HIGHLIGHTS OF NEW IRB-01 POLICY
EFFECTIVE 01/19/18

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Objectives

1) Discuss significant changes to IRB-01 policy
2) Know where to find additional information
3) Understand whom to contact for help
IRB-01 Policy Manual

Investigators and Key Research Personnel

- Preparing submissions

- Conduct of research and study closure

IRB

Review and Oversight of DMC research
Activities Requiring Initial IRB Review (13-14)

- An FDA regulated clinical investigation or clinical trial

- A non-FDA regulated activity when the activity is:
  - a systematic investigation
  - designed to develop or contribute to generalizable knowledge
  - Involves living individuals about whom an investigator conducting research either obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
Activities Requiring IRB Review (13-14) continued...

- **As defined by federal regulations:**
  - **Intervention**
    - includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the research participant or the research participant’s environment that are performed for research purposes.
  - **Interaction**
    - includes communication or interpersonal contact between investigator and research participant.
Activities Requiring IRB Review (13-14) continued...

- **Private Information**
  - includes information about behavior that occurs in context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
Activities Requiring IRB Review (13-14) continued...

- **Identifiable private information**
  - is private information for which the identity of the research participant is or may readily be ascertained by the investigator or associated with the information.

- An **identifiable biospecimen**
  - is a biospecimen for which the identity of the research participant is or may readily be ascertained by the investigator or associated with the biospecimen.
In general, the DMC IRB uses the above definitions to determine if any non-FDA regulated activities require IRB approval.

The IRB retains final judgement as to whether a particular activity is covered by this policy – and this judgement shall be exercised consistent with the ethical principles of the Belmont Report.
In general, the activities that require prospective IRB review and approval are:

- Human research
- Use of Humanitarian Use Device (HUD) for clinical or research purpose
- Research activities that involve an interaction or intervention with a living individual
Activities Requiring IRB Review (13-14) continued...

- In general, the activities that require prospective IRB review and approval are:

  - Research activities that involve obtaining, accessing, using, reviewing, sharing, analyzing, or disclosing protected health information (PHI), individually identifiable private data, identifiable sensitive information, or personal data, regardless of whether it is recorded or eventually de-identified.
In general, the activities that require prospective IRB review and approval are:

- Research activities involving the use, analysis or generation of identifiable biospecimens.

- Research requiring IRB approval as required by NYS PHS Article 24A, the Common Rule, FDA regulations, or tribal law passed by an official governing body of the American Indian or Alaskan Native tribe.
An activity which meets the definition of research under the Common Rule, regardless of whether it is supported or conducted by a federal department or agency or regulated by the FDA or NY State.

Expanded Access Use (Compassionate Use) of investigational agents.

New IRB Application for Review for expanded access to investigational drugs for treatment use
And then there’s HIPAA… (14)

- Even when the activity does not meet the definition of human research, or even when the research is exempt from HHS and FDA regulations, *HIPAA regulations still apply if PHI is involved in the research activity*, AND…

  - **HIPAA Authorization**
  - **Privacy Board (DMC IRB) grants a HIPAA Waiver**
  - **Business Associate Agreement (BAA), Data Use Agreement (DUA), or other HIPAA instrument.**
**Protected Health Information (PHI)**  
**Includes Health Information & Identifiers:**

- Names
- Geographic subdivisions, including address (except initial 3 digit zip code of over 20K people)
- All elements of dates (except year)
- Ages or dates indicative of ages 89 or over (except that age 90 or over may be aggregated)
- Telephone or FAX numbers
- E-mail addresses
- Social Security Number
- Medical Record Number
- Health Plan Numbers
- Account Numbers
- Certificate/License numbers
- VIN, serial #, license plate numbers
- Device Identifiers & serial #
- Web Universal Resource Locators (URL’s)
- Internet Protocol (IP) address
- Biometric identifiers, finger or voice print
- Full face photographs and comparable images
- Any other unique identifying number, characteristic, or **code** (including initials)
Activities that require IRB review and approval beyond the initial review include:

- Amendments to previously approved research;
- Continuing review/progress reports;
- Reportable events;
Activities that require IRB review and approval beyond the initial review include:

- Closure (final) reports; or
- Other considerations, as described in this policy or regulations.
Activities Not Requiring IRB Review (14-18)

- The following activities do NOT require initial IRB review and approval:
  - Case Reports or Case Series involving up to three individuals
  - Scholarly and Journalistic Activities
  - Public Health Surveillance Activities
  - Collection and Analysis of Information, Biospecimens, or Records by or for a Criminal Justice Agency
  - Authorized Operational Activities
Activities Not Requiring IRB Review
(14-18) continued...

☐ The following activities do NOT require initial IRB review and approval:

☐ Clinical Care

☐ Off-label use of an FDA-approved drug or biologic

☐ Changes necessary to eliminate apparent immediate hazards or to protect the life or physical well-being of the research participant enrolled in previously approved research

☐ Emergency use of an Investigational or Unlicensed drug, biologic, or device

☐ Notify the IRB within 5 days after the administration of the test article.
A Certificate of Confidentiality (CoC) is intended to prohibit disclosure of sensitive, identifiable information in response to legal demands.

Certificates are issued by NIH and other Health and Human Services (HHS) agencies to help protect the privacy of the research participants enrolled in sensitive, health-related research.

Effective October 1, 2017, all research that was commenced or ongoing on or after December 13, 2016 and is within the scope of NIH Policy for issuing CoCs is deemed to be issued CoC and is therefore required to protect the privacy of those research subjects.
The general applicability was 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 or 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
Certificates of Confidentiality (47-48) continued...

- This update applies retroactively to NIH funded research that was approved after December 13, 2016. It will be important to update any informed consent documents to include the new language regarding CoC.

- 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 in our revised Consent template. Also found here: 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 on this topic: https://humansubjects.nih.gov/coc/faqs
An investigator may not involve a participant in a research activity covered by this policy, unless the investigator has obtained the legally effective informed consent of the research participant or his/her Legally Authorized Representative (LAR), when permissible.

An investigator shall seek such consent only under circumstances that provide the prospective participant or the LAR sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
Informed Consent Requirements (58-60) continued…

- The prospective research participant or LAR should be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
Informed Consent Requirements (58-60) continued...

- Changes meant to facilitate subjects’ understanding of the reasons to participate (or not) in the research.

- Requires that key information essential to decision making receive priority by:
  - Being presented first in the consent discussion;
  - Appearing at the beginning of the consent document
For research which is federally supported or conducted, or when otherwise applicable to the research or required by the IRB, one of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens should be included:

- A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the research participant or LAR, if this might be a possibility; OR

- A statement that the research participant’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
For research that is federally supported or conducted or when otherwise applicable to the research or required by the IRB, the following elements are recommended:

- A statement that the research participant’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the research participant will or will not share in this commercial profit;

- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to research participants, and if so, under what conditions; or
Informed Consent Requirements (58-60) continued…

- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

- Any requirements of any applicable federal, state, or local law.

- Any requirements of any applicable tribal law passed by the official governing body of an American Indian or Alaskan Native tribe.
A request to waive informed consent may be made when the PI wishes to waive the entire process of consent (including documentation). This is generally used for research involving review of retrospective data (i.e., medical charts).

The specific criteria used for the IRB to determine whether informed consent may be waived is dependent upon the nature of the research.
Waiver of Informed Consent Requirements (61-62)

- For most research, including FDA regulated clinical investigations, an IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the above requirements to obtain informed consent, provided the IRB finds and documents that:
Waiver of Informed Consent Requirements (61-62)

- The research involves no more than minimal risk to the subjects;
- The research could not practicably be carried out without the requested waiver or alteration;
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.
IRB Attendance, Quorum, and Voting (71-72)

☐ Recusals:

☐ No IRB may have a member participate in the board’s initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

☐ An IRB member who is listed as PI, Co-investigator, or key personnel is conflicted and therefore is automatically recused from participation in the discussion and voting, except (s)he can provide any information that is requested by the IRB.
Recusals:

- An IRB Member with a potential or real conflict of interest will be considered recused and cannot vote on the project. The conflicted member will leave the room during discussion and voting, if required by the IRB Chair or Vice Chair. The abstention and absence, if applicable, will be noted in the IRB meeting Minutes.

- If a sponsor requires documentation of a recusal to be stated in an IRB approval letter, please contact the IRB for assistance.
Emergency Use of an Investigational or Unlicensed Drug, Biologic or Device

Emergency use is the use of a test article (investigational or unlicensed drug, biologic, or device) for a patient in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval. Emergency uses are not considered research, but rather the practice of medicine for the treatment of patients with non-FDA-approved products.

This section was updated to clarify the important steps a clinician must take if (s)he wishes to prescribe a test article that is considered to be Emergency Use of an investigational or unlicensed drug, biologic, or device.
Other Administrative Changes...

- We have added information on FDA exemptions (page 21). This is not new information, but was not included in policy in the past.

- We clarified a study may not be expedited at the time of initial review if the research includes a medical intervention with children, pregnant women, neonates, prisoners, or cognitively impaired adults (page 22).

- We clarified and streamlined our process for External IRB reviews (pages 26-29).
Other Administrative Changes...


- We added information on in-vitro fertilization (IVF) research. See page 45.

- We clarified that we have guidance for the review of research that recruits participants who are students, residents, fellows or volunteers. See page 47.
Other Administrative Changes…

- We clarified that all research involving drugs and biologics must comply with DMC’s Investigational Drug/Dispensing and Utilization policy (PHA-11).

- We removed our appeals process from our policy as it is not a regulatory requirement. Future and more detailed guidance on appealing IRB decisions is forthcoming.
Institutional Review Board (IRB)

Electronic Submissions and Management of Downstate IRB Activities:

The Downstate Medical Center IRB uses an electronic IRB submission and reporting system (IRBNet) for the electronic submissions and management of human research activities and required reporting. Please refer to the guidance for the IRBNet (IRB Application and Reporting System) for more details on how to use the system. Application forms and template materials are provided below. Guidance and policy can be viewed by clicking on tab within the IRB Menu for Policies & Guidance. Information on required training and conflict of interest disclosures can be viewed by clicking on the tab within the IRB Menu for Training & Conflict of Interest.

Anyone associated with Downstate may create an IRBNet user name and password by following the instructions below:
Note: Each user agrees to comply with the Individual User Terms of Use policy which may be found at https://www.irbnet.org/release/public/terms.jsp

**Step 1: Create an IRBNet user account**

- Go to [www.irbnet.org](http://www.irbnet.org) and click the “New User Registration” link. Follow the online instructions. Complete all items with red asterisk (*). When asked to identify your “organization” type SUNY in the text box and then select “SUNY Downstate Medical Center, Brooklyn, NY”.
- Remember to click on the “Register” button in order to finalize your “New User Registration.”
- Press the “Continue” button on the “Registration is Complete” page and follow “Step 2” to activate your IRBNet user account.

**Step 2: Activate your IRBNet user account**
# IRB Contacts

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http://research.downstate.edu/irb/irb.html
Summary

- This presentation covered key highlights of the new IRB-01 policy
- Refer to IRB Policy and Guidance for additional information
- Contact the IRB for help (x8480)
QUESTIONS?