**GUIDANCE FOR IRB MEMBERS:**

**INITIAL REVIEW OF A FULL BOARD OR EXPEDITED STUDY**

- Respect for Persons
- Beneficence
- Justice

- This guidance document will aid the IRB Member in completing a meaningful and substantive review.
- Please either attach a completed “IRB Member Checklist for Initial Review of a Full Board or Expedited Study” form OR enter all comments to the reviewer note section in IRBNet.
- For more information please refer to regulations, Policy IRB-01, guidance, or contact the IRB at 718-613-8480 or IRB@downstate.edu

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**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](https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2015-september-28-attachment-a/index.html)

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**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:**

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<tr>
<th>Number</th>
<th>Question</th>
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<tbody>
<tr>
<td>1.</td>
<td>Does this study evaluate the safety and effectiveness of a “medical device” study?</td>
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<tr>
<td>2.</td>
<td><em>If yes to (1), does the study meet the criteria for IDE Exemption [21 CFR 812.2(c)]?</em></td>
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</table>
| 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 see a Device Package Insert for an IDE study? |

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

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

1. Risks to research participants are minimized:
   a) by using procedures which are consistent with sound research design and which do not unnecessarily expose research participants to risk, and
   b) whenever appropriate, by using procedures already being performed for diagnostic or treatment purposes.
2. Risks to research participants are reasonable in relation to anticipated benefits, if any, to research participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB considers only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies research participants would receive even if not participating in the research). The IRB does 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 research participants is equitable. In making this assessment the IRB takes into account the purposes of the research, the adequacy of inclusion and exclusion criteria, and the setting in which the research will be conducted. The IRB is particularly cognizant of the special problems of research that involves a category of research participants who are vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, and handicapped individuals.
4. Informed consent (and HIPAA research authorization, when applicable) will be sought from each prospective research participant or his/her legally authorized representative (LAR), in accordance with, and to the extent required by the federal regulations and will be appropriately documented, unless waived.
   a) The IRB members review the informed consent document to ensure all required elements and appropriate additional elements are provided to the research participant at the time of initial review.
   b) At the time of continuing review, the IRB must also review the informed consent document to determine if any additional changes are required.
5. Informed consent (and HIPAA research authorization, when applicable) will be appropriately documented or waived in accordance with Policy IRB-01.
6. When appropriate, the research plan must make adequate provision for monitoring the data collected to ensure the safety of research participants.
7. When appropriate, there are adequate provisions to protect the privacy of research participants and to maintain the confidentiality of data.
8. When some or all of the research participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, individuals with impaired decision-making...
capacity, or economically or educationally disadvantaged persons, or handicapped individuals the IRB must evaluate whether additional safeguards have been included in the study to protect the rights and welfare of these research participants based on the IRB application materials. The IRB may require additional safeguards, if needed.

9) 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.

10) 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.

11) 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.

12) 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.

13) 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, Deid Fetus, or Fetal Material
   g) Prisoners

14) 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

15) For clinical trials which follow ICH-GCP requirements, 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 fulfill 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)

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)

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<th>Categories of permissible research for children</th>
<th>Evaluation</th>
<th>Requirements</th>
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| **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  
✓ 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 | ✓ 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) | ✓ 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 |

**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:
   - To describe the prevalence or incidence of a disease by identifying all cases, or
   - 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:
   - The research presents no more than minimal risk and no more than inconvenience to the research participants, and
   - 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.

**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)
5. Information Sheet
6. Information Sheet/HIPAA Authorization
7. Pregnancy Follow-Up Consent Form
8. Consent Form Addendum for NCI CIRB Approved Clinical Trials
9. Assent Form
10. Short Form(s)
11. Phone Script
12. HIPAA Preparatory to Research Certification
13. HIPAA Waiver
14. Waiver of Informed Consent Requirements
15. Subject Recruitment Authorization Form – Internal
16. Subject Recruitment Authorization Form – External
17. Recruitment Materials
18. Questionnaires or Surveys
19. Data Collection Tools
20. FDA Form 1572
21. IND Letter
22. Investigator Brochure
23. IDE Letter
24. Package Insert for IDE Study
25. Scientific Review Committee Worksheet
26. Other

**Study design/statistical considerations:**

Questions for consideration, if applicable:

1. Were there any concerns from the scientific reviewer?
2. Is the protocol methodology scientifically sound and adequately designed?
3. Are the hypotheses, clinical objectives and planned analyses clearly stated?
4. Are the planned interventions and their timing clearly stated?
5. For drug trials, are dosages, changes in dosages, and duration of administration clearly stated?
6. Are the primary and secondary outcome measures defined?
7. Is the sample size projected on the basis of statistical calculation?
8. Are the statistical analyses of outcome measures appropriate?
9. Is the randomization method described and appropriate (if applicable)?

**Data security**

For more information, see [IRB guidance on Data Security](#).

Questions for consideration, if applicable:

1. Are all information security requirements met?
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 lap top 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.
Informed consent requirements:
For more information, see IRB guidance: Obtaining Legally Effective Informed Consent and HIPAA Research Authorization

1) Process requirements:
   a) Except as provided elsewhere in POLICY IRB-01, an investigator may not involve a participant in research covered by this policy, unless the investigator has obtained the legally effective informed consent of the research participant or his/her legally authorized representative (LAR).
   b) An investigator shall seek such consent only under circumstances that provide the prospective participant or the LAR sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
   c) The prospective research participant or LAR should be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
   d) The information that is given to the participant or the LAR shall be in language understandable to the participant or the representative.
   e) No informed consent may include any exculpatory language through which the participant or the LAR is made to waive or appear to waive any of the participant’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

2) The following is required for federally funded or supported research; however, recommended for all studies:
   a) Informed consent should begin with a concise and focused presentation of the key information that is most likely to assist a prospective research participant or LAR 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.
   b) Informed consent as a whole should present information in sufficient detail related to the research, and should 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 LAR’s understanding of the reasons why one might or might not want to participate.

3) When seeking informed consent, the following basic elements of informed consent shall be provided to each prospective participant (unless waived by the IRB):
   a) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant’s participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
   b) A description of any reasonably foreseeable risks or discomforts to the participant;
   c) A description of any benefits to the research participants or to others that may reasonably be expected from the research;
   d) A disclosure of appropriate alternative procedures or courses of treatment, if any alternatives are available, that might be advantageous to the research participant;
   e) A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records (if the research is FDA regulated);
   f) For research involving more than minimal risk, an explanation as to whether there is any compensation for potential study-related injury 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;
   g) An explanation of whom to contact for answers to pertinent questions about the research and research participants’ rights, and whom to contact in the event of a research related injury to the participant;
h) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

i) For research which is federally supported or conducted or when otherwise applicable to the research or when required by the IRB, one of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens should be included:
   i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the research participant or LAR, if this might be a possibility; or
   ii) A statement that the research participant’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

j) When seeking informed consent for an “Applicable Clinical Trial” (see checklist), 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."

k) When Individually Identifiable Health Information (IIHI) or Protected Health Information (PHI) and/or identifiable biospecimens are involved in the study, the required HIPAA authorization language must be included with the informed consent to cover the uses and disclosures of IIHI (or PHI). This language is included in the templates in the IRB Application and Reporting System. For additional information see:
   i) DMC IRB Informed Consent Template or Information Sheet with HIPAA Authorizations
   ii) DMC HIPAA-28 Policy: Uses and Disclosures for Research Purposes

4) When appropriate, one or more of the following additional elements of information must be provided to each research participant or the LAR:
   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’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) For research which is federally supported or conducted or when otherwise applicable to the research or when required by the IRB, the following elements are recommended:
      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).
   h) Any requirements of any applicable federal, state, or local law.
i) Any requirements of any applicable tribal law passed by the official governing body of an American Indian or Alaska Native tribe
j) Include applicable Downstate template language regarding HIV-related information.
k) When the study involves genetic testing for CLINICAL PURPOSES, include all the required statements described for NYS 79-L. **Note:** See informed consent template for details. When genetics testing is done only for research purposes, NYS 79-L does not apply; however, some statements in the ICF template may be helpful to inform the participants.
l) **Certificate of Confidentiality (COC) language** must be added to all NIH studies, or whenever a COC is required or requested.

5) **Diagnostic Genetic Tests:**
   a) Recommend using the tiered consent option for diagnostic genetics test that is part of the informed consent template.
   b) 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.
      i) A general description of the test;
      ii) A statement of the purpose of the test;
      iii) 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.
      iv) The name of the person or categories of persons or organizations to whom the test results may be disclosed;
      v) 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.
   c) If the research permits such degree of specificity, include the following:
      i) 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;
      ii) A general description of each specific disease or condition tested for;
      iii) The level of certainty that a positive test result for that disease or condition serves as a predictor of such disease.
      iv) A description of the policies and procedures to protect patient confidentiality;
      v) 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;
      vi) A statement allowing individuals to consent to future contact for any or all purposes, including the following:
         (1) research purposes;
         (2) provision of general information about research findings; and
         (3) 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
         (4) a statement explaining the benefits and risks of consenting to future contact

6) **Future Use of Specimens or Information**
   a) Specify whether specimens or information will be stored for future studies. See Informed Consent template for suggested language.
b) Do not permit “unspecified future use.”

c) 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.

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

7) HIPAA Authorization (Required when Protected Healthcare Information (PHI) or Individual Identifiable Healthcare Information (IIHI) is involved in the study):

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

i) 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.

ii) 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.)

iii) 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?

iv) Description of each purpose for which the specific PHI identified earlier is to be used or disclosed

v) An expiration date or event (this must be a certain date or an event tied to the individual). For example, a statement provides 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., “until the completion of the research”)

vi) 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).

b) The following statements must be included:

i) 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)

ii) 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.

iii) 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

c) 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.

References: HIPAA Privacy Rule 45 CFR 164.502 & 508(b).
8) **The EU General Data Protection Regulation (GDPR)**, effective 25 May 2018, is a data privacy law applies to certain EU research, including the transfer of private data between countries.
   a) For assistance with determining whether the GDPR regulations apply to this study, please contact the IRB Office or Privacy Officer.
   b) If the EU General Data Protection Regulation (GDPR) is applicable to this study, the investigator should work with the sponsor of the study or the IRB or Privacy Officer to include the appropriate GDPR disclosures.
   c) The IRB must confirm all required disclosures are included in the consent.
   d) Helpful references:
      - [https://www.eugdpr.org/](https://www.eugdpr.org/)

9) A researcher must obtain informed consent (parental or legal guardian permission) for research involving Newborn Screening Spots when receiving federally funding.

10) Lines should be added for the Names of the following individuals:
   a) Child under 13
   b) Cognitively impaired adult

11) Lines should be added for the Names, Signatures, and Dates, as indicated below:
   a) **Child providing assent.** In general, can be added to consent for assent ages 13-17; otherwise an assent document should be used 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) **Pregnant Minor.**
   g) **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, Pregnant Minor, or a Ward. An Independent Consent Monitor may not be a member of the research team.
   h) **Adult Research Participant.** For adults who are 18 years of age or older
   i) **Personal Representative (Legally Authorized Representative).** Required when obtaining surrogate consent for enrolling adults who are cognitively impaired.
   j) **Interpreter.** Required when there are plans to enroll participants with individuals who have Limited English Proficiency or communicate with sign language.
   k) **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

1) Impartial Witness.

i) Required for a Clinical Trial that follows ICH-GCP requirements when enrolling non-English reading research participants.

ii) Recommended (not yet required) for any situation that requires a “witness” as indicated above.

12) 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 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:

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

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.


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:
- 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 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?

**Ancillary Reviews:**

Consider whether ancillary reviews are needed for:
- UHB Pathology
- Institutional Biosafety Committee (IBC)
- NIH Recombinant DNA Advisory Committee (RAC)
- Pharmacy
- Radiology
- Radiation Safety
- Other Department Chair(s)

**Conflict of Interest Disclosures**

Consider the following regarding conflict of interest disclosures:
1. Are all required Annual and Transactional reviewers complete?  
   *Note: The IRB Office checks these and usually places a copy of the check list in the reviewer notes under office workspace, so they may not be visible to other IRB members.*
2. Are Management Plans in place for any Significant Financial Interests?
Note: A study is flagged by IRB Office if there is a SFI reported. A copy of the COI Management Plan that is in place is attached to the submission in the reviewer notes of an IRB Office member.

3. Are appropriate disclosures included in the informed consent document?
   (See COI Management Plan for requirements; however, IRB may be more stringent)

### Training Requirements

Consider whether all required trainings are complete?
(IRB Office checks – see checklist)

### 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.