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|  | **University Hospital of Brooklyn**  **College of Medicine**  **College of Health Related Professions**  **College of Nursing**  **School of Graduate Studies**  **Graduate Program in Public Health** | IRB Update Memorandum |

DATE: October 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)

**Complimentary Virtual PRIM&R Conference!!!**

The SUNY Research Foundation - Downstate Medical Center and the NYC Health + Hospitals, Kings County have partnered to sponsor a virtual **2017 Advancing Ethical Research Conference** by Public Responsibility in Medicine and Research (PRIM&R), which will take place from **Sunday, November 5** through **Wednesday, November 8, 2017.**

Virtual meeting attendees will have access to four keynote addresses, seven plenary sessions, and select breakout session content (including those related to the changes in the revised Common Rule). [**Click here to view the meeting agenda**](https://primr.org/aer17/vm/agenda/). If you are unable to watch the virtual meeting in real time, the content will be available to those who register for 30 days after the meeting. [Click here](https://primr.org/aer17/vmfaq/) for FAQs & technical requirements.

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| [**Click here**](https://downstate.co1.qualtrics.com/jfe/form/SV_eLkiJBQF6J5OCR7) **by the deadline of October 27th** to register to participate in the PRIM&R virtual meeting space. You will need to provide your name, affiliation, and e-mail address.  **WARNING: DO NOT REGISTER ON THE PRIM&R WEBSITE**  You should receive an e-mail with the password to participate in the virtual meeting space by November 5th. Those who are affiliated with Downstate will be notified by the Downstate IRB. Those affiliated with Kings County will be notified by Kings County.  After the conference is complete, you will receive an invite to complete a survey to evaluate the program and to receive a certificate of attendance for your participation. |

**CHANGE IN FDA’s EXPANDED ACCESS FOR A SINGLE PATIENT IND:**

The FDA has created a new mechanism for IRB Chair approval of individual patient expanded access treatment use of investigational drugs. Previously, Full Board IRB approval was required. To request this, the physician (or sponsor) must complete [Form FDA 3926](https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM504572.pdf). For more information see [FDA Guidance](https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM351261.pdf).

**REVISED NIH POLICY FOR CERTIFICATES OF CONFIDENTIALITY:**

The NIH has updated their policy for issuing Certificate of Confidentiality (CoC) to automatically apply more broadly to NIH funded studies, including those which commenced or are ongoing on or after 12/13/16. CoCs are intended to prohibit disclosure of sensitive, identifiable information in response to legal demands. The general applicability has been broadened to automatically apply to any of the following types of NIH funded research:

* All human research (including exempt research) when individuals can be readily identified.
* Research involving identifiable biospecimens data sources that could be used to deduce the identity of an individual’s biospecimens.
* Research that generates individual-level human genomic data from biospecimens, or the use of such data.
* Any other research that involves information about an individual that could be used to deduce the identity of an individual.

For currently IRB approved studies that receive NIH funding and involve an informed consent document, the IRB recommends the PI submit an amendment to the IRB prior to the deadline for the next time of continuing review to include NIH’s [updated consent language](https://humansubjects.nih.gov/coc/suggested-consent-language).

For NIH funded studies, NIH will no longer provide a paper certificate. The award itself may be used as confirmation that CoC protections are in place. The NIH CoC website has now been updated and includes [FAQs](https://humansubjects.nih.gov/coc/faqs) on this topic.

**ADDENDUM TO ICH-GCP E6 GUIDELINES:**

The International Council for Harmonization (ICH) has issued an [addendum](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf) to the E6 Guideline for Good Clinical Practice (GCP). If a sponsor requires you to follow GCP guidelines, please review the addendum to ensure you are up to date with the latest requirements. To review an excellent Kinetiq blog regarding ICH modernization and what it means for you, [click here](https://kinetiqideas.com/ich-modernization-and-what-it-means-for-you/?utm_source=kinetiq-list&utm_medium=email&utm_campaign=kinetiq-pulse&utm_content=link-ich-gcp-addendum-impact-iyer-4-20-17&utm_term=?link=ctabutton&mkt_tok=eyJpIjoiTTJJNFlUWXpaREJtWWpRNSIsInQiOiJ1SFM3d2xxeUJmaGMzMUMxbWFyaVVoMkU5d3V5aUt6cFh0MG9ReU1HV3NlU2N0Wk91alUwMzV1MFpGczNOQVVDbHJQV2VVdFdYOXE3QXQydHVRUVwvT3VaSkR5bEsrazQwUFlLSmg0dER2N3I2bEJ4a1dTXC9JZzZJdzdwVGQxQ0JkZGVieGpLMkkwMThBUmF0MmZRNGd2UT09In0%3D).

**compliance date extended for final 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](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html). The original compliance date for the Final Rule was to be January 19, 2018; however, on October 7, 2017, the White House Office of Information and Regulatory Affairs posted a 1-Year delay in the general implementation date while allowing the use of three burden-reducing provisions during the delay year. The IRB will be monitoring this new development and issue a revised IRB-01 policy as soon as possible.

**FUTURE BROAD CONSENT PROCESS:**

The revised Common Rule will allow for a mechanism to obtain consent from patients to have their medical records and specimens broadly used for future research. The IRB would like to work with key stakeholders to develop a process at Downstate and Kings County to achieve this process. If a patient provides their consent for this type of research, their materials can be approved to be used for research via an exemption review process. If interested in this type of research please let us know by writing to [IRB@downstate.edu](mailto:IRB@downstate.edu)

**STAY TUNED FOR AN EDUCATIONAL NEEDS ASSESSMENT SURVEY:**

In the near future, we will be inviting you to participate in an educational needs assessment survey. The survey is designed to rate the importance of certain knowledge, skills, & abilities and rate the importance of creating new educational initiatives around these topics.

We hope many of you will volunteer in this important effort. Your feedback will help guide us in the development of initiatives that are best suited for our general research community.