IRB Guidance: IRB Training Requirements for Investigators and Key Personnel & Financial Conflict of Interest (COI) Requirements for “Investigators for the Purposes of COI”

For more information, contact the SUNY DOWNSTATE IRB at (718) 613-8480 or IRB@downstate.edu. For verification of training or COI submissions of the members of the Downstate Workforce, please contact Nakih Gonzales at (718) 270-4372 or nakih.gonzales@downstate.edu

TIP: 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 Policy RFDOWNSTATE-01 Downstate Research Conflict of Interest Policy:

Investigator (for the purposes of COI): 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.

Note - 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.

Note: External employees should consult with their organization to determine if they have any additional requirements by their institution

Updated 10.24.2019
**TRAINING REQUIREMENTS FOR INVESTIGATORS AND KEY PERSONNEL:**

<table>
<thead>
<tr>
<th>Training</th>
<th>Who must take the training?</th>
<th>Institution from where the Investigators or Key Personnel are located:</th>
<th>NYC H + H, Kings County</th>
<th>Others</th>
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</thead>
<tbody>
<tr>
<td><strong>Human Research Protections training</strong></td>
<td>All investigators and key personnel</td>
<td><strong>SUNY Downstate Workforce:</strong>&lt;br&gt;For the purposes of the Downstate IRB, the Downstate Workforce includes individuals who act on behalf of Downstate, including, but not limited to:&lt;br&gt;• Downstate Faculty members, employees, and staff&lt;br&gt;• Individuals with a Downstate Volunteer Faculty appointment with medical privileges&lt;br&gt;• Retired Downstate faculty member with emeritus status&lt;br&gt;• Residents, Fellows, or Medical Students that are sponsored by Downstate&lt;br&gt;• Students in a Downstate Academic Program&lt;br&gt;• Contractors and internal consultants who work on behalf of Downstate&lt;br&gt;• Temporary Employees working on behalf of Downstate • Downstate Volunteers (officially approved by the Downstate Volunteer Office) • Employees or staff of the Research Foundation for SUNY, working on behalf of Downstate</td>
<td><strong>Same as SUNY Downstate – be sure to affiliate CITI account with SUNY DOWNSTATE, so that the IRB can check results.</strong> &lt;br&gt;<strong>Note:</strong> Be sure to complete the optional HIPAA training module and COI training</td>
<td>Includes individuals who are not members of the Downstate Workforce, such as:&lt;br&gt;• External consultants&lt;br&gt;• External employees&lt;br&gt;• Individuals with Volunteer Faculty appointments without medical privileges</td>
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1) Register online for **Collaborative Institutional Training Initiative (CITI) training** at [https://www.citiprogram.org/](https://www.citiprogram.org/)<br>2) Affiliate your account with SUNY DOWNSTATE.<br>3) Choose anyone of three groups (See Appendix for detailed training modules)<br>   -Group 1: Biomedical Investigators and Key Personnel, Basic Course<br>   -Group 2: Social / Behavioral Investigators and Key Personnel<br>4) Sign up for supplemental (optional) training as desired or required.<br>5) Refresher training is required every 4 years.
| HIPAA Compliance Training | All investigators and key personnel | 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.  
**The HIPAA Compliance Training valid if completed in April 2013 or later.**  
The IRB will check the Downstate HIPAA training online; therefore it is not necessary to upload the training certificate in the IRB application.  
**For Students in a Downstate Academic Program:**  
Follow the instructions at:  
[https://sls.downstate.edu/registrar/hipaa_training.html](https://sls.downstate.edu/registrar/hipaa_training.html)  
Medical Students complete HIPAA certification upon matriculation and again prior to beginning clinical years.  
HIPAA training for students is valid for 2 years. If the HIPAA training is older than 2 years, contact OCAS to set up new training, as indicated above for the Downstate Workforce.  
*Note: If a student has been designated as an "investigator" for COI purposes, OCAS would need to assign the COI training. If HIPAA was completed within 2 years as a student, OCAS will identify HIPAA as "exempt" on the employee OCAS record.*  
(see HIPAA and COI details below) | Complete the optional CITI HIPAA training (module #14) offered through affiliation with SUNY Downstate.  
-OR-  
Attending Clinicians at NYC H+H, Kings County may provide copies of the HIPAA Compliance training module completed through People Soft.  
**COI Training**  
*TIP: See the tip on the cover page of this guidance document to*  
Those who are designated by the PI as an “Investigator for COI purposes”  
Take the COI training required at Downstate: “Conflict of Interest (COI) and Research Misconduct Training.”  
To register an investigator who is a member of the Downstate Workforce for HIPAA training or COI training/disclosures, please refer to the OCAS Workforce Training website. Forward completed form to compliance@downstate.edu  
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 optional CITI Conflict of Interest training module (various modules are available, including #488, #681) offered through affiliation | Complete the optional CITI Conflict of Interest training module (various modules are available, including #488, #681) offered through affiliation |
| **determine who is considered an “Investigator for the purposes of COI” to determine if they must complete COI training and disclosures.** | **This training is valid for 4 years.**

*NOTE: Downstate employees are no longer required to take the optional CITI COI training module.* | **with SUNY Downstate.**

- **OR-**

Provide copies of the COI training required by the institution where the individual is employed.

- **OR-**

Complete an Individual Investigator Agreement (IIA) with Downstate, to request COI training. |

| **Dangerous Goods Shipping Certification** | Individuals who are involved with shipping specimens, infectious substances, biological or hazardous substances | Enroll in free online training online provided by the Mayo Clinic:


Complete the Section 1 on Investigator Education and Training.

Individuals must pass this quiz with a score of 80% or greater in order to obtain a dangerous goods shipping certificate. Please attach a copy of the certificate to the submission.

**The expiration date of the training is on the certificate.** |

| **GCP Training** | All NIH-funded investigators and clinical trial site staff who are responsible for the conduct, management, and oversight of NIH-funded clinical trials must be trained in Good Clinical Practice (GCP). 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.

See:

Training Options:
- Take one of the CITI GCP training modules (see above) or go to: https://about.citiprogram.org/en/homepage/
- Take another form of GCP training such as those listed at: https://grants.nih.gov/policy/clinical-trials/good-clinical-training.htm

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.

Note: The IRB does not monitor GCP training for non-NIH funded studies; however, the Sponsor may request documentation. After completing the training, it is recommended the investigator submit copies of certificates with the IRB application for acknowledgement of such training. This can be done with the initial IRB Application, Application for Amendment, or an Application for Acknowledgement.

DoD Training
For Department of Defense (DoD) funded research, check with the DoD sponsor to determine if any additional training is required. After completing the training, please submit copies of certificates with the IRB application, if the DoD sponsor requires IRB acknowledgement of such training.

Note: The IRB does not monitor DoD training; however, the DoD may request documentation. After completing the training, please submit copies of certificates with the IRB application, if the DoD requires IRB acknowledgement of such training.

FINANCIAL CONFLICT OF INTEREST (COI) REQUIREMENTS FOR “INVESTIGATORS FOR THE PURPOSES OF COI:

TIP: See the tip on the cover page of this guidance document to determine who is considered an “Investigator for the purposes of COI” to determine if they must complete COI training and disclosures.

<table>
<thead>
<tr>
<th>Type of Conflict of Interest (COI) Disclosures</th>
<th>Who must submit?</th>
<th>Institution from where the Investigators or Key Personnel are located:</th>
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<tbody>
<tr>
<td>SUNY Downstate Workforce</td>
<td></td>
<td>For the purposes of the Downstate IRB, the Downstate Workforce includes individuals who act on behalf of Downstate, including, but not limited to:</td>
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<td></td>
<td></td>
<td>- Downstate Faculty members, employees, and staff</td>
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<td>NYC H+H, Kings County</td>
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<td>Other Institution’s</td>
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<td>Including individuals who are not members of the Downstate workforce, such as:</td>
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<td></td>
<td></td>
<td>- External consultants</td>
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<td></td>
<td></td>
<td>- External employees</td>
</tr>
</tbody>
</table>
Annual COI Disclosures

Investigators or Key Personnel who are members of the Downstate workforce who are also designated by the PI as an “Investigator for COI purposes”

- 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.
| “Transactional Questionnaire” | “Downstate employees designated by the PI as an “Investigator for COI purposes”” |
|--------------------------------|---------------------------------------------------------------------------------
| ▪ 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. |
| ▪ To contact someone to answer questions regarding COI disclosures, please see: [http://www.downstate.edu/coi/contact.html](http://www.downstate.edu/coi/contact.html) |
| ▪ 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. |
| ▪ To contact someone to answer questions regarding Transactional Questionnaires, please see: [http://www.downstate.edu/coi/contact.html](http://www.downstate.edu/coi/contact.html) |
| **COI determination document (e.g. adjudication letter)** | **Non-Downstate employees designated by the PI as an “Investigator for COI purposes”** | **E-mail the completed the NYC H+H COI Disclosure Form to Christina Pili, Director, Research Administration:** Christina.pili@nychhc.org  
For more information, call Ms. Pili at (718) 458-2743.  
Once NYC H+H issues the (COI) determination (e.g. adjudication letter), please add the document in the IRB submission package in IRBNet. The NYC H+H develops Management Plans for any SFI disclosure for sharing with the IRB and SUNY Downstate Conflict of Interest Committee. | **Provide the conflict of interest (COI) determination document (e.g. adjudication letter) from their employer.**  
-OR-  
Independent investigators or external investigators who are from a site that do not grant COI adjudication nor have a COI policy, must complete the Individual Investigator Agreement (IIA) and send it the IRB for processing; then send a copy of the completed form with all signatures to OCAS for processing: Compliance@downstate.edu |