SUNY RF
The Research Foundation for
The State University of New York

Institutional Review Board
& Privacy Board

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SUNY Downstate Medical Center

IRB UPDATE MEMORANDUM

DATE: **October 2018**

TO: **Research Community**

FROM: **SUNY Downstate Medical Center IRB & Privacy Board**

RE: **Key Updates**

Dear Research Community:

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

WORKING WITH THE IRB & PRIVACY BOARD:

Date:	Time:	Location:	Presenter:
October 17th (Wednesday)	**12 Noon**	**Classroom 8B**	**Diann Johnson, MPH** **Associate IRB Administrator**
October 26th (Friday)	**12 Noon**	**Perrin Long Library B6-508**	**Danielle Lewis, MD** **IRB Management Analyst**
October 26th (Friday)	**3 PM**	**Lecture Hall 1A**	**Kevin Nellis, MS, CIP** **Executive Director, Human Research Protections and Quality Assurance**

The IRB will host the above informational sessions to go over working with the IRB and keys to success for submitting IRB applications. Topics include:

- WHY is IRB approval required?
- WHEN do activities require IRB approval?
- WHO can be a Principal Investigator?
- HOW is IRB approval obtained?

- WHAT are some tips for success?
- WHERE is the IRB located?

The presenters will cover key findings of a recent joint internal audit of the IRB and Downstate Investigators by the Research Foundation Office of Internal Audit Services and the Downstate Office of Compliance & Audit Services (OCAS).

You will learn how to submit IRB applications and avoid research non-compliance from this presentation.

PUBLIC RESPONSIBILITY IN MEDICINE & RESEARCH MEETING:

The IRB purchased unlimited access to allow any Downstate Employee, Fellow, Resident, or Student to attend the 2018 PRIM&R Virtual Meeting, on **November 15 – 17, 2018**. You may obtain a password to the Virtual Meeting by sending an e-mail to the IRB at IRB@downstate.edu using your **Downstate e-mail address**.

CONSENT TEMPLATE UPDATES:

The IRB has updated templates for Informed Consent, Information Sheets, and Addendums to comply with the 2018 Common Rule and HIPAA regulations.

In response to the RF Policy on Human Subjects Payments, the IRB created a Consent Addendum for SUNY RF Payment. This is required when a research participant receives compensation of $600 or more during the calendar year paid through the SUNY RF. This does NOT include payments for travel reimbursements.

IRB GUIDANCE:

The IRB updated the following guidance documents, which are available on the IRB Policy and Guidance web page:

- Fee Schedule for Industry Sponsored Research
- Local Research Context for External IRB
- Guidance for IRB Members: Full or Expedited Review
- IRB Checklist for Full or Expedited Review
- Statement of Compliance

The IRB Policy and Guidance web page includes a selection of relevant polices for Conflict of Interest, Investigational Drug/Dispensing and Utilization, HIPAA, Information Security, Data Back-up, RF Central Office, and NYC H+H (Kings County Hospital).

REGULATORY CHANGES:

The U.S. Department of Health and Human Services revised the Common Rule (Title 45 CFR part 46) in 2018, with a compliance date set for research approved by the IRB on or after January 21, 2019. These revisions are an effort to modernize, simplify, and enhance the current system of oversight.

Key Changes in the 2018 Common Rule (CR) include:

- Redefining activities that require and do not require IRB approval.
- Eliminating (or prolonging) the requirement for continuing review of certain categories of research, unless FDA regulated.
- Eliminating congruency review of grant applications.
- New categories for research that qualifies for exemptions from the CR and changes to the IRB review process for exempt research, including "limited IRB review" for some categories.
- Updated requirements for the informed consent process.
- New elements that must be included in the informed consent document.
- New requirement to post an informed consent document used in a Clinical Trial (as is newly defined in the CF) to a public website.
- Updated rules for surrogate consent for adults with cognitive impairment.
- New considerations for a broad consent process as an alternative to standard informed consent requirements.
- New criterion for waiver of informed consent.
- New exception to consent requirements for screening and recruitment.
- Single IRB (sIRB) review requirements to be effective on 1/20/20. However, please note that all multi-center studies funded by the NIH after 1/25/18 require the use of a sIRB.

Based on the current requirements of NYS Public Health Article 24A (Protection of Human Subjects), SUNY Downstate Medical Center **MUST** apply the 2018 Common Rule to **ALL RESEARCH**, regardless of whether it is FDA regulated or federally funded. Therefore, any human research approved on or after January 21, 2019 must comply with the all of the provisions of the 2018 Common Rule.

The IRB is in the process of implementing final changes to Policy IRB-01 and affected IRB forms and templates. We will educate our research community in the upcoming months. Stay tuned!

We anticipate future legislative changes to NYS Article 24A, which should allow us to be more flexible with the applicability of the Common Rule (e.g., limit some provisions to only federally funded or conducted studies).

The FDA and HIPAA regulations may also change in efforts to harmonize with the Common Rule. Stay tuned!

FAREWELL TO DR. CUKOR:

The IRB wishes to thank Dr. Daniel Cukor for his role as Vice-Chair on the IRB for almost four years. He had over 10 years of dedicated service as an IRB member and over 16 years at Downstate. The IRB especially thanks him for his constant advocacy to protect those who graciously volunteer their participation in research, while enhancing the quality of the IRB. We wish him the best in his new position at Weill Cornell. It has been a pleasure working alongside him.

Clinical and Translational Science Center (CTSC)

Faculty with IRB-approved protocols may use the CTSC to carry out clinical research and clinical trials. The CTSC is approximately 15,000 square feet and located on the 5th floor of University Hospital of Brooklyn. Full-time staff include a Director, Receptionist, Research Pharmacist, and Phlebotomist.

Investigator resources include a research participant waiting room, 10 research participant rooms, exam tables, a zero gravity treadmill, and an emergency crash cart. The facility includes a group research participant meeting room, seminar room, kitchen, pharmacy dispensary, phlebotomy facility, and a core laboratory with refrigerated centrifuge, microscopes and other equipment. The CTSC provides refrigerators and freezers for temporary storage of biospecimens and other materials.

Annually, the Downstate's Department of Scientific Medical Instrumentation calibrates CTSC equipment, including exam room instruments for vital sign measurements.

European Union General Data Protection Regulation (GDPR):

The EU GDPR regulation, effective May 25, 2018, is a new data privacy law that may apply to some research including research conducted in the EU, research sponsored by an EU entity, or research involving transmission of protected data within the EU.

The U.S. Office of Human Research Protections (OHRP) released a completion of guidance on EU GDPR and the Secretary's Advisory Committee on Human Research Protections (SACHRP) released recommendations related to the GDPR.

For assistance with determining whether the GDPR regulations apply to a study, please contact the Sponsor of the study, the IRB Office, OCAS, or the Downstate Privacy Officer. The investigator should work with the sponsor of the study to include the appropriate GDPR disclosures within an informed consent document. Before approval, the IRB will generally consult with OCAS or the Privacy Officer to ensure the required disclosures are appropriately included in the informed consent document (or an addendum) for the study.