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|  | <p>University Hospital of Brooklyn</p> <p>College of Medicine</p> <p>College of Health Related Professions</p> <p>College of Nursing</p> <p>School of Graduate Studies</p> <p>Graduate Program in Public Health</p> | <p style="text-align: center;"><b>IRB UPDATE<br/>MEMORANDUM</b></p> |
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DATE: May 2017

TO: Research Community

FROM: SUNY Downstate Medical Center Institutional Review Board (IRB)

RE: Key Updates

Dear Research Community:

Greetings! The following information provides key updates with the SUNY Downstate Medical Center IRB. If you have questions, suggestions, or wish to request training, please contact the IRB Office at (718) 613-8480 or [IRB@downstate.edu](mailto:IRB@downstate.edu)

**NEW IRB POLICY**

The [new IRB Policy \(IRB-01\)](#), “Human Research Protections Program,” has been approved by the Executive Performance Improvement Committee and Medical Executive Board. **The effective compliance date for this policy is June 30, 2017.**

Before finalizing the policy the IRB received feedback from many Investigators, Department Chairs and Deans. Based on your feedback, we created a policy that protects the rights and welfare of research participants, ensures regulatory compliance, and eliminates excess burdens of past practices. Questions may be directed to [IRB@downstate.edu](mailto:IRB@downstate.edu)

The IRB will host informational training sessions to go over the new policy:

| Date:                 | Time:                                     | Location:      |
|-----------------------|---|----------------|
| May 15, 2017 (Monday) | 11 am – 12 noon (Followed by Q&A session) | Lecture Hall 1 |
| May 26, 2017 (Friday) | 2 pm – 3 pm (Followed by Q&A session)     | Lecture Hall 1 |
| June 9, 2017 (Friday) | 12 noon – 1 pm (Followed by Q&A session)  | Lecture Hall 1 |

**UPDATED IRB WEBSITE**

We have updated the [SUNY Downstate Medical Center IRB Website](#). Direct links for key content are provided below:

- [IRB Home Page](#)
- [Electronic Submissions](#)
- [Training & Conflict of Interests](#)
- [Members & Staff](#)
- [Meeting Schedule](#)
- [Policies & Guidance](#)
- [Resources](#)
- [FAQs](#)
- [IRBNet](#)
- [CITI Investigator Education Certification](#)

## **REVISED FDA REGULATIONS FOR CLINICALTRIALS.GOV**

The FDA issued the [Final Rule](#) regarding “Applicable Clinical Trials (ACT)” which must be registered by the responsible party at [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov). ACTs which must be registered include:

- [All NIH funded Clinical Trials](#).
- Any ACT initiated after September 9, 2007, which meets the [requirements of FDAA 801](#).
- An ACT initiated after January 18, 2017, defined by the [Clinical Trials ACT Checklist](#).
- A clinical trial which meets the [criteria of the VA, CMS, WHO, PCORI, or ICMJE journals](#).

At Downstate, the Responsible Party is determined by the following criteria:

1. The sponsor (funding agency) - either the holder of the IND or the IDE
2. The Downstate PI that initiates the Clinical Trial when awarded a grant (i.e. the NIH grantee).  
*NOTE: In the case of Cooperative Agreements, the PI and study team must agree ahead of time who will be the responsible party. It will not be the NIH.*
3. The funder of a procurement agreement (i.e. funding by a contract). There are instances with a federal contract that NCI may be the responsible party (this should be identified in advance).
4. The provider of the study drug (typically the industry or pharmaceutical company providing the funding). The contract should clearly outline the responsible party.  
*NOTE: In the case of an investigator-initiated clinical trial, the Downstate PI is the responsible party, regardless of whether an IND is involved.*

A Downstate PI, who is the “Responsible Party,” must contact [Sharon Levine-Sealy](#) to establish a user name and password to register the ACT in the Protocol Registration and Results System (PRS). The ACT must be registered 1) before enrolling the first research participant, when there are plans to publish results in an ICMJE journal, or 2) within 21 days after enrolling the first research participant.

In addition, the responsible party must [submit administrative and scientific information including adverse events and results of the research](#) within the required reporting timelines.

### **Failure to meet the requirements will lead to the following actions:**

- Federal Agencies are prohibited from releasing **ANY funding to Downstate!!!**
- Fines of up to **\$250,000 to the responsible party** or **\$10,000 per day to Downstate!!!**
- Inability to publish in an ICMJE journal.
- The IRB may issue an enrollment hold, suspend or terminate a study, or make a finding of serious or continuing non-compliance. Such actions must be reported to federal authorities and funding entities.

## **INFORMED CONSENT TIPS:**

Informed consent is a “PROCESS,” not just a FORM!!! [IRB Guidance](#) is available for “**Obtaining Legally Effective Informed Consent and HIPAA Authorization.**” Additional tips are provided below:

- The IRB recently updated the “**Informed Consent Template,**” which is posted on the [IRB Electronic Submission website](#).
  - If a current research project uses multiple consent forms (e.g., main consent form, genetics testing consent, tissue storage consent, HIPAA authorization, optional research consent form, etc.), please consider amending your study to combine all forms into one.
  - The use of a single form will allow for a more efficient informed consent process and help ensure regulatory compliance.
- For sponsored research, please use the sponsor’s model informed consent template, but be sure to include all language required by local research context including NY state laws (e.g., specific information for genetic testing, storage of samples, HIV testing, use of psychiatry notes, cognitively impaired adults, video/audio recording, etc.) and applicable HIPAA Authorization language. The local research requirements are described in the [IRB Guidance](#) on “**Local Research Context for External IRB.**”

## **PROTOCOL TEMPLATES**

The following protocol templates are available on the [IRB Electronic Submissions website](#):

- [Research Protocol \(with guidance\)](#)
- [Research Protocol \(shell template\)](#)
- [Phase 2 or 3 Clinical Trial Protocol with guidance \(Developed by NIH & FDA\)](#)

## **FINAL REVISIONS TO THE COMMON RULE**

The U.S. Department of Health and Human Services and fifteen other Federal Departments and Agencies' published revisions to the Federal Policy for the Protection of Human Subjects (Title 45 CFR part 46, Subpart A) on January 19, 2017. These revisions are an effort to modernize, simplify, and enhance the current system of oversight. The Final Rule and additional related information can be accessed on the [OHRP website](#). IRB-01 policy will be revised before the compliance date for the rule or by January 19, 2018.

## **REVISED GOOD CLINICAL PRACTICE TRAINING REQUIREMENTS**

NIH [announced](#), effective January 1, 2017, 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 research participants 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. The NIH will accept documentation of training from any of the following groups:

- [CITI GCP Training Module \(optional elective\)](#)
- [NIAID GCP Learning Center Training](#)
- [National Drug Abuse Treatment Clinical Trials Network](#)

## **DON'T FORGET THE HIPAA RULES**

The SUNY Downstate Medical Center IRB serves as a Privacy Board to approve HIPAA Research Authorizations and waivers. The IRB is very diligent regarding these documents and waivers. Please keep in mind that investigators cannot have access to Protected Health Information (PHI) without IRB Approval or another HIPAA instrument, such as a Preparatory to Research Certification, Business Associates Agreement or a Data Use Agreement, or Certification for PHI of Decedents Form. If you have any questions about [HIPAA Rules](#), you may direct them to the IRB, our Privacy Officer, Shoshana Milstein (X7470) or our Information Security Officer, David Loewy (X2431).

The HHS Office of Civil Rights (OCR) takes this very seriously as well and will issue heavy fines for violations. [The Memorial Healthcare System \(MHS\) recently settled a case for \\$5.5 Million.](#)

## **OVERCOMING BARRIERS WITH RESEARCH RECRUITMENT**

The IRB has several [guidance documents](#) which may help overcome barriers when trying to improve enrollment. Please see the IRB Guidance on "[Recruitment, Referral and Screening of Research Participants, Advertising, & Incentives](#)" to help you understand the flexibilities and possibilities for recruiting potential study participants.

Is there a need to enroll study participants with Limited English Proficiency (LEP), or those with low literacy and numeracy, physical challenges, or a religious objection to signing documents? The IRB can help you with these situations. For more information, see the IRB Guidance on "[Obtaining Legally Effective Informed Consent and HIPAA Research Authorization](#)" or call the IRB at X8480.