- If research falls under a PHS Award, follow the requirements of their employer, and submit their COI training certificate to the IRB.	Follow Employer requirements. <i>This is N/A for Downstate IRB review, because an IIA cannot be established with an external investigator who is determined to be an investigator for the purposes of COI.</i>