

IRB UPDATE

DATE: February 11, 2020

TO: Research Community

FROM: SUNY Downstate Health Sciences University IRB & Privacy Board

Dear Research Community:

The following information provides key information regarding the Downstate IRB. If you have questions, suggestions, or wish to request training, please contact the IRB Office at (718) 613-8480 or IRB@downstate.edu

TOPICS:

The following topics are discussed below:

- Information sessions
- Policy IRB-01
- Clarification of scientific/scholarly review requirements
- New IRB Website

INFORMATION SESSIONS:

All are invited! The following information sessions are available regarding:

- Understanding when IRB approval is required,
- Information presented in this update, and
- How to submit an online application for IRB approval.

Date	Time	Location	Host
February 19, 2020 (Wednesday)	3:00 PM	Lecture Hall 1B (HSEB)	Radiology
March 10, 2020 (Tuesday)	Noon	Classroom 2B (PHAB)	School of Health Professions
April 15, 2020 (Wednesday)	5:30 PM	4-038 Conference Rm (Space is limited) (PHAB)	School of Public Health

POLICY IRB-01:

The IRB has posted revisions to [Policy IRB-01](#), effective November 22, 2019. In summary, the following changes were made:

- The requirement for scientific review of all cancer studies was removed.
- The requirement to obtain parental/legal guardian permission for research on newborn screening (dried blood) spots for HHS regulated research may now be waived, provided all of the criteria are met to grant the waiver.

CLARIFICATION OF SCIENTIFIC/SCHOLARLY REVIEW REQUIREMENTS:

Scientific/Scholarly Review (SR) is required prior to IRB approval of the following types of research projects:

- Downstate Full Board Applications, and
- Downstate Expedited Review Applications that qualify for research reviewed under categories [\(1A\) or \(1B\)](#) (e.g., studies involving a drug, biologic, or medical device).

Unless otherwise required by the Department Chair or Dean, the IRB does NOT require Downstate SR review on the following activities:

- Application for Exempt Review,
- Application for Expedited Review, unless the reviewed under categories [\(1A\) or \(1B\)](#),
- IRB Decision Aid-Application for a Determination Letter to State IRB Approval is NOT Required,
- Application for Humanitarian Use Device (HUD) for Clinical Purposes,
- Application for Expanded Access to Investigational Drug/Biologic for Treatment Use,
- Application for External IRB Oversight, unless local SR is required by the external IRB, or
- Application for Independent Honest Broker Assurance Agreement.

NEW IRB WEBSITE:

A [new IRB website](#) has been published. If you have any trouble finding information or have suggestions for improvement, please send an e-mail to IRB@downstate.edu. Major changes include new content created based on feedback from our investigators. The new site includes [step by step guidance for preparing and applying for IRB approval of human research](#). It includes very specific guidance on which IRB forms and templates to use. Some of the new content includes:

- **Determining whether investigators are members of the Downstate workforce.** This will help determine training and conflict of interest disclosure requirements, whether additional agreements are required, and which IRB to use. For full information, see [Step 4 on the IRB Electronic Submission Process website](#).
- **Determining which IRB to use and establish any required agreements.** The Downstate IRB must acknowledge a qualifying External IRB's approval of a study and confirm all local research requirements are met to activate the study at Downstate. For full information, see [Step 5 on the IRB Electronic Submission Process website](#).