

**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 the IRB at 718-613-8480 or IRB@downstate.edu

Applicability of Key Regulations

1) Use the table below to determine which key regulations apply to a specific human research study:

Guidelines:	Key Regulations:
<p>Downstate certifies the following to the NYS Department of Health:</p> <ul style="list-style-type: none"> • Downstate conducts human research that is subject to policies and regulations promulgated by any agency of the federal government for the protection of human research participants; • Downstate conducts or proposes to conduct or authorize human research that is not subject to any policies and regulations promulgated by any agency of the federal government for the protection of 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. 	<p>NYS Article 24A.</p>
<p>Downstate applies the 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 regulations.</p> <p>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).</p> <p><i>Note: Downstate does not apply exemption category 7 or 8 to research. Downstate does not have a policy for the use of Broad Consent under these exemption categories.</i></p>	<p>Common Rule (July 19, 2018 edition of 45 CFR 46) (45 CFR 46, Subpart A).</p> <p>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 Common Rule) on July 19, 2018. Refer to the OHRP website regarding the Revised Common Rule for additional information.</p>

<p>Federal Expedited review categories apply, when applicable.</p> <p>Subparts B, C, D, and E apply when applicable, as indicated within the regulations.</p> <p>Research approved 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.</p> <p><i>Note: The 2018 Common Rule does not apply to FDA-regulated and DOJ-supported research.</i></p>	
<p>U.S. Department of Justice (DOJ) regulated research.</p>	<p>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.</p>
<p>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.</p> <p>FDA exemptions apply to FDA regulated clinical investigations, when applicable.</p> <p>Federal Expedited review categories apply, when applicable.</p>	<p>Applicable FDA regulations apply to the research as defined by the FDA (e.g., clinical investigations that must comply with 21 CFR 50, 56, 312, 320, 812, 814, etc.)</p>
<p>Research conducted or supported by a Federal Department or Agency.</p>	<p>Apply any additional requirements from Federal Departments or Agencies, when they fund or conduct the research.</p>
<p>HIPAA Privacy and Security Rules.</p>	<p>The HIPAA Privacy & Security Rules (45 CFR Parts 160, 162, and 164) applies to any research involving Protected Health Information (PHI), also known as Individually Identifiable Health Information (IHII).</p>
<p>2) Other regulations and policy: Regardless of the key regulation that applies to the research as indicated above, other regulations and policy apply as noted below:</p>	

- The [HIPAA Privacy Rule \(45 CFR Parts 160, 162, and 164\)](#) applies to any research involving Protected Health Information (PHI), also known as Individually Identifiable Health Information (IIHI).
- When required by the NIH or sponsor, investigators must follow the principles of [Good Clinical Practices](#) when conducting clinical trials.
- The IRB and investigators must comply with Policy IRB-01 and all other applicable DMC policies pertaining to research, including those of the [DMC Office of Compliance and Audit Services \(OCAS\)](#).
- Principal Investigators (PI) and *investigators for the purposes of conflict of interest (COI)*, as determined by the PI, must follow the [NIH regulations on financial Conflicts of Interest](#), as outlined in [DMC Conflict of Interest Policy](#). Investigators who are not employees of DMC must comply with their institution’s COI policy. For additional information, please see the IRB guidance: [Training and COI Disclosures](#).
- The DMC follows law passed by the official governing body of an American Indian or Alaska Native tribe and any foreign law or regulation when applicable to the research that provide additional protections for research participants.
- Additional regulations, which may be applicable to certain research, as determined by the IRB.

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.

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 populations that are vulnerable by virtue of their condition or circumstances.

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).

For further guidance, here is the link to The Secretary’s Advisory Committee on Human Research Protections (SACHRP) Attachment A: Recommended Guidance on Minimal Risk Research and Informed Consent: <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2015-september-28-attachment-a/index.html>

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 Investigators Brochure (IB) present? (Required for ICH-GCP trial)

Medical device studies:

Questions for consideration, if applicable:

1. Does this study evaluate the safety and effectiveness of a “medical device”?
2. *If yes to (1), does 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?
5. Does the IRB need to see a package insert for the medical device?

Criteria for IRB approval of (Non-Exempt) Research:

The following requirements must be satisfied to approve non-exempt human research:

- 1) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(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.**

Note: To evaluate the above for a clinical investigation involving an IND, the IRB may wish to obtain and review the following information, as applicable for the review:

- *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 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 take into account the purposes of the research and the setting in which the research 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 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](#).

(5) **Informed consent will be appropriately documented or appropriately waived** in accordance with [§46.117](#).

(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.**

(i) The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.

(ii) [Reserved.]

(8) For purposes of conducting the limited IRB review required by [§46.104\(d\)\(7\)](#), the IRB need not make the determinations at paragraphs [\(a\)\(1\)](#) through [\(7\)](#) of this section, and shall make the following determinations:

(i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of [§46.116\(a\)\(1\)-\(4\)](#), [\(a\)\(6\)](#), and [\(d\)](#);

(ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with [§46.117](#); and

(iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

- 2) **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.**
- 3) 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](#).
- 4) In order to approve FDA regulated clinical investigations involving some or all research participants that include children, the IRB must also ensure the research is in compliance with regulations to the extent required by [21 CFR 50, subpart D](#).
- 5) 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.
- 6) For investigational device studies, the IRB's determination that a device study is significant risk (SR) or non-significant risk (NSR) can be made at a convened meeting. A SR device study must have an IDE from the FDA before the IRB can approve the investigation.
- 7) 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](#)
- 8) Additional criteria must be met when a study is funded or conducted by
- a) NIH
 - i) [Single IRB Review for multi-site studies](#)
 - ii) [Certificate of Confidentiality](#)
 - b) [VA VHA Handbook 1200.05](#)
 - c) [Department of Defense](#)
 - d) [Department of Justice](#)
- 9) Congruency review of federal grant is required for research funded by DOJ or when following the PRE-2018 Common Rule.
- 10) Clinical investigations for measuring bioavailability or demonstrating bioequivalence shall be subject to principles and requirements of [21 CFR 320](#).
- 11) 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 course of 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."

12) For clinical trials which follow [ICH-GCP](#) requirements¹, the following IRB review requirements must be met:

- a) An IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects. Special attention should be paid to trials that may include vulnerable subjects. **(3.1.1)**
- b) The IRB/IEC should obtain the following documents: trial protocol(s)/amendment(s), written informed consent form(s) and consent form updates that the investigator proposes for use in the trial, subject recruitment procedures (e.g., advertisements), written information to be provided to subjects, Investigator's Brochure (IB), available safety information, information about payments and compensation available to subjects, the investigator's current curriculum vitae and/or other documentation evidencing qualifications, and any other documents that the IRB/IEC may need to fulfil its responsibilities. **(3.1.2)**
- c) The IRB/IEC should consider the qualifications of the investigator for the proposed trial, as documented by a current curriculum vitae and/or by any other relevant documentation the IRB/IEC requests. **(3.1.3)**
- d) The IRB/IEC should conduct continuing review of each ongoing trial at intervals appropriate to the degree of risk to human subjects, but at least once per year. **(3.1.4)**
- e) The IRB/IEC may request more information than is outlined in paragraph 4.8.10 be given to subjects when, in the judgement of the IRB/IEC, the additional information would add meaningfully to the protection of the rights, safety and/or well-being of the subjects. **(3.1.5)**
- f) When a non-therapeutic trial is to be carried out with the consent of the subject's legally acceptable representative (see 4.8.12, 4.8.14), the IRB/IEC should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials. **(3.1.6)**
- g) Where the protocol indicates that prior consent of the trial subject or the subject's legally acceptable representative is not possible (see 4.8.15), the IRB/IEC should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials (i.e., in emergency situations). **(3.1.7)**

¹ NOTICE OF GCP COPYRIGHT: Information regarding GCP requirements is from: International Council for Harmonisation (ICH) Harmonized Guideline: [Integrated Addendum to ICH E6 \(R1\): Guideline for Good Clinical Practice E6 \(R2\)](#).

- h) The IRB/IEC should review both the amount and method of payment to subjects to assure that neither presents problems of coercion or undue influence on the trial subjects. Payments to a subject should be prorated and not wholly contingent on completion of the trial by the subject. **(3.1.8)**
- i) The IRB/IEC should ensure that information regarding payment to subjects, including the methods, amounts, and schedule of payment to trial subjects, is set forth in the written informed consent form and any other written information to be provided to subjects. The way payment will be prorated should be specified. **(3.1.9)**

Categories of permissible research for children	Evaluation	Requirements
Category 404 (45 CFR 46.404 and 21 CFR 50.51)	<ul style="list-style-type: none"> ✓ No greater than minimal risk 	<ul style="list-style-type: none"> ✓ Permission of one parent/guardian ✓ Assent
Category 405 (45 CFR 46.405 and 21 CFR 50.52)	<ul style="list-style-type: none"> ✓ 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. 	<ul style="list-style-type: none"> ✓ Same as 404
Category 406 (45 CFR 46.406 and 21 CFR 50.53)	<ul style="list-style-type: none"> ✓ 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 ✓ 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 	<ul style="list-style-type: none"> ✓ 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 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)	<ul style="list-style-type: none"> ✓ 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. 	<ul style="list-style-type: none"> ✓ Includes 406 requirements ✓ OHRP (or by the FDA, if FDA regulated) must

		also approve the research
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Categories of permissible research for prisoners:

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.

This is an epidemiological study that meets the criteria for a waiver as described below:

[Health and Human Services has waived the applicability of 45 CFR 46.305\(a\)\(1\) and 46.306\(a\)\(2\)](#) for certain research conducted or supported by HHS that involves epidemiological studies that meet the following criteria:

1. In which 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. Where the IRB has approved the research and has fulfilled its duties 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. 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).
4. 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.

In order for a 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 research participants and to maintain the confidentiality of the data.

Screening, Recruitment, or Determining Eligibility:

CAUTION: This section does not apply to FDA or DOJ regulated research.

The Downstate may approve a research protocol in which an investigator will obtain information or biospecimens for screening, recruiting, or determining the eligibility of prospective research participants or the LAR/surrogate, when one of the following conditions are met; however, a HIPAA waiver may still be required,

- The investigator will obtain information through oral or written communication with the prospective research participant or the LAR/surrogate, OR
- The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

Questions to consider:

1. Is a HIPAA waiver required?

2. Is a HIPAA Authorization required?
3. Should the research use Research Subject Recruitment Authorization Forms: These forms may be used to obtain contact information for patient recruitment through their clinicians. Refer to Policy HIPAA-28: Use and Disclosure for Research Purposes.
 - Subject Recruitment Authorization - Internal Authorization for Recruitment Contact
 - Subject Recruitment Authorization - Internal Verbal Authorization for Recruitment Contact
 - Subject Recruitment Authorization - External Authorization for Recruitment Contact

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. Does the research need to comply with Family Educational Rights and Privacy Act (FERPA)?
4. Does the research need to comply with Protection of Pupil Rights Amendment (PPRA)?
5. Does the research need to comply with Children's Online Privacy Protection Act (COPPA)?
6. Must the research be approved by the NYC Department of Education IRB?

For more information, consult with the IRB Guidance: Students, Residents, Fellows, Employees, or Volunteers as Research Participants.

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

IRB application materials

Are there any concerns with any of the applicable application materials?

1. IRBNet Registration Form
2. IRB Application
3. Protocol
4. Informed Consent Form (with HIPAA Authorization)

Note: Please use confirm use of version date of 12.26.2018 (or later) for any NEW research approval on or after 1.21.2019. Be sure to require additional modifications based on regulatory requirements if using prior version for NEW studies.
5. Information Sheet (no PHI/no signatures)
 - a. If applicable, ensure documentation of IC is waived and/or HIPAA waiver/alteration is provided and meet criteria for waivers
6. Information Sheet/HIPAA Authorization
 - a. Include signatures on form, unless HIPAA waiver/alteration is provided
7. Pregnancy Follow-Up Consent Form
8. Consent Addendum for SUNY RF Payment
9. Consent Form Addendum for NCI CIRB Approved Clinical Trials
10. Assent Form (generally required for 7-12 y/o participants)
11. 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
12. 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.
13. Telephone or other verbal recruitment script(s)
14. HIPAA Preparatory to Research Certification
15. Data Use Agreement (DUA) – Require for activities involving limited data sets.
16. Business Use Agreement (BAA) –Require for activities involving business associates.
17. HIPAA Waiver
18. Waiver of Informed Consent Requirements
19. Honest Broker Agreement
20. Recruitment Materials Recruitment Materials
 - a. Include flyers, brochures, ads, e-mails, telephone or verbal script, web site materials, social media postings, etc.
 - b. NOTE: Any Downstate representation on social media must be authorized by SUNY Downstate’s Office of Institutional Advancement after IRB approval is granted. See: <http://www.downstate.edu/policy/>
21. Questionnaires or Surveys
22. Data Collection Tools
23. For Clinical Investigations involving an investigational drug, requiring an IND:
 - a. FDA Form 1572
 - b. IND Letter
 - c. Investigator Brochure
24. 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
25. Scientific Review Committee Worksheet
26. CV or Biosketch of PI: Required for clinical trials that follow GCP. Generally optional, unless the PI is new; however, the IRB may request CV to evaluate the PI’s qualifications, as required by the FDA and OHRP regulations.
27. Credentials of PI or other study staff. Generally not needed, unless the IRB needs to evaluate qualifications of research staff.
28. Sponsor contract. Generally not needed, unless the IRB needs to review language in the informed consent regarding injuries, additional costs, or disclosures requirements of EU GDPR or confirm additional data security requirements for research that follows EU GDPR.
29. Other

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. Are data stored behind the Downstate firewall?
6. Are encrypted laptop and thumb drives used?
7. Are employee controls adequate?

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.

Legally Effective Informed Consent or HIPAA Research Authorization:

Note: Suggested language is included in the informed consent template posted on the IRB website.

e) Informed Consent Requirements

a) *General.* General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) through (d) of this section. Broad consent may be obtained in lieu of informed consent obtained in accordance with paragraphs (b) and (c) of this section only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. 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 is described in paragraph (e) of this section. General waiver or alteration of informed consent is described in paragraph (f) of this section. Except as provided elsewhere in this policy:

(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) Except for broad consent obtained in accordance with paragraph (d) of this section:

(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 as a whole 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 biospecimens** 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.* Except as provided in paragraph (d), (e), or (f) of this section, one or more of 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 course of 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;**

d) When seeking informed consent for an "Applicable Clinical Trial", as defined FDA Amendments Act of 2007 (FDAAA); the following statement must be included in the informed consent documents and should be included in the information sheet, when documentation of informed consent is waived by the IRB: "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."

e) **SUNY RF PAYMENT CONSENT:**

Required for research payments (including travel reimbursement) of either

1) \$600 or more in a calendar year, or

2) more than \$100 per study visit

f) Include **HIPAA authorization language** with the informed consent to cover the uses and disclosures of Protected Healthcare Information (PHI) or Individual Identifiable Healthcare Information (IIHI), including when such information is about specimens.

i. The following core elements must be present in plain language for a research authorization to be valid:

1. 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.

2. 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.)
 3. 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?
 4. Description of each purpose for which the specific PHI identified earlier is to be used or disclosed
 5. 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”)
 6. 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).
- ii. The following statements must be included:
1. A statement that the individual may revoke the authorization in writing at any time (except to the extent that a provider has taken action in reliance of the authorization), and instructions on how to exercise such right (who does the individual need to write, name and address)
 2. 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.*
3. 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
- iii. There are additional requirements for authorizations for using PHI for marketing purposes, sale of PHI, or for the use or disclosure of psychotherapy notes. Contact the IRB or Privacy Officer for additional information or refer to [SUNY Downstate HIPAA \(Health Insurance Portability and Accountability Act\) Policies and Forms](#).
- iv. For additional information see:
1. [DMC HIPAA-28 Policy: Uses and Disclosures for Research Purposes](#)
 2. [DMC HIPAA-32 policy: Uses and Disclosures Requiring Patient Authorization](#).

g) When appropriate, include one or more of the following additional elements in the informed consent document:

- a. A statement that the particular treatment or procedure may involve risks that are currently unforeseeable to the participant (or to the embryo or fetus, if the participant is or may become pregnant);
- b. Anticipated circumstances under which participation in the research may be terminated by the investigator without regard to the research participant’s or LAR/surrogate’s consent;
- c. Any additional costs to the participant that may result from participation in the research;
- d. The consequences of a participant’s decision to withdraw from the research and procedures for orderly termination of participation;
- e. A statement that significant new findings developed during the course of the research that may relate to the participant’s willingness to continue participation will be provided to the participant;

- f. The number of participants (approved by the IRB) to be involved in the study. For multi-site studies, it is best to indicate both the number that will be enrolled at the local site and all sites.
- g. When applicable to the research include the following:
 - i. A statement that the research participant's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the research participant will or will not share in this commercial profit;
 - ii. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to research participants, and if so, under what conditions; or
 - iii. 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).
 - iv. Any requirements of any applicable federal, state, or local law.
 - v. Any requirements of any applicable tribal law passed by the official governing body of an American Indian or Alaska Native tribe

h) Elements of Informed Consent for Diagnostic Genetic Tests

- i. The IRB recommends using a tiered consent option for diagnostic genetics test that is part of the informed consent template.
- ii. For studies involving genetic testing (or possible genetic testing) for diagnostic purposes (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.
 - 1. A general description of the test;
 - 2. A statement of the purpose of the test;
 - 3. 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.

- 4. The name of the person or categories of persons or organizations to whom the test results may be disclosed;
- 5. 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.
- 6. If the research permits such degree of specificity, include the following:
 - a. 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;
 - b. A general description of each specific disease or condition tested for;
 - c. The level of certainty that a positive test result for that disease or condition serves as a predictor of such disease.
 - d. A description of the policies and procedures to protect patient confidentiality;
 - e. 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;
 - f. A statement allowing individuals to consent to future contact for any or all purposes, including the following:
 - i. research purposes;
 - ii. provision of general information about research findings;
 - and

- iii. 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
- iv. a statement explaining the benefits and risks of consenting to future contact

i) Future Use of Specimens or Information

- i. Specify whether specimens or information will be stored for future studies. See Informed Consent template for suggested language.
- ii. In general, the IRB does not permit “unspecified future use.”
- iii. Present the use or disclosure of identifiable (or coded) information/specimens for future either as an optional provision (e.g., tiered consent) or as a separate optional consent form. 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 his/her Protected Health Information (PHI) for such future research.

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 be required for future research.

- iv. If applicable, include an option for future contact to invite participates to consider other research.

j) Consent Addendum for SUNY RF Payment

- a. The Consent Addendum for SUNY RF Payment must be included with an IRB submission when providing compensation (including travel reimbursements) to research participants of \$600 or more per calendar year or more than \$100 per study visit.

k) Obtaining Informed Consent from Individuals with Limited English-Speaking Proficiency (LEP)

- a. The information given to the research participant or the representative shall be in language understandable to the research participant or the representative.
- b. Unless waived by the IRB, the consent form may be either of the following, as approved by the IRB:
 - i. A written informed consent document that meets all the requirements outlined above. The investigator shall give either the participant or the LAR/surrogate adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the research participant or the LAR/surrogate.
 - ii. A short (written informed consent) form stating that the elements of informed consent required above have been presented orally to the participant or the participant’s LAR/surrogate and that key information that is most likely to assist a prospective research participant or LAR/surrogate in understanding the reasons why one might or might not want to participate in the research was presented first to the research participant, before other information, if any, was provided.
 - iii. When this method is used, there shall be a witness to the oral presentation.
 - iv. Also, the IRB shall approve a written summary, if the entire consent is not read, of what is to be said to the research participant or the representative.
 - v. The short form itself is to be signed by the participant or the representative.
 - vi. The witness shall sign both the short form and a copy of the summary (or consent form), and the person obtaining consent shall sign a copy of the summary (or consent form).
 - vii. A copy of the summary (if used) and the consent form shall be given to the participant or the representative, in addition to a copy of the short form.
 - viii. For additional guidance, including how to obtain translations, please refer to the IRB Guidance document on [Obtaining Legally Effective Informed Consent and HIPAA Research Authorizations](#).

l) Informed Consent Process

- a. 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.
- m) A researcher must obtain informed consent (parental or legal guardian permission) for research involving Newborn Screening Spots when receiving federally funding.**
- a. The IRB considers all HHS supported or conducted research using newborn dried blood spots to be human research regardless of whether the specimens are identifiable.
 - b. The IRB may NOT waive informed consent under for research involving newborn dried blood spots for HHS supported or conducted research.
 - c. For more information, please see [The Newborn Screening Saves Lives Reauthorization Act of 2014](#).
- n) Lines should be added for the Names (no signature nor date) for the following individuals, when applicable for the research:**
- a. **Child under 13.**
 - b. **Cognitively impaired adult.**
- o) Lines should be added for the Names, Signatures, and Dates, 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 category 406 & 407 research.
 - d. **Emancipated Minor.** 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.
 - e. **Married Minor.**
 - f. **Independent Consent Monitor.** Required when enrolling an Emancipated Minor [when the research does not involve a clinical treatment (e.g., "survey" on HIV or STD) for an emancipated minor], Married Minor, or a Ward. An Independent Consent Monitor may not be a member of the research team.
 - g. **Adult Research Participant.** For adults who are 18 years of age or older
 - h. **Personal Representative (Legally Authorized Representative).** Required when obtaining surrogate consent for enrolling adults who are cognitively impaired.
 - i. **Interpreter.** Required when there are plans to enroll participants with individuals who have Limited English Proficiency or communicate with sign language.
 - j. **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.
 - k. **Impartial Witness.**
 - i. Required for a Clinical Trial that follows ICH-GCP requirements when enrolling non-English reading research participants. May be required by a sponsor for enrolling other vulnerable populations such as cognitively impaired adults.
 - ii. Recommended for any situation that requires a "witness" as indicated above.
- p) The following are not requirements but may also be considered based on guidance/practices, if applicable:**

- a. To the extent possible, explain technical, medical, and scientific concepts in lay terms that are understandable to someone who is educated to the 6th to 8th grade level. 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 in separate sentences.
 - b. Consider adding pictures, diagrams, tables, or charts if they will improve understanding.
 - c. Avoid the use of the first-person tense (e.g., "I understand that ..."), as it can be interpreted as suggestive, may be relied upon as a substitute for sufficient factual information, and can constitute coercive influence over a subject. It is OK to use the first-person tense in the signature lines of the consent form.
 - d. Avoid the passive tense.
 - e. When applicable, change the title in header (e.g., PARENTAL PERMISSION, HEALTHY VOLUNTEER INFORMED CONSENT, etc.).
 - f. Remove references to "NYC Health + Hospitals, Kings County" in the header and throughout this form if they are not involved in the research.
 - g. Use bold text and/or boxes around critical text for emphasis.
 - h. Provide the names of the sponsor(s) and the institution(s) that support the study (Downstate Medical Center and/or NYC H+H, Kings County).
 - i. Describe the standard of care options offered, if the participant does not wish to participate.
 - j. Description of prohibited materials (medications, supplements, biologics, devices)
 - k. Description of exclusion criteria.
 - l. Information about pregnancy testing and/or birth control requirements.
 - m. Information about pregnancy follow-up studies.
 - n. Description of the consequences of withdrawing from the study.
 - o. Description of financial relationships or interests or conflict of interest management plans.
 - p. Description of specimens or information may be stored for future studies.
 - q. Include a tiered consent for optional research.
 - r. Include permission to collect contact information for a personal representative.
- NOTE: Requires a waiver of informed consent to collect this information.*
- s. Include option to provide contact information of the research participant or legally authorized representative.
 - t. The amount and schedule of all payments to the participant.
 - u. Include language regarding any anticipatable incidental finding. For more information see Downstate Guidance on Legally Effective Informed Consent or the Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) report: [Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to Consumer Contexts](#), the primer for [IRB Members: Incidental and Secondary Findings](#), or the primer for [Researchers: Incidental and Secondary Findings](#).
 - v. Include a version # or version date.
 - w. For FDA regulated research, the "date" of the signature must be included; however, a date always be included.

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 effected, done or put into practice; and that may be practiced or performed;
- 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 threats to privacy by having to link otherwise de-identified data with nominal identifiers in order 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. Is the PI qualified to conduct and oversee the research?
Note: Review CV if not familiar with the investigator.
2. Does the PI need to submit a CV?
3. Does the PI have the required PI Status?
4. Should other investigators be added to the study?
5. 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:

- o [Compliance and enforcement lists posted on FDA's website](#)
- o [Clinical Investigator Status \(Biologics\)](#)
- o [Inspection Classification Database Search](#)
- o [Clinical Investigators - Disqualification Proceedings](#)
- o [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 no, 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:

The Downstate Department Chair or Dean must review and approve the following types of applications, prior to IRB approval:

- IRB Applications for Exempt review, Expedited review, Full Board review, or External IRB Oversight
- Application for a HUD for Clinical Purposes
- Application for Expanded Access to Investigational Drug/Biologic for treatment

For details, see Step 15 at: [SUNY Downstate ORA IRB - Electronic Submissions](#)

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: [SUNY Downstate ORA IRB - Electronic Submissions](#)

Training Requirements

For details, see Step 6 at: [SUNY Downstate ORA IRB - Electronic Submissions](#)

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](#), [Nuremburg Code](#), [Declaration of Helsinki](#))?
NOTE: The Declaration of Helsinki is followed in Clinical Trials which follow ICH-GCP Standards.

IRB Guidance:

Consider other IRB Guidance as posted on the [IRB website](#):

- [Consolidated IRB guidance related to COVID-19](#)
- [Applicable Clinical Trial \(ACT\) Checklist](#)
- [Belmont Report](#)
- [Data Security](#)
- [FDA Guidance](#)
- [Enrolling or Excluding Pregnant People, Contraception, Pregnancy Testing, and Partners of Participants Who Become Pregnant](#)
- [Fee Schedule](#)
- [Genome-Wide Association Studies \(GWAS- NIH\)](#)
- [GWAS FAQs \(NIH\)](#)
- [ICH GCP \(E6-R2\) 2016](#)

- [IRBNet \(IRB Application and Reporting System\)](#)
- [Lay-Person Summary](#)
- [Local Context for Reviewing \(External\) IRB](#)
- [Material Transfer Agreements](#)
- [Military Health System Research Regulatory Oversight Office](#)
- [Obtaining Legally Effective Informed Consent and HIPAA Research Authorization](#)
- [Office for Human Research Guidance \(Alphabetical List\)](#)
- [Qualtrics Survey Software](#)
- [Recruitment, Referral, Screening, Advertising, and Incentives](#)
- [REDCap: Research Data Capture and Analysis System](#)
- [Students, Residents, Fellows, Volunteers, or Employees as Research Participants](#)
- [Veterans Affairs Office of Research and Development](#)