GUIDANCE FOR IRB MEMBERS: INITIAL REVIEW OF A FULL BOARD OR EXPEDITED STUDY

- ✓ This guidance document will aid the IRB Member in completing a meaningful and substantive review.
- ✓ For more information, please refer to IRB Policy & Guidance or contact IRB@downstate.edu

TABLE OF CONTENTS

APPLICABILITY OF KEY REQUIREMENTS

1) **Use the table below to determine which key regulations, policy, and guidance apply to a specific human research study.**

Guidelines:	Key Regulations/Policy:
The **Downstate Health Sciences University** (Downstate) attests the following to the NYS Department of Health: • Downstate conducts human research subject to policies and regulations promulgated by any federal government agency for the protection of human research participants. • Downstate conducts or authorizes human research not subject to any policies and regulations promulgated by any federal government agency for the protection of research human participants. • Downstate complies with policies and regulations promulgated by any agency of the federal government for the protection of human participants; and • Downstate does or shall comply with such policies and regulations promulgated by any agency of the federal government for the protection of human participants in carrying out its human research activities, whether subject to the Federal Human Research Protection Regulations or not.	NYS Article 24A.
Downstate applies the Revised Common Rule (July 19, 2018 edition of 45 CFR 46) regulations for federally funded, conducted, or supported research and to all other research that is **not** regulated by the FDA or HIPAA (Health Insurance Portability and Accountability Act) regulations. The Common Rule Exemptions (categories 1-6) can apply, when applicable, except most of these exemptions cannot be applied to FDA or DOJ regulated research (see below). *Note: Downstate does not apply exemption category 7 or 8 to research. Downstate does not have a policy for using Broad Consent under these exemption categories. Therefore, the Downstate IRB may not approve or activate a project that requires a Broad Consent process.* Federal Expedited review categories apply, when applicable. Subparts B, C, D, and E apply when applicable, as indicated within the regulations. Research approved under the Common Rule prior to January 21, 2019 is grandfathered under the Pre-2018 Common Rule requirements. However, when there is a compelling reason to transition the research, the IRB or an investigator may amend the research to comply with this version of the policy on or after January 21, 2019.	Revised Common Rule (July 19, 2018 edition of 45 CFR 46) (45 CFR 46, Subpart A). 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 (the Revised Common Rule) on July 19, 2018. Refer to the OHRP website: Revised Common Rule Educational Materials for additional information.
U.S. Department of Justice (DOJ) regulated research.	The DOJ is not a signatory to the July 21, 2018, Common Rule. Follow the Pre-2018 Common Rule and policies of the National Institute of Justice (NIJ) for NIJ funded studies.
Investigational studies involving research participants (including specimens) and FDA regulated articles (e.g., drugs including biologics, food or color additives, and medical devices), including bioavailability and bioequivalence studies, follow applicable FDA regulations.	Applicable FDA regulations apply to research as defined by the FDA (e.g., clinical investigations that must

FDA exemptions apply to FDA regulated clinical investigations, when applicable. Federal Expedited review categories may apply to FDA regulated research, when applicable. Clinical investigations for measuring bioavailability or demonstrating bioequivalence shall be subject to principles and requirements of 21 CFR 320.	comply with 21 CFR 50, 56, 312, 320, 812, 814, etc.) *Note: The FDA has proposed new rules for harmonizing with the Common Rule and Single IRB requirements; however, are not yet finalized. The information presented on this guidance will need to be updated once the new FDA rules go into effect.*
Apply any additional requirements from Federal Departments or Agencies that fund, support, or conduct research, under the Common Rule. **Congruency review** of federal grant is required for research funded by **DOJ** or when following the **PRE-2018 Common Rule**.	• Federal Departments or Agencies. • Single IRB Review for multi-site studies • Certificate of Confidentiality • VA VHA Handbook 1200.05 • Department of Defense • Department of Justice
HIPAA Privacy and Security Rules applies to any research involving Protected Health Information (PHI), also known as Individually Identifiable Health Information (IHII).	HIPAA Privacy & Security Rules (45 CFR Parts 160, 162, and 164)
When required by the NIH or sponsor, investigators must follow the principles of Good Clinical Practices when conducting clinical trials.	Good Clinical Practices
ICH GPC guidelines apply to interventional clinical trials of investigational products, that are intended to be submitted to regulatory authorities. These guidelines are typically required by sponsors conducting international research. The Principles of GCP in the guidelines may also be applicable to other interventional clinical trials of investigational products that are not intended to support marketing authorization applications.	ICH Harmonized Guideline: Guideline for Good Clinical Practice E6 (R3)
Downstate follows law passed by the official governing body of an **American Indian** or **Alaska Native tribe** and any **foreign requirements** when applicable to the research that provide additional protections for research participants.	Consult with the tribe or international standards, regulations, laws, and local research context as applicable to the research.
Downstate must comply with other applicable requirements, as determined by the IRB, PI, Sponsor, RF, or Downstate.	
Investigators must comply with Policy IRB-01 and all other applicable Downstate policies pertaining to research, including but not limited to review of the following: • IRBNet Registration Form • Investigators: the PI must have PI Status, investigators must be members of the Downstate workforce or that external investigators must establish an IRB Reliance Agreement with their institution, or an Individual Investigator Agreement. • Investigators who are "Investigators for the purposes of COI must complete COI disclosures. • Investigators must complete training. • CMRC review is required when applicable (see CMRC Review Request form for criteria for CMRC review) • A protocol must be submitted for IRB review. • Informed consent forms, including any applicable Short Forms, assent forms, or applicable waivers must be submitted for IRB review.	• Downstate IRB Policies and Guidance. • Electronic Submissions | Institutional Review Board | Office of Research Administration | SUNY Downstate

• SUNY RF Payment Consent Form: required for research payments of either 1) $600 or more per calendar year, or 2) more than $100 per study visit. • PI must submit a current CV, resume, or NIH Bio-sketch. • Recruitment materials must be approved by the IRB • Social media postings must be approved by the Office of Communications and Marketing. The IRB will forward the ad to them for approval after conducting a preliminary review. • The IRB reviews data collection tools, questionnaires, and surveys. • The IRB reviews documentation related to IND studies (e.g., IB, FDA Form 1572, IND Letter, additional information as applicable to the study). • HIPAA Preparatory to Research Certification Form • IRB Application and supplemental forms • Documentation of SRC or CMRC review when required.	
IRB members and investigators must complete training and submit conflict of interest disclosures.	See Step 6 at: Electronic Submissions | Institutional Review Board | Office of Research Administration | SUNY Downstate
Certain research involving students and children may need to comply with additional regulations, when applicable, such as FERPA, PPRA, and COPPA. Please see relevant sections below for more details. Human research being conducted in schools or with NYC public school students, staff, or affiliates must be reviewed and approved by the NYC DOE IRB.	• Family Educational Rights and Privacy Act (FERPA) described at 34 CFR Part 99. • Protection of Pupil Rights Amendment (PPRA) described at 34 CFR Part 98. • Children's Online Privacy Protection Act (COPPA), described at 16 CFR Part 312 • NYC Department of Education IRB
When the Downstate IRB reviews research of other engaged sites, the IRB must ensure the research complies with the local requirements of that site. For example, all research conducted by Kings County investigators must comply with the Common Rule, regardless of source of funding.	• Refer to the details in the IRB Authorization Agreement or the Local Research Context Requirements with a specific institution to determine any additional requirements.

IRB APPLICATION MATERIALS

Are there any concerns with any of the applicable application materials, as applicable for the study?

1. IRBNet Registration Form
2. IRB Application(s), including supplement applications when applicable
3. Protocol
4. Sponsor and funding information
5. Informed Consent Form (with or without HIPAA Authorization, as applicable)
   Note: Please use confirm use of version date of template used. Be sure to require additional modifications based on regulatory requirements if using prior version for NEW studies.
6. Information Sheet (with PHI or no PHI/no signatures, as applicable)
   a. If applicable, ensure documentation of IC is waived and/or HIPAA waiver/alteration is provided and meet criteria for waivers
7. Information Sheet/HIPAA Authorization
   a. Include signatures on form, unless HIPAA waiver/alteration is provided

8. Pregnancy Follow-Up Consent Form
9. Consent Addendum for SUNY RF Payment (REQUIRED FOR RESEARCH PAYMENTS OF EITHER 1) $600 OR MORE PER CALENDAR YEAR OR 2) MORE THAN $100 PER STUDY VISIT.
10. Consent Form Addendum for NCI CIRB Approved Clinical Trials
11. Assent Form (generally required for 7-12 y/o participants)
12. Research Subject Recruitment Authorization Forms
    a. Subject Recruitment Authorization - Internal Authorization for Recruitment Contact
    b. Subject Recruitment Authorization - Internal Verbal Authorization for Recruitment Contact
    c. Subject Recruitment Authorization - External Authorization for Recruitment Contact
13. Short Form(s)
    a. Confirm use of Short Forms with version date of 11.14.2018, for corresponding Downstate consent forms with a version date of 12.17.18 (or later) and for research initially approved by the IRB on or after 1.21.19 or for previously approved research that transitions to the requirements of the revised Common Rule; otherwise, use Short Forms with version 05.18.2016.
    b. Note: It may be appropriate to use older Short Forms if the research is not subject to the Common Rule (for example FDA regulated research that it is not federally funded/supported).
14. Telephone or other verbal recruitment script(s)
15. HIPAA Preparatory to Research Certification
16. Data Use Agreement (DUA) – Require for activities involving limited data sets.
17. Business Use Agreement (BAA) –Require for activities involving business associates.
18. HIPAA Waiver
19. Waiver of Informed Consent Requirements
20. Honest Broker Agreement
21. Recruitment Materials Recruitment Materials
    a. Including flyers, brochures, ads, e-mails, telephone or verbal script, web site materials, social media postings, etc.
    b. Any Downstate representation on social media must be approved by the Office of Communications and Marketing. The IRB will forward the ad to them for approval after conducting a preliminary review.
22. Questionnaires or Surveys
23. Data Collection Tools
24. For Clinical Investigations involving an investigational drug, requiring an IND:
    a. FDA Form 1572
    b. IND Letter
    c. Investigator Brochure
25. For Clinical Investigations involving a medical device, requiring an IDE:
    a. IDE Letter or SR/NSR determination, as applicable
    b. Package Insert for medical device, if available
26. Scientific Review Committee Worksheet, when required
27. Central Methodology Review Committee Certificate, when required
28. CV, Resume, or Bio Sketch of PI (and any Co-PI)
29. Credentials of PI or other study staff: Generally, not needed unless the IRB needs to evaluate qualifications of research staff. The Department Chair/Dean's approval via e-signature is accepted to confirm the PI is qualified to do the research, including having appropriate credentials, licensure, and faculty appointment.
30. Sponsor contract: Generally, not needed, unless the IRB needs to review language in the informed consent regarding injuries, additional costs, disclosures requirements, or additional data security requirements for research that follows other regulatory or sponsor requirements.
31. Have all the appropriate e-signatures been obtained (Department Chair/Dean, SRC, Research Pharmacist, Pathology review, etc.)
32. IBC approval

RISK ASSESSMENT

Minimal risk in research involving individuals who are not prisoners and who are not involved in DoD funded research means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Minimal risk in research involving **prisoners** is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

When following **Department of Defense (DoD)** regulations, the definition of minimal risk based on the phrase "ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests" shall not be interpreted to include the inherent risks certain categories of research participant's face in their everyday life. For example, the risks imposed in research involving research participants focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

Note: In general, the IRB interprets "minimal risk" to be calibrated to the life of normal, healthy individuals and daily life to be those activities to which most individuals are exposed. The IRB may determine that procedures that are considered minimal risk for normal healthy individuals constitute greater than minimal risk for the population being studied by virtue of their condition, circumstances, or vulnerability.

For further guidance, see The Secretary's Advisory Committee on Human Research Protections (SACHRP) Attachment A: Recommended Guidance on Minimal Risk Research and Informed Consent.

REQUIREMENTS FOR IRB APPROVAL

DRUG AND BIOLOGIC STUDIES

Questions for consideration, if applicable:

1. If investigational drugs or biologics are used, is there an IND Letter from the sponsor or FDA?
2. If an FDA approved drug is used in an unapproved way, is there an IND number or is it exempt from IND requirements?
3. If an IND exemption is requested, does the protocol meet the criteria for an IND exemption?
   Note: IND exemption criteria are listed at 21 CFR 312.2(b)(2)(ii).
4. Should the IRB request the PI provide confirmation from the FDA?
5. Does the IRB application include the FDA Form 1572?
6. Is the Investigator's Brochure (IB) present? (Required for ICH-GCP trial and helpful for evaluating risks disclosed in the consent document)

MEDICAL DEVICE STUDIES

Questions for consideration, if applicable:

1. Does this study evaluate the safety **or** effectiveness of a "medical device"?
2. ***If yes to (1),*** *d*oes the study meet the **criteria for IDE Exemption** [21 CFR 812.2(c)]:

   (c) Exempted investigations. This part, with the exception of 812.119, does not apply to investigations of the following categories of devices:

   (1) A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.

   (2) A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance

with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.
(3) A diagnostic device, if the sponsor complies with applicable requirements in 809.10(c) and if the testing:
(i) Is noninvasive,
(ii) Does not require an invasive sampling procedure that presents significant risk,
(iii) Does not by design or intention introduce energy into a subject, and
(iv) Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

3. ***If no to (2),*** is this a Significant Risk (SR) or Non-Significant Risk (NSR) device study?
If NSR, the study will be under an abbreviated IDE by the IRB (no IDE needed from FDA).
If SR, an IDE is needed from the FDA.
4. Does the IRB need to request an IDE Letter or SR/NSR determination letter from the sponsor or FDA? (not required for NSR determinations, but may be helpful)
5. Does the IRB need to see a package insert for the medical device? (Generally not required, but may be helpful)

CRITERIA FOR IRB APPROVAL OF NON-EXEMPT HUMAN RESEARCH UNDER THE REVISED COMMON RULE (111 REQUIREMENTS)

NOTE: For FDA regulated clinical investigations, see next section.

The following requirements must be satisfied to approve non-exempt human research, reviewed under the 2018 (Revised) Common Rule. These requirements are found in §46.111 and are referred to as the "111 Requirements."

(1) Risks to subjects are minimized:
(i) By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and
(ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment, the IRB should consider the research's purposes and the setting in which it will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

(4) Informed consent (subject to the Common Rule) will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116 (General Requirements for Informed Consent). See details below.

(5) Informed consent will be appropriately documented or appropriately waived in accordance with §46.117 (Documentation of informed consent). See details below.

(6) When appropriate, the research plan makes adequate provision for **monitoring the data** collected to ensure the safety of subjects.

(7) When appropriate, there are adequate **provisions to protect the privacy** of subjects and to maintain the **confidentiality of data**.

(8) When some or all of the subjects are likely to be **vulnerable to coercion or undue influence**, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, **additional safeguards** have been included in the study to protect the rights and welfare of these subjects.

(9) Additional criteria must be met for the following **vulnerable populations**, as indicated in the links below:

a. Children
b. Children who are Wards
c. Children in Clinical Investigations
d. Children who are Wards in Clinical Investigations
e. Pregnant women or fetuses or neonates
f. Research Involving Placenta, Dead Fetus, or Fetal Material
g. Prisoners

(10) In order to approve research involving some or all research participants that include vulnerable populations, the IRB must also ensure the research is in compliance with regulations to the extent required by 45 CFR 46, subpart B, C, and D.

REQUIREMENT FOR POSTING CLINICAL TRIAL CONSENT FORM FOR RESEARCH APPROVED UNDER THE REVISED COMMON RULE: [45. CFR 46.116(H)]

1. The Common Rule defines a Clinical Trial as a 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.
2. For each clinical trial, as defined (see paragraph above) by the Common Rule, conducted or supported by a Federal department or agency, the awardee or the Federal department or agency component conducting the trial must post one IRB-approved informed consent form used to enroll research participants on a publicly available Federal Web site established as a repository for such informed consent forms. This posting must take place **after the clinical trial is closed to recruitment** and **no later than 60 days after the last study visit by any research participant**, as required by the protocol.
3. A Federal department or agency supporting or conducting the clinical trial may determine that certain information should not be made publicly available on a Federal Web site (e.g., confidential commercial information), and may permit or require redactions to the information posted. The following websites are available for posting the consent form:
    a. www.ClinicalTrials.gov, or
    b. Docket folder on www.Regulations.gov (Docket ID: HHS-OPHS-2018-0021).

Note: The above information is included in Policy IRB-01. The PI or sponsor must ensure the consent form is posted within the required time frame.

CRITERIA FOR IRB APPROVAL OF FDA REGULATED RESEARCH UNDER 21 CFR 56.111 (111 REQUIREMENTS)

Note: The criteria for non-FDA regulated research, follows the criteria outlined in the Common Rule (see above).

The following requirements must be satisfied to approve FDA regulated Clinical Investigations as described at 21 CFR 56.111, also referred to as the "111 Requirements:"

(a) In order to approve research covered by the FDA regulations the IRB shall determine that all the following requirements are satisfied:

(1) **Risks to subjects are minimized**:

(i) by using procedures which are consistent with sound research design, and which do not unnecessarily expose subjects to risk, and

(ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

Note: To evaluate whether the risks to subjects are minimized the IRB may wish to review the following information, when applicable:

- *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.*

(2) **Risks to subjects are reasonable** in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) **Selection of subjects is equitable**. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.

(4) **Informed consent will be sought** from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by part 50. See details below.

(5) **Informed consent will be appropriately documented**, in accordance with and to the extent required by § 50.27. See details below.

(6) Where appropriate, the research plan makes adequate provision for **monitoring the data** collected to ensure the safety of subjects.

(7) Where appropriate, there are adequate provisions to protect the **privacy of subjects** and to maintain the **confidentiality of data**.

(b) When some or all of the subjects, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be **vulnerable to coercion** or **undue influence additional safeguards** have been included in the study to protect the rights and welfare of these subjects.

(c) In order to approve research in which some or all the subjects are **children**, an IRB must determine that all research follows 21 CFR part 50, subpart D.

In addition, the following is required, as applicable to FDA regulated investigations:

1. FDA requires the sponsor or the sponsor-investigator to determine whether an IND or IDE is required for a particular study. The IRB may request the basis for the determination or request supporting documentation from the FDA. If the IRB is unable to resolve the issue, it will be considered a controverted issue and cannot approve the study until the matter is resolved.
2. For investigational device studies, the IRB may determine that a device study is significant risk (SR) or non-significant risk (NSR). A SR device study must have an IDE from the FDA before the IRB can approve the investigation.
3. Clinical investigations for measuring bioavailability or demonstrating bioequivalence shall be subject to principles and requirements of 21 CFR 320.

For clinical trials which follow ICH-GCP requirements, consult with ICH E6 Guidance:

NOTICE OF GCP COPYRIGHT: Information regarding GCP requirements is from: International Council for Harmonisation (ICH) Harmonized Guideline: ICH E6 (R3) Guideline for Good Clinical Practice [06 January 2025 (effective 23 July 2025)]

Note: for review of research, prior to July 23, 2025, please see section 4.8 (page 24) of ICH E6(R2), which is effective until 22 July 2025.

For a complete list of GCP requirements, please see links noted above.

For specific informed consent requirements, see below (pages 20-21)

ADDITIONAL IRB APPROVAL CRITERIA FOR RESEARCH WITH CHILDREN		
Categories of permissible research for children	**Critria**	**Requirements**
Category 404 (45 CFR 46.404 and 21 CFR 50.51)	✓ No greater than minimal risk	✓ Permission of one parent/guardian ✓ Assent
Category 405 (45 CFR 46.405 and 21 CFR 50.52)	✓ Greater than minimal risk ✓ Presents prospect of direct benefit to the individual research participants ✓ The risk is justified by the anticipated benefit to the participants; and ✓ The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.	✓ Same as 404
Category 406 (45 CFR 46.406 and 21 CFR 50.53)	✓ Greater than minimal risk ✓ Minor increase over minimal risk ✓ No prospect of direct benefit to the individual research participants ✓ Likely to yield generalizable knowledge about the research participants' disorder or condition	✓ Permission must be obtained by **both parents (or guardians)**, unless one is deceased, unknown, incompetent or not reasonably available, or when only one parent has legal

	✓ Intervention/procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations	responsibility for the care and custody of the child ✓ Assent ✓ If children are wards of the state or any other agency, institution, or entity are included, additional requirements of 45 CFR 46.409 must also be met.
Category 407 (45 CFR 46.407 and 21 CFR 50.54)	✓ Research is not otherwise in category 404, 405, or 406, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.	✓ Includes 406 requirements ✓ **OHRP (or by the FDA, if FDA regulated) must also approve the research**

ADDITIONAL IRB APPROVAL CRITERIA FOR RESEARCH WITH PRISONERS UNDER THE COMMON RULE

Research with prisoners reviewed under the Common Rule must be determined to be within one or more of the permissible categories of research and must comply with the requirements of Subpart C of the Common Rule.

Note: For reference, see 45 CFR 46.306(a)(2).

Category #1: Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the research participants;

Category #2: Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the research participants;

Category #3: Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after OHRP has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his/her intent to approve such research; or

Category #4: research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the research participants. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after OHRP has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research.

Epidemiological studies conducted or supported by HHS involving prisoners qualify for a Health and Human Services Waiver of the applicability of 45 CFR 46.305(a)(l) and 46.306(a)(2) when it meets the following criteria:

1. The sole purposes are:
   a. To describe the prevalence or incidence of a disease by identifying all cases, or
   b. To study potential risk factor associations for a disease, and
2. The IRB approves the research under 45 CFR 46.305(a)(2)– (7) and determined and documented that the following conditions are met:
   a. The research presents no more than minimal risk and no more than inconvenience to the research participants, and
   b. Prisoners are not a particular focus of the research.
3. The specific type of epidemiological research subject to the waiver involves no more than minimal risk and no more than inconvenience to the research participants.
4. The waiver would allow the conduct of minimal risk research that does not now fall within the categories set out in 45 CFR 46.306(a)(2).

5. The range of studies to which the waiver would apply includes epidemiological research related to chronic diseases, injuries, and environmental health. This type of research uses epidemiologic methods (such as interviews and collection of biologic specimens) that generally entail no more than minimal risk to the research participants.

EXAMPLE: An example of an epidemiological study that could be permitted under the proposed waiver is one in which all persons with HIV, but with none of the known risk factors for HIV, are asked to participate in a study involving an interview, review of medical records, and collection of a blood specimen. The purpose of the study is to determine 5 other potential risk factors for HIV. All states with mandatory HIV reporting laws report these cases to the Centers for Disease Control and Prevention (CDC), DHHS. Each person who meets the study definition would be asked to participate, and prisoners could well be members of the potential study group. For the study to be approved under this waiver, the IRB would need to ensure that, among other things, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.

INFORMED CONSENT REQUIREMENTS

INFORMED CONSENT PROCESS

The IRB evaluates and ensures the informed consent process is adequate and determines whether informed consent is documented and sought in accordance with regulations and policies based on information provided in the IRB application materials, including the IRB application and protocol.

HELPFUL TIPS REGARDING INFORMED CONSENT FORM REVIEW

The following tips are included on the Downstate Informed Consent template for investigators and is provided here as a reference for IRB Members.

- ✓ *Informed consent is a "PROCESS," not just a FORM!!! This template focuses on the regulatory requirements for the "form." Please review additional IRB Guidance on "Obtaining Legally Effective Informed Consent and HIPAA Authorization.*
- ✓ *The design of this "All-In-One" template is for all research types and includes built-in guidance.*
- ✓ *There is another "SIMPLE" template available that can be used, but please refer to this template for complete guidance.*
- ✓ *Refer to the IRB Guidance: Obtaining Legally Effective Informed Consent and HIPAA Research Authorization.*
- ✓ *The HIPAA Authorization language is included in this template which is the preferred approach; however, if a sponsor requires a stand-alone HIPAA authorization, please refer to the stand-along template on the IRB website.*
- ✓ *If the research has an external sponsor, please consider using the sponsor's model informed consent template, rather than this template. However, be sure to include all language required by local research context:*
    - *Required HIPAA authorization language when a study involves Protected Health Information (PHI). Include the elements described in IRB-01 policy, including disclosures of research involving video/audio recording or pictures or images. Use the recommended language in template below or use the stand-alone HIPAA Authorization.*
    - *Information for diagnostic (clinical) genetic testing*
    - *Option to use coded (de-identified) specimens and/or information for future research*
    - *Use of psychiatry notes (include separate HIPAA Authorization; template on website)*
    - *All required signature lines, as applicable to the study*
    - *Information regarding HIV education/testing, when applicable*
    - *Information regarding payment for research participation, when applicable*

- *Optional authorizations (e.g., future contact to obtain or share information about genetic testing, sharing information/specimens for future research, future contact for other studies, release of medical information)*

✓ *Items in italics or red are general instructions which must be deleted (or changed when applicable) before submitting the final form to the IRB.*

✓ *Informed consent must present information in sufficient detail related to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective research participant's or surrogate's understanding of the reasons why one might or might not want to participate. Change the suggested order of this template, as needed, to facilitate informed consent.*

✓ *To the extent possible, explain technical, medical, and scientific concepts in lay terms that are understandable to someone who is educated* ***from a 6th to 8th grade level****. Note that grade 6-8 reading level is a goal, but some required language may necessarily be worded at a higher reading level. The aim is still to provide comprehensive information; whenever possible, reducing the reading level should* ***NOT*** *entail eliminating information. Avoid long sentences and medical/technical jargon, and clearly define any technical terms whenever they are used. If the definitions of technical terms are lengthy, describe them in separate sentences. The PI is encouraged to test the readability within Microsoft Word.*

✓ *Consider adding pictures, diagrams, tables, or charts if they will improve understanding.*

✓ *Avoid or minimize passive voice to the extent possible. Example of passive voice: "A summary of results will be sent to all study participants." Example of active voice: "We will send you a summary of the results."*

✓ *Pronouns matter. Write directly to the reader, as though you are explaining the facts in person. Write in the second person ("you"), not in the first person ("I"). Avoid the frequent use of first-person pronouns (I, me, my, we, us, etc.).*

✓ *When applicable, change the title in header (e.g., PARENTAL PERMISSION, HEALTHY VOLUNTEER INFORMED CONSENT, etc.).*

✓ *Remove references to "NYC Health + Hospitals, Kings County" in the header and throughout this form if they are not involved in the research.*

✓ *Use bold text and/or boxes around critical text for emphasis.*

✓ *Include any requirements of any applicable federal, state, or local law.*

✓ *Include any requirements of any applicable tribal law passed by the official governing body of an American Indian or Alaska Native tribe (e.g., Research focus on American Indians, Alaskan Natives, or indigenous people). NOTE: A Tribe may require their own tribal IRB approval, prior to submission to Downstate IRB*

✓ *Please consider numbering the sections to help with the informed consent process.*

INFORMED CONSENT REQUIREMENTS FOR RESEARCH APPROVED UNDER THE COMMON RULE

NOTE: For FDA regulated research, see section below.

The following outlines the informed consent requirements for research reviewed under the Common Rule:

(a) **General Requirements of Informed Consent.** Except when otherwise waived by the IRB, the general requirements for informed consent, whether written or oral, are set forth below:

(1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.

(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and

consider whether or not to participate and that minimize the possibility of coercion or undue influence.

(3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.

(4) The prospective subject or the legally authorized representative must 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.

(5) Informed consent must be obtained in accordance with the following:

(i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
(ii) Informed consent must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

(6) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

(b) **Basic elements of informed consent.** Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others that may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
(ii) A statement that the subject's information or biospecimen collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

(c) **Additional elements of informed consent.** Unless informed consent or the elements or informed consent are waived, the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the research that may relate to the subject's willingness to continue participation will be provided to the subject;

(6) The approximate number of subjects involved in the study;

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

(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

(9) 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).

Note: Downstate does not have provisions to approve research using Broad consent, as outlined in the Common Rule, for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens; therefore, the Downstate IRB does not evaluate such research.

DOCUMENTATION OF INFORMED CONSENT OR WAIVER OF DOCUMENTATION OF INFORMED CONSENT FOR RESEARCH REVIEWED UNDER THE COMMON RULE

NOTE: For FDA regulated research, see section below.
For FDA guidance and FAQs on this topic, please see: Informed Consent: Guidance for IRBs, Clinical Investigators, and Sponsors.

Informed consent will be appropriately documented or appropriately waived in accordance with §46.117 (Documentation of informed consent):

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form.

(b) Except as provided in paragraph (c) of this section, the informed consent form may be either of the following:

(1) A written informed consent form **(long form)** that meets the requirements of §46.116. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.

(2) A **short form** written informed consent form stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative, and that the key information required by §46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a **written summary** of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a **witness to the oral presentation**. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign the short form and a copy of the summary (the summary can be the long form), and the person obtaining consent shall sign one. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form.

Note: All the regulations only require the signature on the Short Form, when it is used as described above, the IRB also requires the signature on the Long Form.

See IRB Guidance for Investigators on Obtaining Legally Effective Informed Consent and HIPAA Research Authorization for guidance when the Long or Short Form may be used.

(c) The IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

(i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
(ii) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
(iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

(2) In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

SCREENING, RECRUITING, OR DETERMINING ELIGIBILITY; & WAIVER OR ALTERNATIONS OF INFORMED CONSENT REQUIREMENTS FOR RESEARCH UNDER THE REVISED COMMON RULE

NOTE: For FDA regulated research, see section below.

The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met: however, a HIPAA waiver or HIPAA Authorization may be required under the HIPAA regulations (see below.)

(1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
(2) The investigator will obtain identifiable private information or identifiable biospecimen by accessing records or stored identifiable biospecimen.

GENERAL WAIVER OR ALTERATION OF CONSENT:

The IRB may waive the requirement to obtain informed consent for research or may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent provided the IRB finds and documents the following:

(1) The research involves no more than minimal risk to the subjects;
(2) The research could not practicably be carried out without the requested waiver or alteration;
(3) 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;
(4) The waiver or alteration will not adversely affect the rights and welfare of the subjects; an
(5) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

WAIVER OR ALTERATION OF CONSENT IN RESEARCH INVOLVING PUBLIC BENEFIT AND SERVICE PROGRAMS CONDUCTED BY OR SUBJECT TO THE APPROVAL OF STATE OR LOCAL OFFICIALS:

The IRB may waive or alter consent for research involving public benefit or service program, provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
(A) Public benefit or service programs;
(B) Procedures for obtaining benefits or services under those programs;
(C) Possible changes in or alternatives to those programs or procedures; or
(D) Possible changes in methods or levels of payment for benefits or services under those programs; and
(2) The research could not practically be carried out without the waiver or alteration.

HIPAA REQUIREMENTS

HIPAA CONSIDERATIONS WHEN SCREENING AND RECRUITING RESEARCH PARTICIPANTS

1. Does or should enrollment with informed consent and HIPAA Authorization, prior to screening the participants for eligibility?

2. Is a HIPAA waiver required? A partial HIPAA waiver (for recruitment purposes) is required to screen PHI, if the investigators are NOT also providing care to the patients who are potentially eligible for recruitment. Is a HIPAA Alteration (waiver of required elements of a HIPAA Authorization, such as signature) required?
3. Is HIPAA Authorization required?
4. Should the research use Research Subject Recruitment Authorization Forms to obtain contact information for patient recruitment through their clinicians, as required by Policy HIPAA-28 Use and Disclosure for Research Purposes. The forms are available in Step 8 at Electronic Submissions | Institutional Review Board | Office of Research Administration | SUNY Downstate
    a. 8-14: Subject Recruitment Authorization - Internal Authorization for Recruitment Contact
    b. 8-15: Subject Recruitment Authorization - Internal Verbal Authorization for Recruitment Contact
    c. 8-16: Subject Recruitment Authorization - External Authorization for Recruitment Contact

Research HIPAA Authorizations

HIPAA authorization language must be provided to cover the uses and disclosures of Protected Healthcare Information (PHI) or Individual Identifiable Healthcare Information (IIHI), including when such information is about specimens. Preferably, the language should be included in a compound authorization (with the consent form); however, a stand-alone document may be used. For templates, refer to Step 8 at Electronic Submissions | Institutional Review Board | Office of Research Administration | SUNY Downstate

1) The following core elements must be present in plain language for a research authorization to be valid:
    A. A specific and meaningful description of the PHI to be used or disclosed.
    Note: The minimum necessary rule does not apply to Authorizations; however, Downstate encourages the investigators to limit the PHI to the minimal necessary PHI that is reasonably necessary to accomplish the purpose of the research.
    B. The name or identification of the person(s) or class of person(s) authorized to make the use or disclosure of PHI. For example, who will disclose the PHI? (e.g., UHB, NYC H+H, Kings County, other hospitals, practice groups, etc.)
    C. The identification of the persons or class of persons to whom the covered entity is authorized to make the disclosure. For example, what internal or external persons or entities will be receiving PHI?
    D. Description of each purpose for which the specific PHI identified earlier is to be used or disclosed.
    E. An expiration date or event (this must be a certain date, or an event tied to the individual). For example, a statement providing that the authorization will expire on a specific date, after a specific amount of time, or upon occurrence of some event related to the research participant. (e.g., "at the completion of the research")
    F. The individual's signature and date, and if signed by a personal representative, a description of his or her authority to act for the individual (e.g., required when recruiting children or cognitively impaired adults).
2) The following statements must be included:
    A. A statement that the individual may revoke the authorization in writing at any time (except to the extent that a provider has acted in reliance of the authorization), and instructions on how to exercise such right (who does the individual need to write, name and address)
    B. A statement that treatment, payment, enrollment, or eligibility for benefits may not be conditioned on obtaining the authorization if such conditioning is prohibited by the Privacy Rule or, if conditioning is permitted, a statement about the consequences of refusing to sign the authorization.
    Note: The PI may condition healthcare on the provision of the authorization for research related treatment (e.g., clinical trial), in which case the provider may refuse to provide the research related healthcare if the research participant refuses to execute the authorization.
    C. A statement about the potential for the PHI to be re-disclosed by the research team (e.g., to another organization) and no longer protected by the Privacy Rule

3) There are additional requirements for authorizations for using PHI for marketing purposes, sale of PHI, or for the use or disclosure of psychotherapy notes.

4) Contact the IRB or Privacy Officer for additional information or refer to Downstate HIPAA Web-Site which includes:
   A. DMC HIPAA-28 Policy: Uses and Disclosures for Research Purposes
   B. DMC HIPAA-32 policy: Uses and Disclosures Requiring Patient Authorization.

Research HIPAA Waivers & alterations

The IRB may approve the uses and disclosures of PHI for research purposes when the investigator submits **Form 8-18: HIPAA Waiver** to waive HIPAA research authorization requirements. This form is available on **Step 8** of the Electronic Submissions | Institutional Review Board | Office of Research Administration | SUNY Downstate.

To approve the requested waiver, it must satisfy all the following criteria:

- The use or disclosure involves no more than a minimal risk to the privacy of the research participants because:
  - There is an adequate plan to protect the "identifiers" from improper use or disclosure. Refer to Downstate Policy on De-Identification of Information (HIPAA-6) for the types of information considered to be identifiers;
  - There is an adequate plan to destroy the identifiers at the earliest opportunity, unless there is a health or research justification for retaining the identifiers or their retention is required by law; and
  - There are adequate written assurances that the protected health information (PHI) will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study or for other research for which the use or disclosure of PHI is otherwise permitted.
- The research could not practicably be conducted without the waiver- research involving treatment will almost never be eligible since most clinical trials could practicably be conducted without a waiver; and
- The research could not practicably be conducted without access to and use of the PHI- If de-identified information or a limited data set can practicably be used, a waiver of authorization should not be granted. The PI should submit the request for waiver using the HIPAA Waiver of Authorization Form.

The IRB will review and approve the waiver, if appropriate, under either normal or expedited review procedures. Refer to Downstate Policy Uses and Disclosures for Research Purposes (HIPAA-28) for more information.

The section below described the three types of HIPAA Waivers (full, partial, and alteration).

NOTE: Both the PI and an IRB member must e-sign the HIPAA waiver and/or the documentation of the approval is outlined in the IRB approval letter. The fully executed HIPAA waiver is published in IRBNet.

A ***Full HIPAA Waiver*** removes the requirement to obtain a HIPAA research authorization from research participants for the use and disclosure of their PHI to conduct a study. Examples where this is appropriate include:

- Retrospective review of PHI (i.e., medical records reviews, lab reports);or
- Exempt research involving PHI, when it is impracticable to obtain a HIPAA research authorization.

NOTE: When applicable, the IRB may use the information in the HIPAA waiver to grant a waiver of informed consent.

A ***Partial HIPAA Waiver*** may be approved to review PHI for recruitment purposes; however, include the HIPAA research authorization language within an informed consent document that uses subsequent PHI.

- A HIPAA waiver is required for review of PHI for recruitment purposes, when the investigators are not the healthcare providers of the potential participants.

NOTE: If the IRB approves a partial HIPAA waiver (e.g., for recruitment purposes), the IRB conditions the use or disclosure of the PHI upon obtaining a HIPAA authorization once consent is obtained.

A ***HIPAA Alteration*** is a type of HIPAA waiver that when approved permits the use of a research authorization that does not contain all of the required elements or statements (e.g., signature or another element), or that otherwise deviates from the format or process prescribed by the HIPAA regulations. This may be useful, for example, when a PI is also seeking waiver of documentation of informed consent, when the only link of a participant to a study is their signature on a consent form and HIPAA research authorization, if it can be considered impracticable to the study's completion to obtain a signed research authorization form as such a requirement might prevent study completion. There also may be other circumstances where a simplified consent and authorization document are appropriate given the nature of the population enrolling in the research and in these cases a request to waive certain but not all elements or required statements of the authorization would be made.

NOTE: When applicable, the IRB may use the information in the HIPAA Alteration waiver to grant a waiver of documentation (signature) of informed consent; however, the Common Rule describes various situations when a waiver of documentation (signature) of informed consent may be approved which are not analogous to a HIPAA waiver and therefore, Form 8-19: Waiver of Informed Consent Requirements may still be required.

FDA INFORMED CONSENT REQUIREMENTS

INFORMED CONSENT REQUIREMENTS FOR FDA REGULATED CLINICAL INVESTIGATIONS

NOTE: For Common Rule regulated research, see section above.

The following outlines the informed consent requirements for research reviewed under the **FDA regulations**:

(1) Informed Consent requirements for **FDA regulated Clinical investigations** are provided below. For more information see 21 CFR 50.25

(a) **Basic elements of informed consent.** In seeking informed consent, the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

(2) A description of any reasonably foreseeable risks or discomforts to the subject.

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research.

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

(8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) **Additional elements of informed consent**. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

(3) Any additional costs to the subject that may result from participation in the research.

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

(5) A statement that significant new findings developed during the research which may relate to the subject's willingness to continue participation will be provided to the subject.

(6) The approximate number of subjects involved in the study.

(c) When seeking informed consent for **applicable clinical trials**, as defined in 42 U.S.C. 282(j)(1)(A), the following statement shall be provided to each clinical trial subject in informed consent documents and processes. This will notify the clinical trial subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank under paragraph (j) of section 402 of the Public Health Service Act. The statement is: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

INFORMED CONSENT REQUIREMENTS FOR RESEARCH FOLLOWING ICH-GCP STANDARDS

Informed consent requirements for clinical trials which follow ICH-GCP requirements.

NOTICE OF GCP COPYRIGHT: Information regarding GCP requirements is from: International Council for Harmonisation (ICH) Harmonized Guideline: ICH E6 (R3) Guideline for Good Clinical Practice [06 January 2025 (effective 23 July 2025)]

Note: for review of research, prior to July 23, 2025, please see section 4.8 (page 24) of ICH E6(R2), which is effective until 22 July 2025.

For a complete list of GCP requirements, please see links noted above.

The informed consent discussion and the informed consent materials to be provided to participants should explain the following as applicable:

(a) The purpose of the trial;
(b) That the trial involves research and summary of the experimental aspects of the trial;
(c) The trial's investigational product(s) and the probability for random assignment to the

investigational product, if applicable;
(d) The trial procedures to be followed including all invasive procedures;
(e) What is expected of the participants;
(f) The reasonably foreseeable risks or inconveniences to the participant and, when applicable, the participant's partner, to an embryo, fetus or nursing infant;
(g) The reasonably expected benefits. When there is no intended clinical benefit to the participant, the participant should be made aware of this;
(h) The alternative procedure(s) or course(s) of treatment that may be available to the participant and their important potential benefits and risks;
(i) The compensation and/or treatment available to the participant in the event of trial related injury;
(j) Any anticipated prorated compensation to the participant for trial participation;
(k) Any anticipated expenses to the participant for trial participation;
(l) That the participant's trial participation is voluntary, and the participant may decide to stop taking the investigational product or withdraw from the trial at any time, without penalty or loss of benefits to which the participant is otherwise entitled;
(m) The follow-up procedure for participants who stopped taking the investigational product, withdrew from the trial or were discontinued from the trial;
(n) The process by which the participant's data will be handled, including in the event of the withdrawal or discontinuation of participation in accordance with applicable regulatory requirements;
(o) That by agreeing to participate in the trial, the participant or their legally acceptable representative allows direct access to source records, based on the understanding that the confidentiality of the participant's medical record will be safeguarded. This access is limited for the purpose of reviewing trial activities and/or reviewing or verifying data and records by the regulatory authority(ies) and the sponsor's representatives, for example, monitor(s) or auditor(s), and in accordance with applicable regulatory requirements, the IRB/IEC(s);
(p) That records identifying the participant will be kept confidential and, to the extent permitted by the applicable regulatory requirements, will not be made publicly available. If the trial results are published, the participant's identity will remain confidential. The trial may be registered on publicly accessible and recognized databases, per applicable regulatory requirements;
(q) That the participant or the participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the participant's willingness to continue trial participation;
(r) The person(s) to contact for further trial information and the trial participant's rights, and whom to contact in the event of suspected trial-related injury;
(s) The foreseeable circumstances and/or reasons under which the participant's trial participation may be terminated;
(t) The expected duration of the participant's trial participation;
(u) The approximate number of participants involved in the trial;
(v) That trial results and information on the participant's actual treatment, if appropriate, will be made available to them should they desire it when this information is available from the sponsor.

ADDITIONAL INFORMED CONSENT CONSIDERATIONS

FUTURE USE OF SPECIMENS OR INFORMATION

In general, the future use of specimens or information (not related to the current research project under review) cannot be a condition of the current research project, <u>unless</u> the primary purpose, as disclosed in the consent form, is to obtain specimens or information for a repository.

The following applies to informed consent and HIPAA authorization disclosures for the future use of specimens or information, unless the primary purpose, as disclosed in the consent form, is to obtain specimens or information for a repository:

1. Require HIPAA authorization language when a study involves Protected Health Information (PHI). The Authorization must include the required elements of HIPAA Authorization, described below, including disclosures of research involving video/audio recording or pictures or images. Recommended language is available in the consent template (compound authorization) or the stand-alone HIPAA Authorization, posted in Step 8 at Electronic Submissions | Institutional Review Board | Office of Research Administration | SUNY Downstate
2. Include the "option" to use coded (de-identified) specimens and/or information for future research.
3. When applicable, include optional authorizations (e.g., future contact to obtain or share information about genetic testing, sharing information/specimens for future research, future contact for other studies, release of medical information, future contact to invite participates to consider other research, etc.)
4. The disclosure must specify whether specimens or information or both will be stored for future studies.
5. In general, the IRB does not permit "unspecified future use."
6. The use or disclosure of identifiable (or coded) information/specimens for future may be presented as either 1) an optional provision **or** 2) as a separate optional Informed Consent/HIPAA Authorization form.
7. Provide an adequate description of the future indications or purposes so that it would be reasonable for the research participant to expect the use or disclosure of their Protected Health Information (PHI) for such future research.
8. There are several options and examples on language which may be used in the templates on the IRB website.
   Note: Unless legally permissible or authorized, additional IRB approval of future research may be required, at which time the IRB can determine if a new consent or HIPAA Authorization, waivers, or Data Use Agreement is to be required for future research.

ELEMENTS OF INFORMED CONSENT FOR DIAGNOSTIC GENETIC TESTS

Elements of Informed Consent for Diagnostic Genetic Tests under **Section 79-L of the NY State Civil Rights Law**

1) Research Genetic Tests must not be given to research participants, unless such results are confirmed by a CLIA or NY State certified lab.
2) For studies involving diagnostic genetic testing (or possible genetic testing) for diagnostic purposes performed by a CLIA or NY State certified lab (e.g., any laboratory test of human DNA, chromosomes, genes, gene products, or DNA profile analysis to diagnose the presence of a genetic variation linked to a predisposition to a genetic disease or disability in the individual or the individual's offspring), include the elements of informed consent described below.
   A. A general description of the test;
   B. A statement of the purpose of the test;
   C. A statement indicating that the individual may wish to obtain professional genetic counseling prior to signing the informed consent;
      NOTE: Information about specific genetic test results on stored specimens cannot be disclosed to the individual or others without obtaining informed consent for the disclosure.
   D. The name of the person or categories of persons or organizations to whom the test results may be disclosed;
   E. A statement the only tests authorized on the specimen are performed and the specimen is destroyed at the end of the testing process or not more than sixty (60) days after the sample was taken, unless a longer period of retention is expressly authorized in the consent.
   F. If the research permits such degree of specificity, include the following:
      1. A statement that a positive test result is an indication that the individual may be predisposed to or have the specific disease or condition tested for and may wish to consider further independent testing, consult their physician or pursue genetic counseling;
      2. A general description of each specific disease or condition tested for;

3. The level of certainty that a positive test result for that disease or condition serves as a predictor of such disease.
4. A description of the policies and procedures to protect patient confidentiality;
5. A statement of the right to withdraw consent to use of the specimen for future use at any time and the name of the organization that should be contacted to withdraw consent;
6. A statement allowing individuals to consent to future contact for any or all purposes, including the following:
    a) research purposes;
    b) provision of general information about research findings; and
    c) information about the test on their sample that may benefit them or their family members in relation to their choices regarding preventive or clinical care; and
    d) a statement explaining the benefits and risks of consenting to future contact

SIGNATURE LINES

The informed consent/HIPAA Authorization/Information Sheet should only use the required signature lines as applicable for the specific study under review. The study team should delete all other signature lines/boxes and instructions not applicable to the research submission.

1) Lines should be added for the <u>Names (no signature nor date)</u> for the following individuals, when applicable for the research:
- **a) Name of a child under 13.**
- **b) Name of a cognitively impaired adult.**

2) Lines should be added for the <u>Names, Signatures, and Dates</u>, as indicated below, when applicable for the research:
- **a) Child providing assent.** In general, add to consent for assent ages 13-17; otherwise, use an assent document for ages 7-12.
- **b) Parent or Legal Guardian.** Required when enrolling a child, under the age of 18.
- **c) 2nd Parent or Legal Guardian (if applicable).** Required for categories 406 & 407 research.
- **d) Independent Consent Monitor**. Required when enrolling a Ward. May be required by the IRB when enrolling an emancipated research participant or a married individual under 18 years, typically when the research does not involve a clinical treatment (e.g., "survey" on HIV or STD). An Independent Consent Monitor may not be a member of the research team.
- **e) Research Participant.**
    - **i)** For adults who are 18 years of age or older
    - ii) Married individuals under 18 years of age may sign as an adult.
    - **iii)** Emancipated research participants signs as an adult. An emancipated minor is defined as either a person who is 16 years or older and living independently from his/ her parents or a minor who is a parent him/herself, or a pregnant person under the age of 18.
- **f) Personal Representative (Legally Authorized Representative/Acceptable Representative).** Required when obtaining surrogate consent for enrolling cognitively impaired adults.
- **g) Interpreter.** Required when there are plans to enroll participants with individuals who have Limited English Proficiency or communicate with sign language.
- **h) Witness.**
    - **i)** Required for the following situations:
        - **(1)** When obtaining consent/permission from research participants, parents/guardians, or personal representatives with Limited English Proficiency.
        - **(2)** When obtaining consent/permission from research participants, parents/guardians, or personal who understand English, but cannot read English.
        - **(3)** When obtaining permission from the personal representative of a cognitively impaired adult.
    - **ii)** A witness is recommended (not required) for clinical trials that involve investigational drug, biologic, or device.

    NOTE: Ensure the witness is listed as an "impartial witness," when required, as described below.
- **i) Impartial Witness.**

i) For a Clinical Trial that follows **ICH-GCP** requirements, an Impartial Witness is a person who is independent of the trial who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the participant or the participant's legally acceptable representative cannot read, and who reads the informed consent form and any other documented information supplied or read to the participant and/or their legally acceptable representative.

ii) Required for a Clinical Trial that follows **ICH-GCP** requirements obtaining consent from a a participant or their legally authorized representative (LAR) who is unable to read, including non-English reading participants or their LAR.

iii) May be required by a sponsor for enrolling other vulnerable populations such as cognitively impaired adults.

iv) May be required by the IRB for any situation that requires a "witness" as indicated above, when the IRB determines additional protections are needed.

Note: Electronic signatures (e.g., e-signatures captured with software or computer equipment) are not permitted for FDA regulated Clinical Investigations, unless the IRB has confirmed 21 CFR part 11 *compliance.*

ADDITIONAL GUIDANCE AND CONSIDERATIONS

RECRUITMENT OF STUDENTS, RESIDENTS, FELLOWS, EMPLOYEES, OR VOLUNTEERS AS RESEARCH PARTICIPANTS

Questions for consideration, if applicable:

1. Have investigators sufficiently minimized coercion and undue influence?
2. Is privacy adequately protected?
3. Is confidentiality of data adequately protected?
4. Does the research need to comply with Family Educational Rights and Privacy Act (FERPA) described at 34 CFR Part 99.
    a. FERPA applies to certain rights for parents regarding their children's educational records.
    b. Is prior parental consent required to disclose personally identifiable information from education records, as described in Subpart D?
    c. What other FERPA regulations apply to the research?
5. Does the research need to comply with Protection of Pupil Rights Amendment (PPRA) described at 34 CFR Part 98.
    a. PPRA affords parents of students' certain rights regarding, among other things, participation in surveys, the collection and use of information for marketing purposes, and certain physical exams.
    b. Is prior parental consent required, as described in Section 98.4?
    c. What other PPRA regulations apply to the research?
6. Does the research need to comply with Children's Online Privacy Protection Act (COPPA), described at 16 CFR Part 312?
    a. COPPA imposes requirements on operators of websites or online services directed to children under 13 years of age, and on operators of other websites or online services that have actual knowledge that they are collecting personal information online from a child under 13 years of age.
    b. Is parental consent required, and in compliance with COPPA, as described in Section 312.5?
    c. What other COPAA regulations apply to the research?
7. Must the research be approved by the NYC Department of Education IRB?
    a. Any research being conducted in schools or with NYC public school students, staff, or affiliates must be reviewed and approved by the NYC DOE IRB to ensure it complies with DOE policies, protects the privacy of students, parents, and staff, and does not disrupt the work of NYC public schools.

For more information, consult the references in the links above and the IRB Guidance: Students, Residents, Fellows, Employees, or Volunteers as Research Participants available on the IRB Policy and Guidance website.

ADEQUACY OF RESEARCH SITE(S)

Questions for consideration, if applicable:

1. Is (are) the site(s) adequate to conduct the research?
2. Are the facility's staff and medical equipment adequate?
3. Are emergency or specialized care adequate if the need arises?
4. Does the IRB need a statement from an external research site regarding adequacy?
5. Does the IRB require additional information regarding any of the following:
    a. Description of the facility where the research will take place
    b. More information on staffing
    c. More information on resources

DATA SECURITY

For more information, see IRB guidance on Data Security.

Questions for consideration, if applicable:

1. Do the study materials meet information security requirements?
2. Are physical safeguards adequate?
3. Are protocol specific safeguards adequate?
4. Are technical safeguards adequate?
5. Is data stored behind the Downstate firewall?
6. Are encrypted laptops and thumb drives used?
7. Are employee controls adequate?
8. Do other state and foreign regulations:
    a. Downstate cannot approve research that must comply with the European Union General Data Protection Regulation (EU GDPR) and most likely cannot approve research that follows other similar regulations of foreign countries.
    b. In general, the Californian Consumer Privacy Act (CCPA) does not apply to Downstate Research.
    c. Downstate OCAS, the Privacy Officer, the Data Security, or General Counsel, may need to assist the IRB in determining applicability of foreign or state regulations and whether Downstate can comply. Contact the IRB for assistance.

STUDY POPULATION

Questions for consideration, if applicable:

1. Is the study population defined, including inclusion/exclusion criteria?
2. Is there appropriate justification for the inclusion/exclusion of populations as outlined in the application materials?
3. Are adequate provisions made for recruiting those with Limited English Proficiency (LEP), when appropriate (i.e., when the study holds the prospect of direct therapeutic benefit), unless there are risks or barriers that prohibit the enrollment of those with LEP.

WAIVER OF INFORMED CONSENT REQUIREMENTS AND/OR HIPAA WAIVERS

Note: See regulatory criteria for granting waivers on the IRB forms.

1. Does the research meet the criteria for granting the requested waivers?
2. Is it impracticable to obtain written informed consent and/or HIPAA Authorization?

Common definitions of "Practicable":

- Feasible;
- Capable of being put into practice, being done, accomplished or performed; or
- Capable of being done or accomplished with available means or resources.

The emphasis being that it is impracticable to perform the research, and not just impracticable to obtain consent.

Concepts that may help determine whether it is impracticable to obtain consent:

1. Scientific validity would be compromised if consent was required. Examples of this might include the following:
    a. The sample size required is so large (e.g., population-based studies, epidemiology trials) that including only those samples/records/data for which consent can be obtained would prohibit conclusions to be drawn or bias the sample such that conclusions would be skewed.
    b. The subjects for whom records would be reviewed are no longer followed and may be lost to follow-up. For example, the proportion of individuals likely to have relocated or died may be a significant percentage of the subject population and the research results may not be meaningful and lose statistical power.
    c. The disclosure of the study purpose as part of the consent process would bias the research subjects so that the results will not be meaningful.
2. Ethical concerns would be raised if consent were required. For example:
    a. There is a risk of creating additional privacy threats by linking otherwise de-identified data with nominal identifiers to contact individuals to seek consent.
    b. There is a risk of inflicting psychological, social or other harm by contacting individuals or families.
3. There is a scientifically and ethically justifiable rationale why the research could not be conducted with a population from whom consent can be obtained.
4. Practicability should not be determined solely by considerations of convenience, cost, or speed.

Reference: https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2008-january-31-letter/index.html

INVESTIGATOR QUALIFICATIONS

Questions for consideration, if applicable:

1. The PI must include their CV/resume/NIH Bio-Sketch
2. Is the PI qualified to conduct and oversee the research?
   Note: Review CV if not familiar with the investigator.
3. Does the PI need to submit an updated CV?
4. Does the PI have the required PI Status?
5. Should other investigators be added to the study?
6. If multiple PIs are used in this project, are there any concerns with the roles, responsibilities or relationship to the primary PI?

Check the following websites when applicable or concerned:

- *Compliance and enforcement lists posted on FDA's website*
- *Clinical Investigator Status (Biologics)*
- *Inspection Classification Database Search*
- *Clinical Investigators - Disqualification Proceedings*
- *Inspections, Compliance, Enforcement, and Criminal Investigations*

DATA AND SAFETY MONITORING PLAN

Questions for consideration, if applicable:

1. Is it appropriate for this research to include a plan to monitor the data collected to ensure the safety of research participants?
2. Has the sponsor or other entity established a Data and Safety Monitoring **Board** (DSMB)?

3. If no DSMB, is the Data and Safety Monitoring **Plan** appropriate?
4. Is an external or independent committee required?
5. Is the proposed composition appropriate?
6. If not, what composition is recommended?

CONSIDERATIONS FOR RECRUITMENT, REFERRAL, SCREENING, ADVERTISING, & INCENTIVES

For more information, see IRB Guidance on "Recruitment, Referral, Screening, Advertising, and Incentives"

Questions for consideration, if applicable:

1. Are the methods for participant recruitment clearly outlined in the protocol?
2. Is voluntariness of participation ensured?
3. Is voluntariness of participation ensured?
4. Are privacy protections in place?
5. Is the process for making referrals appropriate?
6. Are recruitment materials and advertising acceptable?
7. Have efforts been made to minimize undue influence and coercion?
8. Are recruitment incentives (compensation, reimbursements) appropriate?

DEPARTMENT CHAIR/DEAN & ANCILLARY REVIEWS:

1. The Downstate Department Chair or Dean must review and approve all applications, prior to IRB approval. For details, see Step 15 at: SUNY Downstate ORA IRB - Electronic Submissions
2. Ancillary reviews by various departments or committees may be required as an administrative process for Downstate policy or at the discretion of the IRB for any human research protection concern. Examples of Ancillary Reviews may include Central Methodology Review Committee (CMRC), UHB Pathology Laboratories Services, Institutional Biosafety Committee (IBC), NIH Novel and Exceptional Technology and Research Advisory Committee (NExTRAC), Downstate Research Pharmacy, or others when applicable. For details, see Step 16 at: SUNY Downstate ORA IRB - Electronic Submissions

CONFLICT OF INTEREST DISCLOSURES

For details, see Step 6 at: Electronic Submissions | Institutional Review Board | Office of Research Administration | SUNY Downstate

TRAINING REQUIREMENTS

For details, see Step 6 at: Electronic Submissions | Institutional Review Board | Office of Research Administration | SUNY Downstate

ETHICAL CONSIDERATIONS

Questions for consideration, if applicable:

1. Is the research guided by the ethical principles set forth in the Belmont Report?
2. Are there any other concerns related to other applicable principles of professional conduct or ethical codes (e.g. Downstate Code of Ethics and Business Conduct, Nuremburg Code, Declaration of Helsinki)?
   NOTE: The Declaration of Helsinki is followed in Clinical Trials which follow ICH-GCP Standards.

INTERNATIONAL RESEARCH CONSIDERATIONS

Questions for consideration, if applicable:

1. Does the PI address all applicable international data or privacy regulations, human research regulations, and local human research policies? Resource: International Compilation of Human Research Standards | HHS.gov
2. Does the research have approval by a local IRB/IEC approval at the host site?

3. Are culturally appropriate access/permissions to the community acceptable, based on cultural norms and laws at the host site?
4. Are appropriate strategies implemented to mitigate risks to participants based on local culture, politics, and economic concerns?
5. Is the consent process appropriate and conducted in the language of the local participants?
6. Is a local participant advocate required and available for participants and if so, is their specific role appropriate?

IRB GUIDANCE

Consider other IRB Guidance and Policy posted at: Institutional Review Board Policies | SUNY Downstate Health Sciences University

Policy:

- ✓ Policy IRB-01 (2/3/2021)
- ✓ Summary of updates (2/3/2021)

IRB Guidance for Investigators:

- ✓ Applicable Clinical Trial (ACT) Checklist
- ✓ Belmont Report
- ✓ COI Requirements
- ✓ CITI Program
- ✓ Data Security
- ✓ Definitions for Clinical Trials
- ✓ Determining which IRB to Use, which Agreements are required, and which IRB fees to budget
- ✓ Enrolling or Excluding Pregnant People, Contraception, Pregnancy Testing, and Partners of Participants Who Become Pregnant
- ✓ FDA Guidance
- ✓ Fee Schedule
- ✓ Form 11-A4 Guidance (How to successfully submit and get approval for Form 11-A4: Application for Determination Letter (IRB Decision Aid) for "Not Research, Not Human Research, or Institution Not Engaged in Human Research"
- ✓ Genome-Wide Association Studies (GWAS- NIH)
- ✓ GWAS FAQs (NIH)
- ✓ ICH GCP (E6 R3) 2025
- ✓ IRB Member Nomination
- ✓ Injury Language
- ✓ IRBNet (IRB Application and Reporting System)
- ✓ Lay-Person Summary
- ✓ Levels of IRB review
- ✓ Local Context for Reviewing (External) IRB
- ✓ Military Health System Research Protections (DHA Office of Research Protections)
- ✓ Obtaining Legally Effective Informed Consent and HIPAA Research Authorization
- ✓ Office for Human Research Guidance (Alphabetical List)
- ✓ Quality Assessment Program
- ✓ Quality Assessment Program -Template Letters to PI
- ✓ Qualtrics Survey Software
- ✓ Recruitment, Referral, Screening, Advertising, and Incentives
- ✓ Rescinding COVID-19 Risk Mitigation Strategies
- ✓ REDCap: Research Data Capture and Analysis System
- ✓ Students, Residents, Fellows, Volunteers, or Employees as Research Participants
- ✓ Training Requirements
- ✓ Veterans Affairs Office of Research and Development
- ✓ Zoom to Teams/Doxy.Me IRB Amendment

Select SUNY Downstate Policy:

- ✓ UHB Policies
- ✓ RFDMC-01: Research Conflict of Interest Policy
- ✓ PHA-11: Investigational Drug/Dispensing and Utilization
- ✓ SUNY Downstate Office of Compliance and Audit Services
- ✓ SUNY Downstate Health Sciences University Information Services Policies and Procedures (HIS 1-12)
- ✓ HIS-13: Encryption and Decryption Policy
- ✓ SUNY Downstate Health Sciences University - Language Services to Patients with Limited English Proficiency
- ✓ SUNY Downstate HIPAA (Health Insurance Portability and Accountability Act) Policies and Forms
- ✓ Select HIPAA policies and forms:
  - o Researcher Certification for Reviews Preparatory to Research
  - o Certification for PHI of Decedents
  - o Business Associate Agreements (BAA) Policy (HIPAA-3)
  - o BAA Template Form
  - o HIPAA De-Identification of Information (HIPAA-6)
  - o Minimum Necessary Guidelines (HIPAA-15)
  - o Use of Limited Data Sets (HIPAA-27)
  - o Data Use Agreement (DUA) Template
  - o Uses and Disclosures for Research Purposes (HIPAA-28)

Select SUNY RF Polices:

- ✓ SUNY RF Policies A to Z
- ✓ SUNY RF Acceptable Use and Security of RF Data and Information Technology
- ✓ SUNY RF Best Practices: Research Involving Human Subjects
- ✓ SUNY RF Human Subject Payments
- ✓ SUNY RF Records Access Policy
- ✓ SUNY RF Records Management Policy