SUNY RF
The Research Foundation for
The State University of New York

Institutional Review Board & Privacy Board

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SUNY DOWNSTATE
Health Sciences University

Training & Financial Conflict of Interest (COI) Disclosures

1) **Downstate workforce** is defined in "**Step 4**" on IRB Electronic Submission web page. Understanding whether a PI, Co-PI, Co-Investigator, or Key Personnel is a member of the "Downstate workforce" will help determine **1)** which IRB(s) will have oversight of the research, **2)** which training and Conflict of Interest (COI) disclosures are required, **3)** whether an IRB Reliance Agreement (IRA) or Individual Investigator Agreement (IIA) must be established, and **4)** whether any additional agreements are required. See "**Step 5**" on the IRB Electronic Submission web page for additional details for required agreements. *However, please note that an IIA cannot be established with an external investigator who is determined to be an investigator for the purposes of COI.*

- **a)** *CAUTION: Do not confuse the term "Investigator" for "Investigator for the Purposes of COI"(see item 5 below).*
- **b)** *NOTE: For FDA regulated clinical investigations involving an IND, the Clinical Investigator (PI) must be listed on the FDA Form 1572, which is sent to the Sponsor. Sub-Investigators (co-investigators) must be listed on the FDA Form 1572. Key Personnel do not need to be listed on the FDA Form 1572. A copy of the signed FDA Form 1572 must be submitted to the Downstate IRB at the time of initial review and when submitting an amendment to change the Clinical Investigator or Sub-Investigators.*

2) **External Investigators** (those who are not part of the Downstate workforce) must follow their Institution's requirements.

- **a)** For **Exempt Review** or **IRB Determinations** (e.g., not human research, not engaged, etc.), External Investigators must follow their Institution's requirements and should not be included on the Downstate IRB application. If their Institution does not have an IRB to make these determinations, an IRA or an IIA may be established with the Downstate IRB to make these determinations.
- **b)** For **Expedited** or **Full Board reviews,** when External Investigators conduct human research activities that make their institution engaged in human research per OHRP guidance, they may use their Institution's IRB or the Downstate IRB (if an IRA or IIA is established).
  - **i)** *A **Single IRB (sIRB)** is required for oversight of any federally funded or conducted study. The PI must obtain approval in advance to use the Downstate IRB as an sIRB and include sIRB fees in the award budget for the review of all sites*
  - **ii)** *CAUTION: The Downstate IRB may be used as a sIRB for a federal funded or conducted study **only if** all external investigators engaged in human research are covered by a fully executed IRA (not an IIA). If an IRA is not possible the PI must use an external sIRB that meets the Downstate requirements.*
- **c)** When an **Application for External IRB oversight** is submitted to the Downstate IRB, only the **Downstate workforce** can be included. External investigators (including KC and UPB) must consult their institution and the external IRB for guidance to be included in their approval process, as the Downstate IRB does not have jurisdiction over External Investigators approved by an External IRB.
- **d)** For applications for either **Expanded Access for Treatment** or a **HUD for Clinical Purposes**, Clinicians from **Kings County** or **UPB** may be included on the Downstate IRB application. Other External Clinicians should seek approval from their Institution's IRB.

3) An **IRB Reliance Agreement (IRA)** may be established between the External Institution and Downstate, if the External Institution falls under one of the following options:

- **a)** **Option 1:** NYC H + H, Kings County (KC) and University Physicians of Brooklyn (UPB) have existing IRAs in place with Downstate. *No additional IRA or IIA is required for these investigators.*
- **b)** **Option 2:** The external institution must meet all of the following requirements: **1)** have an FWA with OHRP, **2)** have a local IRB or a research office that can confirm local research requirements, **3)** be a HIPAA covered entity, **4)** have a PHS/NIH compliant Conflict of Interest Policy and process for review and management of COI disclosures, and **5)** have a Compliance Program in place.

c) **Option 3:** If the external institution does not qualify for an IRA (as indicated in option 1 or 2, above) follow the IIA process or contact the Downstate IRB for guidance. If an IRA is required by the External Institution, the Downstate IRB will consult with OCAS to determine next steps.

4) An **Individual Investigator Agreement (IIA)** may be established with External Investigators (or External Key Personnel) if there is no IRA in place to cover their human research activities. *However, please note that an IIA cannot be established with an external investigator who is determined to be an investigator for the purposes of COI.*

5) For COI disclosure and COI training requirements, the PI determines who on the research team is an "**Investigator for the Purposes of COI**," as defined in the Research Conflict of Interest Policy (RFDMC-01): The project director, Principal Investigator, co-Principal Investigator, personnel who are considered to be essential to work performance or any other person, regardless of title or position, who is responsible for the **design, conduct or reporting of research**. The PI is responsible for identifying all Investigators involved in their research activities. If the role of an individual is unclear and that individual is listed as an Investigator, compliance with all training and filing requirements will be expected.

a) Transient staff and trainees, such as medical students, residents and fellows, who may recruit patients and/or collect and handle data under supervision, but are not key to the design, conduct or reporting of research are not considered Investigators for purposes of COI. In addition, staff or trainees who merely implement a protocol developed by an Investigator or enter data into an electronic data capturing system are also not considered Investigators for purposes of COI. However, if a medical student, resident and/or fellow is applying for a research grant, s/he is considered an investigator for COI purposes and, therefore, must complete COI requirements.

b) COI disclosures are required by HHC for **Kings County** investigators who are considered to be "Covered Individuals" as defined by HHC Policy 180-9. A "Covered Individual" means Principal Investigators, Sub-investigators, Collaborators, Consultants, and other Key Research personnel responsible for the **design, conduct, or reporting of the research**.

c) COI disclosures do not apply to other **External Investigators**, UNLESS the study has a PHS Award, as defined in the Downstate COI policy.

i) PHS Award(s)- Any grant, contract, award, or sub-award including SBIR/STTR Phase II applicants/awardees, but not Phase I SBIR/STTRs, issued or awarded by the United States Public Health Service and its agencies: Agency for Healthcare Research and Quality; Agency for Toxic Substances and Disease Registry; Centers for Disease Control and Prevention; Food and Drug Administration; Health Resources and Services Administration; Indian Health Service; National Institutes Health; and the Substance Abuse and Mental Health Services Administration; and their sub-agencies.

ii) External Investigators should contact their employer to determine if they have any additional COI disclosure requirements.

6) Additional training may be required by the IBC, OCAS, Sponsored Research Administration, IACUC, or others as applicable to the study.

7) Individuals (including consultants) who perform activities that do not require IRB approval (see Policy IRB-01 for details) should not be listed on the Downstate IRB application; however, these individuals are encouraged to take CITI training.

8) For more information or for verification of training or COI submissions of the please contact IRB@downstate.edu

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	Anyone conducting human research. Recommended for all others. *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.*	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). 2) Choose either Group 1 (Biomedical Investigators and Key Personnel, Basic Course) or Group 2 (Social / Behavioral Investigators and Key Personnel) 3) Sign up for optional training as desired or required (e.g., GCP, IRB Member training, etc.). 4) Refresher training is required every 4 years. For detailed help, see Create CITI Account.	Complete the same requirements as SUNY Downstate workforce by affiliating with Downstate on the CITI training website.	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. -OR- Complete the same requirements as SUNY Downstate workforce by affiliating with Downstate on the CITI training website.	Complete the same requirements as SUNY Downstate workforce by affiliating with Downstate on the CITI training website.
HIPAA Compliance Training	1) Anyone conducting human research 2) Anyone with access to PHI for non-human research projects, including applications for IRB Determinations,	**For SUNY Downstate workforce (except for students as noted below):** • 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/compliance/hipaa/bridge.html	Complete the Downstate workforce requirements if dual member of the Downstate workforce (e.g., KC Clinician with UHB credentials). -OR- If above does not apply, complete the optional CITI HIPAA training	Complete the Downstate workforce requirements if a dual member of the Downstate workforce (e.g., UPB Clinician with UHB credentials). -OR- If the investigator is from an institution, meeting the requirements for "Option 2" (see cover	Same as Downstate workforce, after IRB notifies OCAS of executed IIA

	Expanded Access for treatment use, and an HUD for clinical use.	**For Students in a Downstate Academic Program:** • 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. **Downstate HIPAA training is valid for 2 years.** The IRB will check the Downstate HIPAA training online; therefore, it is not necessary to upload the training certificate in the IRB application.	offered through affiliation with SUNY Downstate. -OR- Attending Clinicians at KC may provide copies of the HIPAA Compliance training module completed through People Soft.	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. -OR- If above does not apply, complete the optional CITI HIPAA training offered through affiliation with SUNY Downstate.	
Dangerous Goods Training	Anyone who causes dangerous goods to be transported by a public carrier.	There are 2 options that the Downstate IRB will accept: **Option 1:** Complete CITI program training: Shipping and Transport of Regulated Biological Materials. -OR- **Option 2:** 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 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.	Same as Downstate workforce.	Complete the Downstate workforce requirements if dual appointment exists that meets the definition of Downstate workforce (e.g., UPB Clinician with UHB credentials). -OR- 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 **Dangerous Goods Training** required by the employee's institution or confirmation from the institution that all	Same as Downstate workforce.

				training requirements are met. -OR- Complete **Dangerous Goods Training** required by the Downstate workforce.	
Good Clinical Practice (GCP) Training	Investigators and key personnel for a trial that follows ICH-GCP standards. -OR- 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. *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.*	Complete one of the following options: • 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. The certificate must not be expired. 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. For NIH guidance see: • 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 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.	Same as Downstate workforce.	Complete the Downstate workforce requirements if **dual** appointment exists that meets the definition of Downstate workforce (e.g., UPB Clinician with UHB credentials). -OR- 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. -OR- Complete **GCP training** required by the Downstate workforce.	Same as 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) *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.*	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 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, follow the requirements of their employer, and submit their COI training certificate to the IRB.	Follow Employer requirements. *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.*

FINANCIAL CONFLICT OF INTEREST (COI) DISCLOSURE REQUIREMENTS:

*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.*

Who must submit?	What must be submitted?	Process:
Downstate workforce designated by the PI as an "Investigator for COI purposes" -AND- **Kings County** investigator who is a **dual** member of the Downstate who is an HHC **Covered Individual**. -AND- Any **UPB** investigator who is a **dual** member of the Downstate for any **PHS funded** study.	**Annual COI Disclosures**	• To obtain access to SUNY DOWNSTATE COI SMART, the PI must first complete the OCAS Research Compliance Training Registration; COI Intake Form (see COI Training above). Enrollment will trigger the issuance of a Login ID and (temporary) Password for SUNY DOWNSTATE COI SMART (Disclosure form database). If you have not yet received your Login ID and Password, you may check the status of this by contacting the Office of Compliance and Audit Services (OCAS) at 718-270-4033 or compliance@downstate.edu. • Complete an Annual COI disclosure in SUNY DOWNSTATE COI SMART, on an annual basis. The log-in screen is located at https://downstate.coi-smart.com/login.php If you forgot your Login ID (full Downstate email address) or Password, you may request a re-set on the login screen. • Revise Annual Questionnaire within thirty (30) days of change /discovering a new Significant Financial Interest (SFI). • Submit confirmation or rebuttal of management plans within thirty (30) days and comply with final, binding management plan. • Certify compliance with management plan, as necessary. • Disclose reimbursed or sponsored travel related to research and/or institutional responsibilities as specified in the policy. • Contact the COI Administrator with any questions.
Downstate workforce designated by the PI as an "Investigator for COI purposes" -AND- Any **Kings County** investigator who is a **dual** member who is an HHC **Covered Individual**. -AND-	**Transactional Questionnaire**	• Complete a "Transactional Questionnaire" in SUNY DOWNSTATE COI SMART when submitting any of the following to the IRB: ○ Application for Expedited Review ○ Application for Convened (Full) IRB Review ○ Application for External IRB Review ○ Application for Exempt IRB Review for FDA Regulated or Federally Funded/Conducted Research ○ Application for an Amendment to be added to the above studies ○ An Application for Progress Report (Continuing IRB) when the progress report is required by the IRB. • Contact the COI Administrator with any questions.

Any **UPB** investigator who is a **dual** member of the Downstate for any **PHS funded** study.		
Kings County investigator who is an HHC Covered Individual and is **NOT** a **dual** member of the Downstate workforce.	**Submit COI disclosure form to NYC H+H.** **Submit COI determination document (e.g. adjudication letter) to IRB after it is issued from NYC H+H.**	• Required when submitting any of the following to the Downstate IRB: ○ Application for Expedited Review ○ Application for Convened (Full) IRB Review ○ Application for External IRB Review ○ Application for Exempt IRB Review for FDA Regulated or Federally Funded/Conducted Research ○ Application for an Amendment to be added to the above studies ○ An Application for Progress Report (Continuing IRB) when the progress report is required by the IRB. ○ Within thirty (30) days of change /discovering a new Significant Financial Interest (SFI). • E-mail the completed the NYC H+H COI Disclosure Form to Christina Pili, Director, Research Administration: Christina.pili@nychhc.org • For more information, contact Ms. Pili at (646) 458-2743 or Bryce Petty at: bryce.petty@nychhc.org • Once NYC H + H issues the (COI) determination (e.g. adjudication letter), please add the document in the IRB submission package in IRBNet. • Investigators or Key Personnel with a Significant Financial Interests (SFI) must provide a copy of their NYC H + H's approved Conflict of Interest Management Plan to the IRB. • For more information see HHC Policy 180-9. Additional HHC requirements may apply.
Anyone from an **Institution with an IRB Reliance Agreement (IRA)** with Downstate who is **NOT** a **dual** member of the Downstate workforce AND designated by the PI as an "Investigator for COI purposes", if research falls under a **PHS Award or when required by their Employer.**	**Check with Employer**	• If the investigator is from an institution, meeting the requirements for "**Option 2**" (see cover page of this guidance) to establish an IRA, do the following: • Submit a conflict of interest (COI) determination document (e.g. adjudication letter) from their employer or IRB, when research is conducted under a PHS Award or when COI disclosures are required by their employer's local policy, for the following submissions to the Downstate IRB: ✓ Application for Expedited Review ✓ Application for Convened (Full) IRB Review ✓ Application for External IRB Review ✓ Application for Exempt IRB Review for FDA Regulated or Federally Funded/ Conducted Research ✓ Application for an Amendment to be added to the above studies ✓ An Application for Progress Report (Continuing IRB) when the progress report is required by the IRB. ✓ Within thirty (30) days of change /discovering a new Significant Financial Interest (SFI). • Investigators or Key Personnel with a Significant Financial Interests (SFI) must provide a copy of their institution's approved Conflict of Interest Management Plan to the IRB. • If the investigator is **NOT** from an institution, meeting the requirements for "Option 2" (see cover page of this guidance) to establish an IRA, contact the IRB to seek collaborative guidance with OCAS.

Anyone with an **Individual Investigator Agreement (IIA).**	**Check with Employer**	Follow Employer requirements. *Note: An IIA cannot be established with an external investigator who is determined to be an investigator for the purposes of COI.*