

FINANCIAL CONFLICT OF INTEREST (COI) DISCLOSURE REQUIREMENTS:

Notes:

1. 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>
2. To determine if an Institution needs to set up an **IRB Reliance Agreement (IRA)** with Downstate or if an Investigator needs to set up an **Individual Investigator Agreement (IIA)**, see **Step 5** at <https://www.downstate.edu/research/research-services/institutional-review-board/electronic-application-process.html>
3. **COI Requirements ONLY** 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 to Investigators on a IRB Determination Requests, **IF** there is a conflict or when one is declared on the IRB application.

Who must submit, when designated by the PI as an “Investigator for COI purposes”?	What must be submitted?	Process:
<p>Downstate workforce, UPB Investigator, and Kings County investigator who has UHB credentials.</p>	<p>Annual COI Disclosures</p>	<ul style="list-style-type: none"> To obtain access to SUNY DOWNSTATE COI SMART (Disclosure form database), the PI must first complete the Office of Compliance and Audit Services (OCAS) Research Compliance Training Registration COI Intake Form. See IRB Guidance on Training Requirements for more details. Enrollment will trigger the issuance of a Login ID and (temporary) Password for SUNY DOWNSTATE COI SMART. Investigators who have not yet received a Login ID and Password may check the status of this by contacting the 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

		<p>forgot your Login ID (full Downstate email address) or Password, you may request a re-set on the login screen.</p> <ul style="list-style-type: none"> • Revise Annual Questionnaire within thirty (30) days of change /discovering a new Significant Financial Interest (SFI). SFIs are defined in the Downstate COI Policy at: https://www.downstate.edu/research/research-services/conflicts-of-interest/index.html • 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. See: https://www.downstate.edu/research/research-services/conflicts-of-interest/contact.html
<p>Downstate workforce, UPB Investigator, and Kings County investigator who has UHB credentials.</p>	<p>Transactional Questionnaire</p>	<ul style="list-style-type: none"> • Complete a "Transactional Questionnaire" in SUNY DOWNSTATE COI SMART when submitting any of the following to the IRB: <ul style="list-style-type: none"> ○ 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.

<p>Kings County investigator who does NOT have UHB credentials, or is not otherwise a member of the Downstate workforce.</p>	<p>Submit COI disclosure form to NYC H+H.</p> <p>Submit COI determination document (e.g. adjudication letter) to IRB after it is issued from NYC H+H.</p>	<ul style="list-style-type: none"> • Required when submitting any of the following to the Downstate IRB: <ul style="list-style-type: none"> ○ 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.
<p>Anyone from an Institution with an IRB Reliance Agreement (IRA) with Downstate who is NOT a member of the Downstate workforce, if research falls under a PHS Award or when required by their Employer.</p>	<p>Check with Employer</p>	<ul style="list-style-type: none"> • If the investigator is from an institution, meeting the requirements to establish an IRA, do the following: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ✓ 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).

		<ul style="list-style-type: none"> 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.
<p>Anyone with an <u>Individual Investigator Agreement (IIA)</u>.</p>	<p>Check with Employer</p>	<p>Follow Employer requirements.</p> <p><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></p> <p><i>Note: If the study receives federal funding AND the external investigator is NOT from an institution which can establish an IRA AND the investigator is determined to be an investigator for the purposes of COI, contact the IRB to seek collaborative guidance with OCAS.</i></p>