# 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.

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<th>Who must submit?</th>
<th>What must be submitted?</th>
<th>Process:</th>
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| 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 log-in 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” | Transactional Questionnaire | • Complete a "Transactional Questionnaire" in SUNY DOWNSTATE COI SMART when submitting any of the following to the IRB:
  o Application for Expedited Review
  o Application for Convened (Full) IRB Review
  o Application for External IRB Review |
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<tr>
<th><strong>Kings County investigator who is a <strong>dual</strong> member who is an HHC Covered Individual.</strong></th>
<th><strong>ANY</strong></th>
<th><strong>Kings County investigator who is an HHC Covered Individual and is NOT a dual member of the Downstate workforce.</strong></th>
<th><strong>Submit COI disclosure form to NYC H+H.</strong></th>
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<td>- <strong>AND-</strong> Any UPB investigator who is a <strong>dual</strong> member of the Downstate for any PHS funded study.</td>
<td><strong>-</strong></td>
<td></td>
<td><strong>Required when submitting any of the following to the Downstate IRB:</strong></td>
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|  | **-** | **Submit COI determination document (e.g. adjudication letter) to IRB after it is issued from NYC H+H.** | **-** 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.  |
|  | **-** | **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).  |
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<th>Anyone with an Individual Investigator Agreement (IIA).</th>
<th>Check with Employer</th>
<th>Follow Employer requirements. <strong>Note:</strong> <em>An IIA cannot be established with an external investigator who is determined to be an investigator for the purposes of COI.</em></th>
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</table>
| • 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. |