POLICY IRB-01 UPDATE

1.10.2019 @ NOON: SPECIAL FUNCTIONS
1.14.2019 @ 2 PM: LECTURE HALL 1A
1.16.2019 @ 10 AM: CLASS ROOM 1A

Presentation Team

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Objectives

- Discuss some but not all changes to Policy IRB-01 primarily driven by changes to the **2018 Common Rule** (Title 45 CFR part 46), effective January 21, 2019.
- Discuss some but not all revisions to IRB forms, templates, & guidance.
- Help ensure regulatory compliance.

Disclaimers

- The US Department of Health and Human services Office of Human Research Protections (OHRP) is in the process of developing new guidance on the new regulations.
- Our goal is to provide as much guidance as possible to support our investigators. However, we may need to contact federal authorities for some guidance for specific or unusual concerns not directly described in the regulations. If we cannot answer any questions or are not clear on how to interpret the regulations, we will contact OHRP or the applicable agency and let you know their response.
- The IRB may also need to consult with the Downstate Privacy Officer or Data Security Officer when HIPAA regulations are more restrictive than the revised Common Rule or Policy IRB-01.
Follow The 10 Minute Rule

If you cannot figure out how to do something within 10 minutes, call or visit the IRB for help.

(718) 613-8480
BSB 3-26

Activities That Do Not Require IRB Approval: (IRB-01: pp 24-28)

- Scholarly and journalistic activities… that focus directly on the specific individuals about whom the information is collected.
- Public health surveillance activities…
- … criminal justice… activities authorized… for criminal investigative purposes
- Authorized operational activities…
IRB Decision Aid (2 Simplified Forms)

- Use the form for “Health Care Operations Activities Only” when there is no intent to develop or contribute to generalizable knowledge:
  - Health care operations activity (e.g., performance improvement),
  - Case report or case series (up to three individuals),
  - Operational activity,
  - Pilot activity, feasibility activity, or evidence-based practice activity,
  - Training or educational activity, or
  - Not engaged in human research.

New Exemption Categories (IRB-01: pp 30-35)

- More restrictive than previous Common rule:
  - Exemption #1: Cannot adversely impact student’s opportunity to learn required educational content or assessment of educator who provides instructions.
  - Exemption #5: Research/Demonstration Project must be published on a federal website.

- Expanded:
  - Exemption #2: Research participants can be identified.
  - Exemption #4: Research can be prospective.
New Exemption Categories
(IRB-01: pp 30-35)

- **New:**
  - Exemption 3: Some benign behavioral interventions.
  - Exemption 7: Storage and maintenance of identifiable data/specimens. **Not used @ Downstate.**
  - Exemption 8: Secondary research for which broad consent is required. **Not used @ Downstate.**

- **Unchanged:** Exemption #6 (FDA exemption).
- Limited IRB review is a condition of some activities under Exemption 2,3,7&8: (§__.104(d)(2)(iii), (d)(3)(i)(C), (d)(7), and (d)(8)).

Category # 3: Benign Behavioral Interventions
(IRB-01: p 32)

- ...benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the research participants, and the investigator has no reason to think the research participants will find the interventions offensive or embarrassing.
- ...examples...include...online game...solve puzzles under various noise conditions...how to allocate a nominal amount of received cash between themselves and someone else
- Requires prospective agreement of research participants
Applicability of Revised Exemptions
(IRB-01: pp 30-35)

- Children/neonates can be included in very limited circumstances under Exemption #2.
- Children/neonates cannot be included in any research under Exemption #3.
- Populations that only incidentally include prisoners can be included.
- Prisoners cannot be included in any exempt research if DOJ or FDA regulated.
- Use IRB Exempt Application for DOJ, as they have not adopted 2018 Common Rule.

NIH Infographic for Exemptions
Clarification of PI Responsibilities
(IRB-01: pp 48-50) Note: Other responsibilities are clarified as well.

- Ensure prospective IRB approval of all investigators who obtain informed consent.
- Obtain all required signatures on the informed consent form and always provide a copy of the signed informed consent document to the research participant.
- Keep the entire original signed informed consent form (not just the signed pages) in a secure location.
- Follow institutional policies for information security.
- Back-up data to a secure network drive or alternative secure location approved by the Data Safety Officer.

IRB Evaluation of Clinical Investigation with an IND may require… (IRB-01: p 54)

- Published literature about the chemistry, manufacturing, and control of the drug substance and product;
- A summary of previous human experience with the drug product;
- Sufficient information regarding the source, purity, quality, and method of preparation and delivery of the drug used in the research; and
- Information regarding the pharmacology and toxicity of the drug product in animals.

FDA Reference:
Certificates of Confidentiality (CoC)  
(IRB-01: p 64)

- A copy of the signed informed consent document which includes the CoC disclosure language must be filed in the medical record to prevent unintentional disclosure by HIM pursuant to a request that does not require patient authorization (e.g. court subpoena).
- Previous Policy IRB-01 made an exception for studies with a CoC; however, this is no longer an exception due to change in NIH guidance.
  - Consider amending currently approved consent forms to include disclosure of consent to medical record.

Medical Record Research Note for Clinical Trials with IND/IDE  
(IRB-01: p 74)

- Place a research note in the electronic medical record (EMR) when enrolling patient into a clinical trial with an IND or IDE at DMC.
  - The information required for note is outlined in Policy IRB-01.
- Previous Policy IRB-01 made an exception for studies with a CoC; however, this is no longer an exception due to change in NIH guidance.
  - Consider amending currently approved consent forms to include disclosure of note in EMR.
**Legally Authorized Representative (LAR or Surrogate):** (IRB-01: p 75)

- Process must follow Policy CONS-01 & Article 81 of NYS Mental Hygiene law
- Revised order of priority of a surrogate is provided in policy and within informed consent template.
  - Do not use Health Care Proxy.
- Amend currently approved research, including informed consent templates to ensure correct process and authority is followed.

**General Requirements of Informed Consent** (IRB-01: p 76; ICF Template)

- Provide information that a reasonable person would want to have in order to make an informed decision...
- …begin with a concise and focused presentation of key information … to assist… in understanding the reasons why one might or might not want to participate
- …present information in sufficient detail… organized and presented in a way… that facilities… understanding the reasons why one might or might not want to participate
Basic Elements of Informed Consent
(IRB-01: p 77)

- If collecting identifiable private information or identifiable biospecimens, include either:
  - A statement that the information or biospecimens will not be used for future research; or
  - A statement that identifiers might be removed for future research without additional informed consent...
  - Caution: HIPAA Authorization with above statement requires OPTIONAL CONSENT for future research of coded materials.

European Union General Data Protection Regulation
(IRB-01: p 78; ICF Template)

- Applicability of EU GDPR, may include:
  - Research conducted in the European Union (EU),
  - EU sponsor, or
  - Transmission of protected data within the EU.
- Include disclosures within the informed consent form.
- Ensure compliance with:
  - Informed consent disclosures, and
  - Security protections outlined by protocol and/or sponsor’s contract.
Additional Elements of Informed Consent (IRB-01: p 79; ICF Template)

- Three new disclosures, when applicable:
  - Whether biospecimens will be used for commercial profit and whether participants will share profits,
  - Whether and under what conditions clinically relevant research results will be provided, and/or
  - Whether research will (if known) or might include whole genome sequencing.

- Include requirements of any applicable laws, including those of American Indian or Alaska Native tribes.

Clinical Trial Informed Consent Posting Requirement (IRB-01: p 81)

- **Clinical trial** means research study in which one or more research participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

- Post one IRB-approved informed consent on a Federal Website, no later than 60 days after last study visit, if federally conducted or supported:
  - ClinicalTrials.gov
  - Docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021)

*Note: FDA & NIH have different definitions for Clinical Trials.*
Documentation of Informed Consent Using Short Form (IRB-01: p 82; New Short Forms)

- Use the Short Forms with version date of 11.14.2018
  - For corresponding Downstate consent forms with a version date of 12.17.18 (or later)
  - Research initially approved by the IRB on or after 1.21.19
  - Previously approved research that transitions to the requirements of the revised Common Rule
- Otherwise, use Short Forms with version 05.18.2016.

New Criterion for General Waiver of Informed Consent (IRB-01: p 83; Waiver Request Form)

- The FDA permits the waiver of the process of informed consent for certain clinical investigations.
- The following additional criteria (under the Common Rule) must be met to waive the process of informed consent:
  - 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 IRB cannot apply waivers to research under which broad consent is required to be obtained.
New Waiver of Documentation of Informed Consent  (IRB-01: p 84-85; Waiver of IC Form)

- For research which is not regulated by FDA or DOJ, the IRB may waive documentation of informed consent, if:
  - Research participant (or LAR/surrogate) are members of a distinct cultural group or community in which signing forms is not the norm,
  - Research presents no more than minimal risk of harm to participants, and
  - There is an appropriate alternative mechanism for documenting that informed consent was obtained.

Screening, Recruitment, & Determining Eligibility  (IRB-01: p 87; IRB Application Forms)

- IRB may approve obtaining information or biospecimens for screening, recruiting, or determining the eligibility of prospective research participants, if:
  - Investigator obtains information through oral or written communication with the prospective research participant or the LAR/surrogate, OR
  - Investigator obtains identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

CAUTION: Approval of this provision may require HIPAA Waiver/Authorization, Subject Recruitment Authorization, or additional consultation with OHRP, OCAS, Privacy Officer, or Data Security Officer.
SUNY Downstate Cancer Program/Institute SRC Review (IRB-01: p 87)

- Cancer studies must undergo Scientific (or Scholarly) Review (SR) by the SUNY Downstate Cancer Program/Institute SRC, regardless of level of IRB review (e.g., full board, expedited, exempt, external IRB review).

Scientific (or Scholarly) Review Committee (SRC) (IRB-01: p 87; IRB Application Forms)

- Unless otherwise noted on previous slide, the IRB requires SR for the following:
  - Full Board Applications
  - Expedited Review Applications that qualify for research reviewed under categories (1A) or (1B) (e.g., studies involving a drug, biologic, or medical device).
  - Department Chair or Dean may require SR for other studies.
Ancillary Reviews Required As A Condition For IRB Approval  (IRB-01: p 87)

- Department Chair or Dean:
  - All applications except IRB Decision Aid.
- Downstate Pharmacy: Clinical trials with IND.
- UHB Pathology: When UHB patient material obtained for research care will affect clinical care of patient
- NIH Recombinant DNA Advisory Committee (RAC):
  - Gene therapy,
  - Recombinant or synthetic nucleic acid molecules, or
  - DNA or RNA derived from recombinant or synthetic nucleic acid molecules.
- Others: As required by IRB.

Continuing Review is Not Required in Certain Circumstances  (IRB-01: p 99)

- Exempt Research, including limited IRB review.
- Research receiving initial expedited approvals after 1.20.2019, unless the IRB justifies why continuing review would enhance protections.
- Progression of research receiving initial full board approval after 1.20.2019 now limited to:
  - Data analysis (including identifiers) and/or,
  - Access to clinical data from clinical care.
- Three year “Check-In” required for any research that does not require annual review, initially approved after 1.20.2019

NOTE: CR required for research approved prior to 1.21.2019 or for non-exempt FDA & DOJ regulated research.
Amendment to Transition Existing Research to 2018 CR (IRB-01: p 120)

- Include the following with an amendment to transition existing research to the 2018 Common Rule:
  - Compelling reason to transition,
  - Include new requirements of revised Common Rule and revised Policy IRB-01, including new informed consent requirements, and
  - Plan to transition to sIRB review by January 20, 2020, for cooperative (multi-site) research.
- IRB determines if investigators must re-obtain consent of all currently enrolled research participants.

Additional Resources

- IRB Update Memo.
- Policy IRB-01 (Effective 1.21.2019):
  - Policy IRB-01 with major changes highlighted, and
  - Summary of changes.
- IRB Website:
  - Electronic submissions,
  - Training & Conflict of Interest Disclosures,
  - Policy and Guidance, and
  - IRB Application Forms.
Summary

- Review and understand requirements of revised Policy IRB-01.
- Follow IRB instructions and guidance.
- Follow the 10 minute rule. Call X8480 for help.