Information Sheet: Summary of IRB-01 Revisions

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OVERVIEW

The SUNY Downstate Health Sciences University Human Research Protections Program Policy and Procedures (IRB-01)[1] contains both policies and procedures, which will be separated into individual documents as the IRB launches new processes with the

1 SUNY Downstate Health Sciences University Human Research Protections Program Policy and Procedures (IRB-01)

MyResearch IRB Module replacing IRBNet. Once established, the latest approved procedure or policy will supersede prior documentation. During this process, the objective is to establish an abbreviated IRB-01 Policy, develop an Investigator's Manual, and create a series of IRB Procedures and Guidance documents.

A copy of the IRB-01 and a copy of a comparison between the current and most recent policy is also posted on the IRB policy and guidance website[2].

ADMINISTRATIVE UPDATES

- Policy title changed to Human Research Protections Program.
- Approval dates updated.
- Table of Contents revised.
- Minor grammatical and editorial edits made throughout.
- All references and web links have been verified or updated. New references were added as footnotes, and this method will be used for future policy and procedure updates.

REGULATORY CLARIFICATIONS

- Policy and Purpose section revised to emphasize compliance with federal and New York State regulations and the applicability of FDA, HHS, and HIPAA regulations.
- Clarified that, according to New York State law, Common Rule Subpart A must at least be applied to research not regulated by the FDA or HIPAA.
- Updated sections on foreign research and multi-site studies to reflect single IRB requirements and international compliance expectations.
- Updated sections on multi-site studies to reflect single IRB (sIRB) mandates.
- Added clarification for research conducted under NYS Article 24-A.
- Updated Certificates of Confidentiality section per current NIH policies.
- Updated Emergency Use of Investigational Products procedures.
- Updated Applicable Clinical Trials section regarding civil monetary penalties.
- Added FDA definitions for clarity.
- Added a definition for Clinical Investigator (CI) and requirements for CI Status for FDA regulated clinical investigations.
- Clarified when multiple PIs may or may not be used in research studies.
- Clarified that clinical trial tasks (not responsibilities) may be delegated to qualified hospital staff and residents.
- Clarified Significant Risks and Non-Significant Risk determinations of medical devices must be made in the convened IRB meetings.

2 IRB Policy and Guidance Website

- Added information about reviewing research involving children and pregnant people based on new FDA guidance.
- Added information about reviewing software functions and mobile applications.
- Updated information about waivers and exceptions of the requirements for informed consent based on updated FDA regulations.
- Added information about IRB review of Investigator Brochures for IND studies and some medical device studies.

HUMAN SUBJECTS PROTECTIONS AND PRIVACY

- Clarified Protected Health Information (PHI) definition and added examples.
- Clarified that honest brokers may be acknowledged but they cannot be investigators or authors.
- Added guidance for case reports and case series (≤3 individuals), including informed consent and HIPAA authorization recommendations, when required by a publication.

IRB OVERSIGHT AND OPERATIONS

- Re-ordered placement of sections so that policy statements are first, following by investigator requirements for IRB initial submissions, then IRB oversight, and then investigator follow-up for post review requirements.
- Updated IRB oversight and compliance section.
- Clarified PI status and responsibilities (including multiple PI scenarios), including the requirement to maintain documentation of study team credentials, when applicable.
- Clarified IRB authority to require modifications to consent, HIPAA, or information sheets prior to approval.
- Added reference to the separate IRB meeting guidance on member roles and responsibilities.
- Updated policy to reflect that most IRB meetings are virtual and members must keep cameras on for quorum verification and voting; voting process is described, with additional details in separate guidance.
- Clarified effective dates for approvals, continuing review, and check-ins.
- Clarified process for IRB letters, notifications, and document review.
- Updated MEC reporting procedures, including discontinuing minute distribution to MEC and requiring quarterly IRB Chair or designee attendance.
- Updated written procedures to comply with latest FDA and OHRP guidance, including specific procedures and clarifications for IRB review, IRB actions, IRB minutes, calculation of effective dates and approval periods, and changed the term “Conditional Approval” to “Conditional Approval with Specific Directed Changes.”
- Clarified IRB stamping requirements.

- Added procedures to better manage lapses in continuing review and study closures, including holding the PI/CI accountable to these actions, such as not allowing submissions of new research, when there are lapses or study expirations.
- Added more controls and requirements for approving the change of a PI/CI.
- Added clarifications for certifying copies of electronic records for FDA regulated research.

REVIEW TYPES AND FORMS

- Updated IRB application types for alignment with the IRB website.
- Clarified that exempt and limited IRB reviews may be referred to members for novel studies.
- Clarified NSR device determination process and full board determination requirements.
- Updated sections on amendments, check-in reports, and continuing review, including form requirements and alignment with CARE-Q certification standards.

AI AND DIGITAL HEALTH

- Added a new section addressing research involving artificial intelligence and digital health technologies, outlining ethical, regulatory, and data governance expectations.
- Added section on use of AI tools for reviewing and editing, emphasizing responsible use, confidentiality, and continued human accountability.

COMPLIANCE AND QUALITY

- Added a Quality Assessment Program section for ongoing evaluation and continuous improvement.
- Expanded non-compliance section to specify actions by IRB Chair/Vice Chair and reporting to institutional offices (IO, OCAS, SVPR, Legal, Risk, Privacy Officer, and Data Security Officer).
- Added policy language regarding harassment toward IRB staff or members.
- Clarified review and reporting procedures for reportable events, emergency modifications, and continuing oversight.

DOCUMENTATION AND DISTRIBUTION

- Clarified distribution requirements for signed consent and assent forms.
- Updated description of post-IRB approval submissions and documentation expectations.

CONCLUSION

These revisions modernize the Human Research Protections Program policy to ensure compliance with evolving federal, state, and institutional requirements, while improving operational clarity, alignment with CARE-Q certification, new FDA guidance, and support for digital and AI-integrated research oversight.

REFERENCES

- Policy IRB-01: SUNY Downstate Health Sciences University, Human Research Protections Program, Policy and Procedures.

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HISTORY

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