

TRAINING REQUIREMENTS FOR INVESTIGATORS (KEY PERSONNEL):

Training	Who must take the training?	Location of Investigators (or Key Personnel):			
		Internal	External (Requires IRA or IIA)		
		<p>SUNY Downstate Workforce <i>Note: To determine if an investigator is a member of the Downstate Workforce, see Step 4a at https://www.downstate.edu/research/research-services/institutional-review-board/electronic-application-process.html</i></p>	<p>NYC H + H, Kings County <i>Note: An IRB Reliance Agreement (IRA) is in place between Kings County & Downstate.</i></p>	<p>Institution with an IRB Reliance Agreement (IRA) with Downstate <i>Note: To determine if an Institution needs to set up an IRA see Step 5G at: https://www.downstate.edu/research/research-services/institutional-review-board/electronic-application-process.html</i></p>	<p>Investigator with an Individual Investigator Agreement (IIA) with Downstate <i>Note: To determine if an Investigator needs an IIA see Step 5G at: https://www.downstate.edu/research/research-services/institutional-review-board/electronic-application-process.html</i></p>
<p>Human Research Protections training</p>	<p>Anyone conducting human research.</p> <p>Recommended for all others.</p> <p><i>Note: Requirements do not apply to Clinicians named on</i></p>	<p>1) Register online at https://about.citiprogram.org/ Use your Downstate e-mail address if you have one; if not affiliate your account with SUNY DOWNSTATE). 2) Choose <u>either</u> Group 1 (Biomedical Investigators and Key Personnel, Basic Course)</p>	<p>Complete the same requirements as SUNY Downstate workforce by <u>affiliating with</u> Downstate on the CITI training website.</p>	<p>Provide <u>copies</u> 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>Complete the same requirements as SUNY Downstate workforce by <u>affiliating with</u> Downstate on the CITI training website.</p>

	<p><i>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>The IRB will check the CITI Training online; therefore, it is not necessary to upload the training certificate in the IRB application.</p>	<p>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 <u>every 4 years</u>.</p> <p>For more detailed help on CITI training, see Step 6b-2 at: https://www.downstate.edu/research/research-services/institutional-review-board/electronic-application-process.html</p>		<p>-OR-</p> <p>Complete the same requirements as SUNY Downstate workforce by affiliating with Downstate on the CITI training website.</p>	
<p>HIPAA Compliance Training</p>	<p>1) Anyone conducting human research</p> <p>2) Anyone with access to PHI for non-human research projects, including applications for IRB Determinations, Expanded Access for treatment use, or HUD for clinical use.</p>	<p>For SUNY Downstate workforce (except for Students or Medical Students as noted below):</p> <ul style="list-style-type: none"> • Contact the Office of Compliance and Audit Services (OCAS) at 718-270-4033 or email compliance@downstate.edu to obtain a User ID to gain access to the training. • For more information: https://www.downstate.edu/about/our-administration/compliance-audit-services/hipaa.html 	<p>Complete the Downstate workforce requirements if the investigator has UHB credentials.</p> <p>-OR-</p> <p>If the KC investigator does not have UHB credentials there are <u>2 options</u>:</p> <p>1) complete the <u>optional</u> CITI HIPAA training offered through affiliation with SUNY Downstate.</p>	<p>Complete the Downstate workforce requirements if investigator has UHB credentials.</p> <p>-OR-</p> <p>If the Investigator under the IRA does not have UHB credentials there are <u>2 options</u>:</p> <p>1) Provide copies of the HIPAA training required by the employee's institution or confirmation from</p>	<p>Same as Downstate workforce. The IRB Director notifies OCAS upon execution of IIA. OCAS provides the investigator with instructions on how to complete the HIPAA training.</p>

		<p>For Students in a Downstate Academic Program:</p> <ul style="list-style-type: none"> Follow the instructions at: https://www.downstate.edu/education-training/student-services/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>2) Attending Clinicians at KC may provide copies of the HIPAA Compliance training module completed through People Soft.</p>	<p>the institution that all training requirements are met.</p> <p>2) Complete the <u>optional</u> CITI HIPAA training offered through affiliation with SUNY Downstate (requires Basic CITI module 1st)</p>	
<p>Dangerous Goods Training</p>	<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: Complete the optional CITI program training module: Shipping and Transport of Regulated Biological Materials.</p> <p style="text-align: center;">-OR-</p> <p>Option 2: Take the free online training for</p>	<p>Same as Downstate workforce.</p>	<p>Complete the Downstate workforce requirements if Investigator has UHB credentials).</p> <p>If the Investigator does not have UHB credentials, they may provide a certificate of the Dangerous Goods Training required by their institution or</p>	<p>Same as Downstate workforce.</p>

		<p>Dangerous Goods Training - Insights (mayocliniclabs.com)</p> <p><i>Note: Attach a copy of the certificate to the IRB submission after taking the quiz.</i></p>		<p>confirmation from the institution that all training requirements are met.</p>	
<p>Good Clinical Practice (GCP) Training</p>	<p>Investigators and key personnel for a Clinical Trial that meets one or more of the following criteria:</p> <ol style="list-style-type: none"> 1) Protocol follows GCP standards 2) Meets definition of Applicable Clinical Trial (ACT) 3) Includes an IND 4) Includes an IDE 5) NIH-funded clinical trial as defined by NIH. See: <ol style="list-style-type: none"> a. http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html b. https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html <p><i>Note: Does not apply to Expanded Access for treatment use or for use of a Humanitarian Use</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>If training other than CITI is done, attach the certificate.</p> <p><i>NOTE: In collaboration with Sponsored Research Programs, the IRB confirms GCP training for 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.</i></p>	<p>Same as Downstate workforce.</p>	<p>Same as Downstate workforce.</p> <p><i>Note: The Investigator must comply with their institutional requirements.</i></p>	<p>Same as Downstate workforce.</p>

	<i>Device (HUD) for clinical purposes.</i>				
Department of Defense (DoD) Training	For DoD funded research, check with the DoD.	In general, the DoD confirms all training requirements after IRB approval. <i>Note: Submit copies of required training certificates with the IRB application, if the DoD sponsor requires IRB acknowledgement of such training in the IRB letter.</i>	Same as Downstate workforce	Same as Downstate workforce	Same as Downstate workforce
COI Training	Anyone who is required to submit COI disclosures (see IRB Guidance on COI Requirements) <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, unless there is a conflict or they declare a conflict.</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 KC Investigator has UHB credentials. -OR- If the KC Investigator does not have UHB credentials, complete the optional 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, and the investigator is NOT a dual member of the Downstate workforce, follow the requirements of their employer, and submit their COI training certificate to the IRB.	Follow Employer requirements. <i>This is Not Applicable 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> <i>Note: If the study receives federal funding AND the external investigator is NOT from an institution which can establish an IRA AND the</i>

					<i>investigator is determined to be an investigator for the purposes of COI, contact the IRB to seek collaborative guidance with OCAS.</i>
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