

	<p>SUNY Downstate Medical Center University Hospital of Brooklyn College of Medicine College of Health Related Professions College of Nursing School of Graduate Studies Graduate Program in Public Health</p>	<p style="text-align: center;">IRB UPDATE MEMORANDUM</p> <p>IRB Mailbox: IRB@downstate.edu Main Phone #: (718) 635-8480</p>
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DATE: December 2016
TO: Research Community
FROM: SUNY Downstate Medical Center Institutional Review Board (IRB)
RE: IRB Update

Dear Research Community,

Happy Holidays! The following information provides a few key updates with the SUNY Downstate Medical Center IRB. For more information, please contact the IRB or review available forms, templates and guidance within the “Forms & Templates” page inside IRBNet (www.irbnet.org). If you have questions, suggestions, or wish to request training please contact the IRB for help.

IRB CONTACTS

The following phone numbers are provided for your convenience:

- Phyllis G. Supino, EdD, IRB Chair: (718) 613-8355
- Daniel Cukor, PhD, Vice Chair, Board A: (718) 270-2077
- Stanley Friedman, MD, Vice Chair, Board B: (718) 270-1335
- Kevin L. Nellis, MS, CIP, Executive Director, Human Research Protection & Quality Assurance: (718) 613-8461
- Diann Johnson, MPH, Associate IRB Administrator: (718) 270-4341
- Angela Cartmell, PhD, CIP, Associate IRB Administrator: (718) 270-4454
- Nakih Gonzales, IRB Assistant: (718) 270-4372
- IRB Office: (718) 613-8480
- IRB E-mail: IRB@downstate.edu

IRB Net™

SUNY Downstate Medical Center (DMC) uses [IRBNet](http://www.irbnet.org) for the electronic submissions and management of its IRB activities. Anyone may obtain a user account by following the instructions below:

Step 1: Create an IRBNet user account

- Go to www.irbnet.org and click the “[New User Registration](#)” link.
- Follow the online instructions. Complete all items with red asterisk (*).
- When asked to identify your “organization” type SUNY in the text box and then select “SUNY Downstate Medical Center, Brooklyn, NY”.
- Click on the “Register” button to finalize your “New User Registration.”
- Press the “Continue” button on the “Registration is Complete” page and follow “**Step 2**” to activate your IRBNet user account.

Step 2: Activate your IRBNet user account

- After successful completion of “**Step 1**,” the User will receive an activation email to the registered email address.
- Click on the link within that email to activate your IRBNet account.
- You may begin using IRBNet as soon as activation is complete.

If you forget your password, navigate to <https://www.irbnet.org/release/public/login/hint.jsp> and follow the instructions on the website.

DEVELOPMENT OF NEW IRB POLICY

The IRB is in the process of developing a new official IRB policy for SUNY Downstate Medical Center. This policy defines procedures to be followed in the preparation of research protocols to the IRB and describe the criteria for IRB approval. A draft of the policy is posted in IRBNet for public comment. To access the policy, please do the following:

- 1) Log in to IRBNet (see above)
- 2) Click on the “Forms & Templates” link on the left side of the screen
- 3) Click on the link for “*SOP1 (DRAFT FOR FEEDBACK) IRB-01 Human Research Protections Program Policy”

We value feedback from our stakeholders in the research community. Please send your feedback to IRB@downstate.edu

UPDATED CITI TRAINING REQUIREMENTS

The IRB has implemented important programmatic updates to the CITI training requirements. In general, we have reduced the burden of required training. We now require fewer modules when an investigator initially signs up to CITI and the training is now be valid for 4 years. Many more additional supplemental modules are available. We encourage everyone to sign up for training in their specific areas of interest.

Downstate employees are required to take HIPAA training and Conflict of Interest (COI) training through Office of Compliance and Audit Services. These topics have been eliminated from CITI requirements, for Downstate employees, but may be requested as optional training modules.

IMPORTANT: When a study team member is not employed by Downstate (Kings County Hospital or other outside institutions) they must provide copies of their certification in HIPAA Training and COI training from their institution of employment. When a study team member is not employed by Downstate, and they are not able to provide documentation of their certification in HIPAA Training and COI training from their institution of employment the CITI HIPAA and CITI COI modules are required to be completed.

The optional modules must be specifically requested when signing up for training on the CITI website: <https://www.citiprogram.org/>

To request optional training modules, log into the CITI website and click on the link to “Add a Course.” When learners initially sign up, they are now given the option to select a group of training modules appropriate to their research activities (Biomedical, Social/Behavioral, or IRB Members), and may request GCP training or COI training. The optional modules for the HIPAA training and a multitude of other courses can be selected after the required training has been completed.

For additional help, you may refer to instructions on the CITI website, refer to the “IRB Guidance: Training and COI Requirements” in IRBNet, or call the IRB.

EXTERNAL IRB REVIEW

The IRB has established a process to allow for the external IRB review of multi-site studies. An external IRB is any IRB other than the Downstate IRB that reviews and approves a multi-site research project that includes Downstate. This can be a Central IRB, a Commercial IRB, a Main Study Site IRB, or a Single IRB; however, the Downstate IRB must establish an IRB Authorization (Reliance) Agreement with the external IRB, acknowledge external IRB approval, and confirm Downstate requirements are met, before the research may begin at Downstate. For more information, please see the “IRB Application for External IRB Oversight” within the “Forms & Templates” page inside IRBNet (www.irbnet.org).

IRB DECISION AID

The IRB encourages the use of the “IRB Decision Aid” tool to help assist with determining whether IRB approval is required or not for a specific activity. Upon request, the IRB may issue an IRB determination letter confirming IRB approval is not required. The form can be accessed on the “Forms & Templates” page inside IRBNet (www.irbnet.org). This form can be used to document activities which do not require IRB approval, for example:

- A case report of up to 3 individuals
- A performance improvement project with outcomes that will remain specific to Downstate, rather than be designed to develop or contribute to generalizable knowledge
- When Downstate is not “engaged in human research,” per regulatory guidelines
- Certain activities which are limited to the use of de-identified data or de-identified specimens

IRB APPLICATION FORMS & GUIDANCE

While our IRB policy focuses on requirements of complex regulations, our IRB application forms, guidance, templates provide additional information and added flexibilities.

Our IRB application forms are often updated to ensure we are following best practices and ensure compliance with regulations. The form can be accessed on the “Forms & Templates” page inside IRBNet (www.irbnet.org). Please be sure to check IRBNet to make sure you are using the most recent form. In general, the IRB will accept older forms, especially if an investigator uses a form which was available within 3 months prior to the version date of a new form.

The IRB has developed multiple guidance documents, which are available on the “Forms & Templates” page inside IRBNet (www.irbnet.org).

Some of the most frequently used guidance documents are:

- Template Research Protocol
- Template Informed Consent Documents
- Submission Requirements for IRB Review
- IRBNet Application and Reporting System
- Training and COI Requirements
- Obtaining Legally Effective Informed Consent
- Research, Recruitment, Referral, Screening, Advertising, and Incentives
- Local Research Context for External IRBs
- Scientific Review Committee Members

We look forward to working with each of you in facilitating the research process.