IRB Procedure: Financial Conflict of Interest (COI) Disclosures and COI Training Requirements

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INTRODUCTION

This procedure outlines how investigators, IRB staff, and IRB members should meet Conflict of Interest (COI) training and reporting requirements for IRB submissions in accordance with SUNY Downstate's COI Policy and RFDHHU-01, supporting conflict management and collaboration between academia and industry.[1]

- **Scope of COI Disclosure:** Investigators and clinicians who meet the requirements for the role of ”COI Disclosure” must complete COI disclosures and complete COI training. The specific process differs for funded and unfunded research and differs depending on whether individuals are processed as Downstate Investigators, or External Investigators.
- **COI Disclosure Frequency:** Annual COI disclosures are required each year. COI disclosures MUST be updated within 30 days of new significant financial interests, or when the COI Discloser confirms information disclosed in their annual (or latest) conflict of interest disclosure changed since the time of initial submission **OR** if any of the information previously disclosed relates to their

1 SUNY Downstate Conflicts of Interest Policy and Conflict Management to Enable Academic and Industry Partnerships

project or other institutional responsibilities.

- **Training Requirements:** Downstate Research Investigators and Downstate Clinicians complete the "Research Compliance Conflict of Interest (COI) Course," valid for four years. External Investigators complete their employers' COI training or an optional CITI module affiliated with Downstate.
- **Mitigation and Research Participant Disclosure:** When significant financial interests exist, Principal Investigators must disclose relevant information in consent documents and follow management plans and IRB requirements to protect research participants. Template language for disclosures is provided.
- **IRB Member Responsibilities:** IRB members review management plans, assess appropriateness of COI disclosures in consent forms, determine IRB approval periods considering management plans, and must recuse themselves from reviews involving their own financial conflicts.
- **IRB Office Staff Roles:** Staff with COI Administrator roles monitor COI disclosure statuses, initiate or withdraw annual COI disclosure requests, notify relevant offices for training needs, share management plans with IRB reviewers, and document findings.
- **Coordination with External Entities:** Kings County investigators and clinicians submit COI disclosures to NYC Health +Hospitals Central Office (NYC H+H) for adjudication letters. Other External Research Investigators must comply with their employer's COI requirements. Those who are not agents of Downstate require review under either an IRB Reliance Agreement (IRA) between Downstate and their employer or they must execute an Individual Investigator Agreement (IIA) with Downstate. Downstate Research Volunteers are regarded as agents (not employees) of the Downstate Workforce and are therefore covered by Downstate's FWA; they do not need an IRA or IIA.

COI DISCLOSER ROLE

Investigators and Clinicians follow the standards outlined in Policies IRB-01[2] and RFDHSU-01.[3]

The following Investigators and Clinicians are considered to be COI Disclosers and must complete the Conflict of Interest (COI) training and disclosure requirements, when submitting Initial Review, Continuing Review, and when being added as an amendment to an existing study to the Downstate IRB, or when the funding status of a study changes resulting in change of COI Disclosers.

2 IRB Policies Website
3 Downstate Conflict of Interest Website

- **Funded** Research (Downstate receives external funding)
  - The **Principal Investigator (PI)**
  - Any investigator determined to be an **"Investigator for the Purposes of COI"** by the PI, as outlined and defined in Downstate's COI policy.
- **Unfunded** Research (Downstate support only):
  - The **PI** and any **Co-PI** on the IRB application.
- **Lead Clinician** named on an IRB Application Form 11-A5 for **Expanded Access** for treatment use or an IRB Application Form 11-A6 a **Humanitarian Use Device** (HUD) for clinical use, **regardless of whether a conflict is declared**.
- **Any Clinicians** named on an IRB Application Form 11-A5 for **Expanded Access** for treatment use or an IRB Application Form 11-A6 a **Humanitarian Use Device** (HUD) for clinical use, **when a conflict is declared**, as required on the IRB application forms. For applications, see Step 11 of the IRB Electronic Submissions website.[4]

DOWNSTATE RESEARCH INVESTIGATORS, RESEARCH VOLUNTEERS, & EXTERNAL RESEARCH INVESTIGATORS.

Downstate IRB COI procedures vary depending on if the investigator is a Downstate Investigator, Research Volunteer, or External Investigator, as well as whether Downstate receives funding.

DOWNSTATE RESEARCH INVESTIGATORS (DOWNSTATE COI DISCLOSERS)

Downstate Research Investigators (Investigators) / COI Disclosers – The designation of Investigator for purposes of COI applies to individuals who conduct research on behalf of Downstate, including:

- Faculty members, employees, staff or temporary employees who are paid by Downstate.
- Individuals with a Downstate Voluntary Medical Faculty appointment with medical privileges (credentialed by University Hospital Downstate[UHD]) / Emeritus Faculty– when such individual:
  - Is issued, and agrees to use, in the course of their research, Downstate Information Technology (IT) accounts – including Downstate email address – to facilitate secure communication and storage of Downstate data; and
  - Has received approval and will be granted oversight by the Downstate Department Chair / Dean requesting to engage the voluntary appointment as a PI in Downstate unfunded research.
- Residents, Fellows, or Medical Students who are sponsored by Downstate, as defined below:

4 Downstate IRB Electronic submissions Website

    - A sponsored Resident or Fellow is any Resident or Fellow who is part of a Downstate Residency / Fellowship training program who goes through the Downstate GME Office, regardless of rotation site or employment status.
    - A sponsored Medical Student is sponsored through one of the Downstate colleges, or through an affiliation agreement.
    - If either a sponsored Resident or Student is paid by another institution, they should check to see if their institution has any additional COI related requirements.
- Students in a Downstate academic program.

If the above criteria are satisfied, an individual may be designated as an Investigator (for COI purposes), provided they also meet the following definition:

The project director, Principal Investigator, co-Principal Investigator, 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 externally funded research. If the role of an individual is unclear and that individual has been previously designated as an Investigator, compliance with all training and filing requirements will be expected. For unfunded and/or internally funded research activities (Downstate support only), only the Downstate PI (and Co-PI as applicable) will be considered an Investigator for COI purposes.

Note – Staff and trainees, such as postdoctoral fellows, graduate and medical students, residents and fellows, research coordinators, phlebotomists, pharmacists, biostatisticians and technicians who perform research tasks (including, but not limited to: recruit patients, collect data, handle data, enter data into an electronic capturing system, analyze data, perform experiments, implement a protocol) under supervision but who are not responsible for the design/ conduct/ reporting of research are not considered Investigators for purposes of COI. However, if a Medical Student, Resident, and/or Fellow is applying for a research grant, they are considered an investigator for COI purposes and, therefore, must complete COI requirements.

RESEARCH VOLUNTEERS

The statements below provide clarification regarding volunteers whose research is reviewed by the Downstate IRB.

VOLUNTARY FACULTY WITH UHD MEDICAL PRIVILEGES

Voluntary Faculty with UHD medical privileges (UHD credentials) who meet the additional criteria for Downstate Research Investigators described above, follow the process for **Downstate COI Disclosers (see above).**

OTHER RESEARCH VOLUNTEERS

The following Research Volunteers are **agents** of the Downstate Workforce for Downstate's Federal Wide Assurance (FWA) and Downstate IRB oversight purposes, so they do not require IRB Reliance or Individual Investigator Agreements. However, as they are **not employees**, they must follow the COI process for **External COI Disclosers (see below)**.

- Voluntary Faculty without UHD medical privileges (UHD credentials).
- Research Volunteers onboarded by the Senior VP or Research Office.
- Downstate Volunteers.

EXTERNAL RESEARCH INVESTIGATORS (EXTERNAL COI DISCLOSERS)

External Research Investigators (Investigators)[5] / COI Disclosers – The designation of Investigator for purposes of COI applies to individuals who are not members of the Downstate workforce and conduct research reviewed by the Downstate IRB, include the following individuals:

- External consultants (e.g., those paid by sponsors or other entities outside of Downstate),
- Independent Contractors, as determined by Research Foundation Human Resources (RF HR) based on IRS Regulations and the RF Engaging Independent Contractors procedure.
- Individuals with Voluntary Faculty appointments at Downstate without UHD medical privileges,
- External residents, fellows, and students (e.g., those without an affiliation agreement with Downstate).
- Individuals, unless they jointly meet the definition of a Downstate Research Investigator, who are employees or agents of institutions that are not listed as components of Downstate's FWA, including:
    - Downstate Health Physicians (DHP),
    - NYC Health + Hospital, Kings County Hospital,
    - Companies within the Downstate Biotech Park,
    - Other institutions, or
    - Private practices.

5 External Research Investigators are not covered by the Downstate FWA. For IRB approval, they must have either an IRB Reliance Agreement between their institution and Downstate or complete an Individual Investigator Agreement.

COI TRAINING REQUIREMENTS & PROCESS

COI training must be completed before submitting COI disclosures, as outlined below, and the type of training depends on whether the investigator follows the process for Downstate COI Disclosers or External COI Disclosers.

DOWNSTATE COI DISCLOSERS

Downstate Research Investigators who are COI disclosers (Downstate COI Disclosers) must complete **"Research Compliance Conflict of Interest (COI) Course."** For additional information refer to Downstate Conflict of Interest website.[6] This training 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; however, if desired, the training certificate can be attached to the submission by the study team.

The COI Business units (IRB, IACUC, SPA, OSP) determine when COI training is required and will notify Downstate Compliance when the investigators must complete the training.

To facilitate the IRB's initiation of COI training or disclosure requests, the Principal Investigator must first submit the IRB application to the Downstate IRB. This submission enables the IRB Office to identify individuals required to complete a COI Disclosure and determine the appropriate procedures based on the type of funding and whether the disclosers are classified as Downstate or External COI Disclosers. Additionally, this process ensures that the IRB is the designated COI Business Unit to initiate the request.

EXTERNAL COI DISCLOSERS

External Research Investigators who are COI disclosers (External COI Disclosers) must complete their employer's required COI training, which is valid for the period determined by their employer's policy.

Alternatively, they may complete the optional COI training module in CITI, after affiliating their CITI account with Downstate. CITI COI training is valid for 4 years.

COI DISCLOSURE PROCESS & FREQUENCY

DOWNSTATE COI DISCLOSERS

6 Downstate Conflict of Interest Website

Downstate COI Disclosers must submit or update their disclosures in the MyResearch[7] COI Module, when submitting Initial Review, Continuing Review, when being added as an amendment to an existing study, or when the funding status of a study changes resulting in them becoming a COI Disclosers. For access to the COI Module, refer to the Downstate MyResearch website.[8] For guidance on how to use the module, refer to the COI Disclosure Quick Reference.[9]

The frequencies for COI disclosures for the **Downstate Research Investigators**, are as described below:

- **Annual Disclosure Certification:**
  - Submit their **Annual Disclosure Certification** in MYResearch COI Module when they receive a notice of this requirement. **New Downstate Investigators** will be notified to submit their annual disclosures at the time of their first IRB application or funding submission.
  - Revise **Annual Disclosure Certification** within thirty (30) days of either developing or discovering they have a new Significant Financial Interest (SFI).
- **Research Disclosure Certification:**
  - An updated Research Disclosure Certification **may** be required at the time of Initial Review, Continuing Review, when being added as an amendment to an existing study to the Downstate IRB, or when the funding status of a study changes resulting in them becoming a COI Disclosers.
  - When the latest COI disclosure was submitted more than 30 days after the IRB submission, the IRB Office will request the a **Research Disclosure Certification** for the specific submission **if** the Downstate COI Disclosure confirms information disclosed in their annual (or latest) conflict of interest disclosure changed since the time of initial COI Disclosure submission **OR** if any of the information previously disclosed relates to their project or other institutional responsibilities.

Management Plans (MPs) must be developed for SFI and be updated when applicable, as Determined by the Downstate Financial COI Committee (COIC). When an MP requires a change in the research (e.g., new or revised disclosures information provided to research participants) an amendment must be submitted to the IRB for review and approval of the change. MPs must be completed between COI Discloser and COIC and reviewed by the IRB before final IRB approval can be granted. To prevent delays or lapses in IRB review, the COI Discloser should promptly submit new SFIs and finalize related MPs. If delays occur, notify the IRB and COIC; for funded research, contact the relevant COI business unit: inform the Director, SPA for grants/awards, or the Executive

7 MyResearch
8 Downstate MyResearch
9 COI Disclosure Quick Reference

Director, OSP for industry-funded clinical research.

EXTERNAL COI DISCLOSERS

Unless they jointly meet the definition of a Downstate Research Investigator, **External COI Disclosers** follow the requirements of their employer, rather than using the COI Module in MyResearch. They submit or update their COI Adjudication Letter when submitting Initial Review, Continuing Review, when being added as an amendment to an existing study, or when the funding status of a study changes resulting in them becoming a COI Disclosers.

External COI Disclosers must provide the following with the applicable IRB submission:

1. A **COI Adjudication (Determination) Letter**, along with the date of the investigator's disclosure and a statement they follow NIH COI policies. If a SFI was disclosed, they must also provide an External MP.
2. Documentation that they have completed the required COI training from their employer. This may be a training certificate or included in a letter or email from their employer.
3. They must provide an **updated COI Adjudication (Determination) Letter, as follows:**
    - Each year, based on the cycle of annual review from their employer, but no later than the time of continuing review.
    - Within thirty (30) days of them either developing or discovering they have a new Significant Financial Interest (SFI).
    - An updated COI Adjudication (Determination) Letter may be required at the time of Initial Review, Continuing Review, when being added as an amendment to an existing study to the Downstate IRB, or when the funding status of a study changes resulting in them becoming a COI Disclosers.
        - When the latest COI Adjudication (Determination) Letter was submitted more than 30 days after the IRB submission, the IRB Office will request the a **Research Disclosure Certification** for the specific submission **if** the Downstate COI Disclosure confirms information disclosed in their annual (or latest) conflict of interest disclosure changed since the time of initial COI Disclosure submission **OR** if any of the information previously disclosed relates to their project or other institutional responsibilities.
    - These **may** be required at the time of Initial Review, Continuing Review, when being added as an amendment to an existing study to the Downstate IRB, or when the funding status of a study changes resulting in them becoming a COI Disclosers.
        - The IRB Office will request the **updated COI Adjudication (Determination) Letter** for the specific submission **if** the External

COI Disclosure confirms information disclosed in their latest conflict of interest disclosure changed since the time of latest submission **OR** if any of the information previously disclosed relates to their project or other institutional responsibilities.

Management Plans must be developed for SFI and be updated when applicable, as Determined by their employer's Financial COI Committee (COIC). When an MP requires a change in the research (e.g., new or revised disclosures information provided to research participants) an amendment must be submitted to the IRB for review and approval of the change. MPs must be completed between COI Disclosers and COIC and reviewed by the IRB before final IRB approval can be granted. To prevent delays or lapses in IRB review, the COI Discloser should promptly submit new SFIs and finalize related MPs. If delays occur, notify the IRB and COIC.

If an **External COI Discloser** is not employed or if their employer lacks the authority, capacity, or ability to comply with NIH COI policies, the investigator must obtain a COI Adjudication (Determination) letter from an external COI Committee, external IRB, attorney, or consultant who can verify adherence to NIH policies. **Please note that this process may incur additional costs to the Downstate Department/College supporting/funding the research, or to the External COI Discloser.**

SFI MITIGATION & DISCLOSURES TO RESEARCH PARTICIPANTS

When there is a Significant Financial Interest (SFI), as defined by the Downstate COI Policy or NIH COI policies, the Principal Investigator and Downstate IRB must ensure relevant disclosures are included in the informed consent document or information sheet, when there are plans for prospective recruitment and enrollment of research participants. The PI must follow any required mitigation strategies outlined in their Management Plan (MP) and follow any additional requirements of the IRB.

Template language for disclosing conflicts of interest is included in the template 8-2: All-In-One Version Informed Consent Template, available in Step 8 of the Downstate Electronic Submission Process website.[10] The language may be modified as applicable to the research and the MP; however, the IRB may require modifications, if needed. As of the date of this document, the following draft disclosure language, included in the template, is provided below:

10 IRB Electronic Submission Process

Do the researchers have any conflicts of interests that may affect your willingness to participate in the research?

Items in italics or red are general instructions which must be deleted (or changed when applicable) before submitting the final form to the IRB.

Disclose any *significant financial interests (SFI)*. Suggested text is provided below based on the situations described. Edit as needed. The IRB will consult with the Conflict-of-Interest Committee to approve or make additional edits as needed.

Always identify sponsor and salaries supported under funds: The National Institutes of Health [or list other sponsor or foundation] provide funding to conduct this study. Some of the funding pays part of the salary for [list all investigators as applicable to the funding].

When an investigator has stock in a company: Dr _____ owns stock in a company that is (performing research/marketing a product) in the same area as this study.

When an investigator owns a company: Dr. _____ is the researcher running this study and is a [founder and] co-owner of _____. This company may develop a commercial product using data from this research. Because Dr. _____ has an investment in the company, the amount of money the investment is worth might be affected by the results of this study. This means that Dr. _____ could gain or lose money depending on the results of this study.

When an investigator is named on a biomedical patent or otherwise has proprietary rights or interests in any medical therapy, drug, device, or method used, tested or studies in this research protocol: Dr _____ has developed _____ which is a (therapy/drug/device/method) that is (used/tested/studied) in this research protocol. Dr. _____ has a personal financial interest in this (therapy/drug/device/method). Dr. _____ and SUNY Downstate may benefit financially if this (therapy/drug/device/method) does what they hope it will do.

When an investigator received an honoraria or travel reimbursement: Dr. _____ has received an honorarium (payment for professional services such as consulting or advising) [or travel reimbursement] during the past 12 months from the study sponsor.

Add when applicable: Research participants will not receive any payment or rights for discoveries, patents or products that may be developed from this research.

Always include Dr. _____ does not participate in the enrollment or informed consent process for this study.

We provide this information in case it affects your willingness to participate in the study. Please ask the researchers or the study coordinator if more information is needed.

DOWNSTATE IRB MEMBER REVIEWER RESPONSIBILITIES

The IRB considers whether research participants should be informed of any financial relationships or interests that are associated with the research, such as payments for services, equity interests, or intellectual property rights. Some conflicting financial interests in the research may affect the rights and welfare of research participants, and

the IRB should consider approaches to assure they are adequately protected, including providing them with information about the financial relationships and interests. The IRB should determine whether participants should be provided with information regarding the source of funding, funding arrangements, financial interests of parties involved in the research, and any financial interest management techniques applied. The IRB should consider the kind, amount, and level of detail of information to be provided to the participants.

When carrying out their IRB reviewing responsibilities, IRB members do the following:

- Review MPs for relevant SFIs and disclosures related to the IRB submission to determine if added protections or disclosures are needed.
- Assess required COI disclosures in consent forms/information sheets.
- Set IRB approval periods per IRB policy and ensure they don't exceed the MP expiration and reduce the IRB approval period if needed.
- Recuse themselves from reviews involving personal SFIs.

EXTERNAL REVIEWING IRB

When an external reviewing IRB oversees a study, the Downstate IRB conducts a local administrative review to activate it. This includes evaluating COI disclosures for Downstate investigators. If significant financial interests or management plans are involved, the Downstate IRB Office may share relevant details with the reviewing IRB for COI assessment. Management plans are only provided as needed and unrelated information may be redacted. The IRB Office may consult with the Downstate COIC or another IRB member to ensure adequate disclosure in consent before study activation. COI review and informed consent procedures follow the reviewing IRB's established policies.

IRB OFFICE PROCEDURES

The procedures followed by the IRB Office vary based on whether the COI Disclosure is being made by a Downstate COI Disclosure or an External COI Disclosure. More information can be found below.

IRB OFFICE PROCEDURES FOR DOWNSTATE COI DISCLOSERS

COI TRAINING

The IRB Office confirms the Downstate Research Investigators who are COI disclosers have completed their required training.

If the COI training is pending, they will notify the PI of the study to ensure the training gets completed. If the COI Disclosures are not yet registered to take the Downstate COI training, the following will occur by the IRB staff:

- If the study is **unfunded**, the IRB Staff will notify Downstate Compliance to register the investigators to complete the required training.
- If the study is **funded by a Grant/Award**, IRB staff inform the Director, SPA that the investigator is not yet registered to complete the COI training.
- If it is an **Industry funded Clinical Research**, IRB staff inform the Executive Director of the Office of Sponsored Programs (OSP), that the investigator is not yet registered to complete the COI training.

DOWNSTATE COI DISCLOSERS

The IRB Office Staff receives training on how to use the MyResearch COI module and may refer to the COI Administrator Quick Reference[11] or contact the Executive IRB Director for guidance, as needed.

The IRB Office Staff, have the COI Administrator role in MyResearch, and do the following for **Downstate Research Investigators who are COI Disclosers:**

- Review the status of submitted COI disclosures for Initial Review, Continuing Review, when being added as an amendment to an existing study, or when the funding status of a study changes resulting in them becoming a COI Disclosers.
    - Click on the COI Module in the MyResearch Dashboard.
        - Annual Disclosures which are in Draft or require an “Administrative Review” appear in the Inbox.
        - To review the status of All COI Certifications, click “COI”, then “Reports”
    - If the COI disclosure is in “**Draft Mode**,” remind the investigators to complete the disclosure.
    - If the Annual Disclosure submission status is “**Administrative Review,”** do the following as applicable for the funding type:
        - If the study is **unfunded**, contact the FCOIC (Financial Conflict of Interest Committee) to request review and provide any necessary details of the study requested by the FCOIC, including, if needed, a copy of the protocol and consent form submitted with the IRB submission.

11 COI Administrator Quick Reference

        - If the study is **funded by a Grant/Award**, inform the Director, SPA the disclosure is pending review and IRB review cannot proceed. They may request the FCOIC review, if necessary.
        - If it is an **Industry funded Clinical Research**, inform the Executive Director of the Office of Sponsored Programs (OSP), the disclosure is pending review and IRB review cannot proceed. They may request the FCOIC review, if necessary.
    - If there is **no COI disclosure**, do one of the following as applicable to the funding type:
        - If the study is **unfunded**, notify the IRB Executive Director or alternate who has the User Management Function to generate the annual COI disclosure. *Do not generate a "Research Initiated Disclosure" for the purpose of an "Annual Disclosure". Only individuals with the User Management Function within the MyResearch software system can generate or withdraw requests for investigators' Annual COI Disclosures.*
        - If the study is **funded by a Grant/Award**, notify Director, SPA to create the annual COI disclosure.
        - If it is an **Industry funded Clinical Research**, notify the Executive Director of the Office of Sponsored Programs (OSP) to request the annual COI disclosure.
    - If the latest Annual or Research Disclosure is **within 30 days** of the IRB submission date and marked **"No Review Required," no action** is needed. However, If it's **over 30 days old** and marked **"No Review Required,"** follow procedures based on your funding type:
        - For **unfunded research**, send the following email to the Investigator:

          RE: IRBNet# XXXX-X; COI Certification -Response Required

          Response Required: Y or N

          Has any of the information that you disclosed in your annual conflict of interest disclosure changed since the time of your initial (or latest) submission OR has any of the information you previously disclosed now related to your project or other institutional responsibilities?

        - For **unfunded research**, upload the response in the COI module, by Logging a PRIVATE comment and attach the response.
            - ✓ If the response is Y, create a Research Certification so that it can be updated, and let the investigator know this needs to be completed:
                - Click on the "COI Module" under the Dashboard in MyResearch.

- Click “Create Res. Certification”
- Select the Research Team Member
- Indicate NA for Sponsor
- Enter IRBNet package # for Research Project ID.
- Enter the study title for the Research Project Name.
- Select IRB for the Research Project Type.
- Click OK

✓ If the response is N, log the comment and proceed with the review.

- If the study is **funded by a Grant/Award**, notify Director, SPA to initiate the email request.
- If it is an **Industry funded Clinical Research**, notify the Director of OSP to initiate the email request.

- Withdraw any Research Certification for an **unfunded** submission that was created in error or is determined to be no longer required.
  - Whenever a MP is required, share the final executed MP with the IRB members reviewing the submission. To do this, publish it as an “Internal” document with the submission and let the IRB members know it is available for their review.

IRB OFFICE PROCEDURES FOR EXTERNAL COI DISCLOSERS

COI TRAINING

The IRB Office confirms the External Research Investigators who are COI disclosers have completed their required training.

If the COI training is pending, they will notify the PI of the study to ensure the training gets completed.

EXTERNAL COI DISCLOSERS

The IRB Office Staff, do the following for **External COI Disclosers:**

- Review COI adjudication letters (and MP, if SFI is disclosed) for **External COI Disclosers** for Initial Review, Continuing Review, when being added as an amendment to an existing study, or when the funding status of a study changes resulting in them becoming a COI Disclosers.
- If the latest COI disclosure (as indicated in their adjudication letters) is **within 30 days** of the IRB submission date and no SFI are noted, **no action** is needed.

However, if it's **over 30 days old** and no SFI are noted, send the following email to the Investigator:

> RE: IRBNet# XXXX-X; COI Certification -Response Required
>
> Response Required: Y or N
>
> Has any of the information that you disclosed in your annual (or latest) conflict of interest disclosure submitted to obtain your annual (or latest) COI Adjudication Letter changed since the time of your initial COI disclosure submission OR has any of the information you previously disclosed now related to your project or other institutional responsibilities?

- Add a note regarding the response in the IRBNet Submission Reviewer Comments and attach the response.
    - If the response is Y, request an updated COI Adjudication letter be submitted in IRBNet.
    - If the response is N, proceed with the review.
- Whenever a MP is required, share the final executed MP with the IRB members reviewing the submission. To do this, publish it as an "Internal" document with the submission and let the IRB members know it is available for their review.

IRB OFFICE DOCUMENTATION & SHARING OF MPS

- The IRB Office documents the findings on the "COI & Training Spreadsheet" and uploads a copy to reviewer notes in IRBNet. Any Communications to the PI/Co-PI should ideally be done in IRBNet; however, if an email is sent outside of the system, please share a copy in IRBNet attached as a Reviewer Note in IRBNet.
- Whenever a MP is required, attach the fully executed MP to the submission and publish it as an Internal document so that it can be viewed by IRB members reviewing the submission.
- Ensure all necessary disclosures in the consent forms are approved by the IRB prior to issuing the IRB approval letter.
- Ensure final IRB approval cannot be granted until any required MP is reviewed by the IRB and the language used for necessary disclosures to the research participants are approved by the IRB and congruent with the MP.
- During the activation of research overseen by an external IRB, the Downstate IRB Office may provide pertinent information to the reviewing IRB for conflict of interest (COI) assessment. Management plans will be shared only as necessary, while any unrelated details may be redacted. The IRB Office may also consult with

the Downstate COIC or another IRB member to ensure appropriate disclosure is included in the consent documents prior to study activation.

- **Ensure the expiration date of an approval, is no later than the expiration date of the MP.**

MYRESEARCH USER MANAGEMENT

The Executive Director, Human Research Protections and Quality Assurance (or designee) may do the following when required by an Investigator or IRB, for an **unfunded** submission:

- Follows the User Management Guide[12] to Update and Maintain User Accounts.
- Request an Oracle Shell by the RF HR Director, for any new Downstate Investigator who meets the requirements of a COI Disclosure and provide the Investigator Name, Department, Sex, and Effective date, when making this request. After the Oracle Shell is built, the user should appear within MyResearch the next day, as the data transfers overnight.
- Assign or remove the COI Disclosure Role to a Downstate Investigator in MyResearch and initiate or withdraw an Annual COI Certification in MyResearch.
- Notify Compliance of new Downstate COI Disclosures so they may initiate COI Training assignments.

REFERENCES

- COI Administrator Quick Reference
- COI Disclosure Quick Reference
- COI Training and COI Spreadsheet.
- Policy IRB-01
- Policy RFDHSU-01
- SUNY RF User and Campus Manager Guides
- User Management Guide

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REVIEW AND APPROVAL HISTORY

IRB Procedure: FCOI-1
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Supersedes: Replaces all prior IRB guidance on COI requirements.

Revision Date: N/A (NEW)

Date Reviewed & Approved	**Revision Required**		**Responsible Staff Name and Title**	
	Yes	No		
01.07.2026		X	Downstate IRB and Privacy Board	