

 SUNY DOWNSTATE Medical Center	University Hospital of Brooklyn College of Medicine College of Health Related Professions College of Nursing School of Graduate Studies School of Public Health	IRB UPDATE MEMORANDUM
---	--	----------------------------------

DATE: January 2018

TO: Research Community

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

RE: Key Updates

Dear Research Community:

Happy New Year! 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

UPDATED POLICY IRB-01:

The SUNY Downstate IRB has posted a revised [Policy IRB-01](#) on the IRB website. The compliance date for this policy is **January 19, 2018**. These changes are primarily made based on regulatory requirements. A detailed summary of the changes are available by [clicking here](#).

The IRB will host informational sessions to go over the revisions:

Date:	Time:	Location:
February 12, 2017 (Monday)	11 am – 12 noon (Followed by Q&A session)	Classroom 1B
February 23, 2017 (Friday)	2 pm – 3 pm (Followed by Q&A session)	Classroom 1B

Some key changes are provided below:

- The “Emergency Use” section of the policy has been updated to clarify important steps for the emergency use of an investigational or unlicensed drug, biologic, or

device. We have also instituted a [new IRB application for Review for expanded access to investigational drugs for treatment use](#).

- We clarified our process for expedited reviews, external reviews, and single IRB reviews. See the [summary of changes to Policy IRB-01](#) for more details.
- The criteria for waivers of informed consent have slightly changed based on new FDA and upcoming Common Rule regulations. Please use the newly revised waiver forms available on the IRB's [Electronic Submissions](#) webpage when submitting a new study.
- There are many new informed consent document recommendations and requirements that are anticipated with the new Common Rule goes into effect in July. Changes which are congruent with the current Common Rule are now implemented. At present those listed as recommendations and not required; however, they will become required for any federally funded or conducted research approved by the IRB on July 19, 2017. Please see our [revised Consent Template](#).

PATHOLOGY ANCILLARY REVIEW:

UHB Pathology conducts an ancillary review of any research that involves the following:

- Patient Material: Use of any past, present, or future patient material (tissue, blood and fluids) requires UHB Pathology Review, except for the following:
 1. Extra blood sample or extra urine sample which will not be tested in the UHB Pathology Lab, provided informed consent to use the sample for research purposes has been obtained from the research participant.
 2. Tissue listed in the UHB Exempt Tissue Policy: "[LAB 03 Human Tissue Fluid and Foreign Matter Exempt From Submission for Pathology Examination](#)."
- Services or assistance of the UHB Pathology Laboratories (Clinical Laboratory, Histology Lab and/or Surgical Pathology).

If uncertain about the need for ancillary review by UHB Pathology, please send an email to both [Susan Gottesman, PhD, MD](#) & [Caitlin Otto, PhD](#) for a determination. It is best to set up an appointment. A list of all specimens that will be used for research purposes will be needed. If they state Pathology Ancillary review is not required, attach a copy of their determination to the IRB submission.

IRB FORM VERSION CONTROL:

Please be sure to use the latest version of the IRB forms and templates available on our [IRB website](#) or within [IRBNet](#). The documents are updated frequently to ensure compliance with the latest regulations and IRB requirements. The IRB will generally accept the previous versions of forms, provided they were available at least 3 months prior to the submission date.

Using the most recent versions will help ensure regulatory compliance and a more efficient IRB review process.

GUIDANCE FOR RECRUITING PARTICIPANTS WHO ARE STUDENTS, RESIDENTS, FELLOWS, EMPLOYEES OR VOLUNTEERS:

The IRB often gets questions on the types of protections that should be in place when recruiting students, residents, fellows, employees or volunteers. The primary concerns are 1) whether investigators have sufficiently minimized coercion or undue influence, 2) whether the research participant's privacy is adequately protected, and 3) whether the research is following any additional applicable federal regulations or NYC Department of Education IRB requirements. For more information please see the IRB on guidance on [Students, Residents, Fellows, Employees, or Volunteers as Research Participants](#).

FUTURE REGULATORY CHANGES:

The U.S. Department of Health and Human Services has delayed the implementation of the revised Common Rule (Title 45 CFR part 46) for another 6 months. For more information, please see the [OHRP News Release](#). Our Policy IRB-01 will need additional revision to ensure Downstate is in compliance on July 19, 2018.

Please be aware that more changes to the FDA and HIPAA regulations are anticipated, but have not been published. This are primarily being driven by requirements of the [21st Century Cures Act](#).

We will continue amend our policies and IRB documents as needed and educate our research community as things change.