

**IRB Guidance:
 Obtaining Legally Effective Informed Consent
 and HIPAA Research Authorization**

This guidance is intended for both investigators and IRB members. The key topics outlined in this guidance include:

- Consent form requirements.
- Applicability of Common Rule, FDA, and HIPAA requirements.
- Meeting the requirements of NIH (CoC & GWAS), GPC, NYS diagnostic testing laws, California and Foreign regulations related to privacy and data security.
- Following other requirements and recommendations for Downstate.
- Process for obtaining informed consent and HIPAA research authorization.
- Obtaining consent from those with Limited English Proficiency (LEP).
- Accommodations.
- Re-obtaining consent.
- Considerations for obtaining informed consent from COVID-19 patients.
- Waivers

For more information, please contact the IRB at IRB@downstate.edu

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INTRODUCTION

Guidance on the informed consent requirements and process for obtaining informed consent are provided below. Informed consent templates and information sheet templates are posted at Steps 8 on the [IRB Electronic Submission Process website](#).

This guidance represents the IRB’s current thinking on this topic; however, the use of the word “must” in this document means the concept is a Downstate policy or regulatory requirement.

The use of the word “*should*” in this document means the concept can be treated as guidance or something is recommended or suggested, but not required. An investigator may use an alternative approach if the approach satisfies regulatory requirements.

ELEMENTS OF INFORMED CONSENT AND HIPAA RESEARCH AUTHORIZATION

COMMON RULE REQUIREMENTS

Downstate applies the [Common Rule \(July 19, 2018 edition of 45 CFR 46\)](#) regulations for informed consent for federally funded, conducted, or supported research and to all other research that is not regulated by the FDA or HIPAA regulations.

Research approved prior to January 21, 2019 is grandfathered under the [Pre-2018 Common Rule requirements](#).

Important note: The FDA is in the process of harmonizing the requirements of informed consent with the Common Rule regulations. The Downstate IRB recommends the requirements of the Common Rule be applied to all research.

The items with a (*) in this section indicate which Common Rule requirements are more stringent than the FDA requirements.

IMPORTANT: The NYC H+H, Kings County hospital applies the Common Rule to all research; therefore, when conducting research with Kings County, be sure the informed consent document meets the requirements of the Common Rule.

GENERAL

General requirements for informed consent, under the [Common Rule \(July 19, 2018 edition of 45 CFR 46\)](#), whether written or oral, are described below:

- Unless waived by the IRB, before involving a participant in human research, an investigator shall obtain the legally effective informed consent of the participant or the participant's LAR.
- An investigator shall seek informed 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.
- The information that is given to the participant or the LAR shall be in language understandable to the participant or the LAR.
- (*) The prospective participant or the LAR 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.
- (*) Informed consent must begin with a concise and focused presentation of the **key information** that is most likely to assist a prospective 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.
- (*) 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 participant's or LAR's understanding of the reasons why one might or might not want to participate.
- No informed consent may include any exculpatory language (see below) 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.

EXAMPLES OF EXCULPATORY LANGUAGE (NOT PERMITTED)

The examples below would be in **violation** of the informed consent regulations because the waiver or release has the general effect of freeing or appearing to free an individual or an entity from malpractice, negligence, blame, fault, or guilt.

- I waive any possibility of compensation, including any right to sue, for injuries that I may receive by participation in this research.
- By agreeing to this use, you should understand that you will give up all claim to personal benefit from commercial or other use of these substances.
- I voluntarily and freely donate any and all blood, urine, and tissue samples to the U.S. Government and hereby relinquish all right, title, and interest to said items.
- By consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research.
- I waive any possibility of compensation for injuries that I may receive as a result of participation in this research.
- If you suffer a research-related injury, neither the institution nor the investigator can assume financial responsibility or liability for the expenses of treatment for such injury.
- If you suffer a research-related injury, your medical expenses will be your responsibility or that of your third-party payer.

BASIC ELEMENTS (REQUIRED)

The following information shall be provided to each participant or the legally authorized representative:

- Include the following:
 - A statement that the study involves research.
 - An explanation of the purposes of the research.
 - The expected duration of participation.
 - A description of the procedures to be followed.
 - Identification of any procedures that are experimental.
- A description of any reasonably foreseeable risks or discomforts to the participant.
- A description of any benefits to the participant or to others that may reasonably be expected from the research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained.
- 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.
- 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.
- The following statements:
 - 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 participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
- (*) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 - (*) (a) 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 participant or the legally authorized representative, if this might be a possibility; **or**
 - (*) (b) A statement that the 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.

Note: If option (a) above is included, include the optional authorization for future use within the consent form when PHI is involved in a treatment study. This requirement is based on the HIPAA rule that one cannot require future disclosures in research as a condition of participation in the current treatment study. A compound authorization must clearly differentiate between the conditioned and unconditioned components of the research and provide the participant with an opportunity to opt in or out of the research activities described in an unconditioned authorization. Alternatively, a separate consent form for the optional research may be used.

ADDITIONAL ELEMENTS (WHEN APPLICABLE)

One or more of the following elements of information, when appropriate, shall also be provided to each participant or the LAR:

- A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) that are currently unforeseeable.
- Anticipated circumstances under which participation may be terminated by the investigator without regard to the participant's or the legally authorized representative's consent.
- Any additional costs to the participant that may result from the research.
- The consequences of a participant's decision to withdraw from the research and procedures for orderly termination by the participant.

- 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.
- The approximate number of participants involved in the study.
- (*) A statement that the participant's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the participant will or will not share in this commercial profit.
- (*) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions.
 - Include statements of returning incidental findings. Sample language for such disclosures can be found in the template posted on the IRB website.
- (*) 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).

FDA REQUIREMENTS

Downstate applies the FDA elements of informed consent for FDA regulated clinical investigations (e.g., clinical investigations involving an IND or IDE) as described at [21 CFR 50.25](#), including when the Common Rule or HIPAA regulations apply.

Important note: The FDA is in the process of harmonizing the requirements of informed consent with the Common Rule regulations. The Downstate IRB recommends the requirements of the Common Rule be applied to all research.

The items with a (@) in this section indicate which FDA requirements are more stringent than the Common Rule requirements.

GENERAL REQUIREMENTS FOR INFORMED CONSENT

The following are the general requirements of informed consent under the FDA regulations:

- (@) Except as provided in Emergency Use situations and for IRB approved exceptions from informed consent for Emergency Research, no investigator may involve a human being as a participant in research covered by the FDA regulations unless the investigator has obtained the legally effective informed consent of the participant or LAR.
- An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
- The information that is given to the participant or LAR shall be in language understandable to the participant or LAR.

- No informed consent, whether oral or written, may include any exculpatory language through which the participant or the LAR 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.

BASIC ELEMENTS OF INFORMED CONSENT (REQUIRED)

In seeking informed consent, the following information shall be provided to each participant:

- Include the following:
 - 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 which are experimental.
- A description of any reasonably foreseeable risks or discomforts to the participant.
- A description of any benefits to the participant or to others which may reasonably be expected from the research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.
- (@) 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.
- 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.
- Include information about the following:
 - 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.
- Include statements about the following:
 - 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 participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

ADDITIONAL ELEMENTS OF INFORMED CONSENT (WHEN APPLICABLE)

When appropriate, one or more of the following elements of information shall also be provided to each participant:

- A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable.
- Anticipated circumstances under which the subject's participation may be terminated (withdrawn) by the investigator without regard to the participant's consent.
- Any additional costs to the subject that may result from participation in the research.
- The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant.
- A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant.
- The approximate number of participants involved in the study.
- (*) Include the following statement verbatim when seeking informed consent for Applicable Clinical Trials, as defined in [Applicable Clinical Trial \(ACT\) Checklist](#), to notify the clinical trial participant of the clinical trial registry databank: "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."

HIPAA AUTHORIZATION REQUIREMENTS

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). For additional information see [SUNY Downstate HIPAA Policies and Procedures](#).

For the purpose of this policy, **Protected Health Information (PHI)** includes individually identifiable health information transmitted or maintained in any form or medium pertaining to the past, present or future physical or mental health or condition of an individual. For example, health information that includes a HIPAA identifier is considered PHI.

GENERAL REQUIREMENTS

Include the required HIPAA authorization language with the informed consent to cover the uses and disclosures of PHI, including when such information is about specimens:

- 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.
- 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.)
- 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?

- Description of each purpose for which the specific PHI identified earlier is to be used or disclosed.
- 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”)
- 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).
- A statement that the individual may revoke the authorization in writing at any time (except to the extent that a provider has acted in reliance of the authorization), and instructions on how to exercise such right (who does the individual need to write, name and address)
- 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.*
- 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.

DISCLOSURE OF PSYCHOTHERAPY NOTES AND MARKETING OR SALE OF PHI

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](#).

Based upon [Downstate Privacy of Psychotherapy Notes \(HIPAA-37\) policy](#), psychotherapy notes are defined as notes made by a mental health professional that document or analyze the contents of a conversation during a private counseling session. These notes are considered to be inappropriate for inclusion in the medical record, are intended to enable the mental health professional to recall the therapy discussion and are of little use to others not involved in the therapy. These notes are kept separate from the rest of the patient’s record. If an EMR is utilized, these notes are entered into a separate section that is not considered part of the designated record set. In contrast, behavioral medicine clinical notes (such as med prescribing/ monitoring, counseling session start & stop times, modalities/ frequency of treatment, results of clinical tests, other mental health info typically needed for treatment) are NOT considered ‘psychotherapy notes’ under HIPAA and would not require separate authorization.

NIH REQUIREMENTS

CERTIFICATES OF CONFIDENTIALITY

When a study is NIH funded or when a [Certificate of Confidentiality \(CoC\)](#) covers non-NIH funded studies, include a disclosure about the CoCs and its' limitations. Template language is included in the consent template in Step 8 on the [IRB Electronic Submission Process website](#).

GENOME WIDE ASSOCIATION STUDIES

Include the required language for NIH funded studies for genomic research in accordance with the NIH required data sharing plan.

For more information, consult with the NIH or refer to their website for [Special Considerations for Genomics Research](#).

Template language is included in the consent template in Step 8 on the [IRB Electronic Submission Process website](#).

GCP REQUIREMENTS

For clinical trials following the [International Conference on Harmonization \(ICH\) Guidance Documents](#), the research and informed consent must meet the following requirements of the [E6\(R2\) Good Clinical Practice](#). The following must be included in the informed consent document as applicable to the research:

- When a research participant cannot read the consent form or other written materials supplied to the participant, an **Impartial Witness** must be included in the informed consent process. The **Impartial Witness** cannot be unfairly influenced by the investigators involved in the trial. **Note: The Downstate IRB recommends an Impartial Witness NOT be a member of the study team or a family member.**
- Informed consent must be obtained from a research participant through a process by which a (s)he voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to his or her decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.

DIAGNOSTIC GENETIC TESTING

To comply with NY regulations, studies involving diagnostic genetic testing (e.g., any laboratory test of human DNA, chromosomes, genes, gene products, or DNA profile analysis to diagnose the presence of a genetic variation linked to a predisposition to a genetic disease or disability in

the individual or the individual's offspring), include the elements of informed consent described below.

- A general description of the test.
- A statement of the purpose of the test.
- 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.*
- The name of the person or categories of persons or organizations to whom the test results may be disclosed;
- 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 collected, unless a longer period of retention is expressly authorized in the consent.

If the research permits such degree of specificity, include the following:

- 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;
- A general description of each specific disease or condition tested for;
- The level of certainty that a positive test result for that disease or condition serves as a predictor of such disease.
- A description of the policies and procedures to protect patient confidentiality;
- A statement of the right to withdraw consent to use the specimen for future use at any time and the name of the organization that should be contacted to withdraw consent;
- A statement allowing individuals to consent to future contact for any or all purposes, including the following:
 - research purposes;
 - provision of general information about research findings; and
 - 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
 - a statement explaining the benefits and risks of consenting to future contact.

CALIFORNIA AND FOREIGN PRIVACY AND DATA SECURITY REGULATIONS

Certain disclosures must be included in the informed consent document, when the research must comply with California requirements or those of foreign locations. For more information, please consult with the [IRB guidance on data security](#). The specific disclosures that are needed will depend on the applicable regulations that apply to the research.

Consult with the sponsor, Data Security Officer, Privacy Officer, or the Office of Compliance and Audit Services (OCAS) to include the appropriate disclosures within a consent form or an

addendum, when the California Privacy Rights and Enforcement Act (CPRA)/ California Consumer Privacy Act (CCPA) apply to the research.

If the European Union (EU) General Data Protection Regulation (GDPR) is applicable to a study, please work with the sponsor, Data Security Officer, Privacy Officer, or OCAS to include the appropriate GDPR disclosures within this consent form or an addendum. The IRB will work with OCAS to confirm all required disclosures are included. Examples for when GDPR applies to the research include the following:

- 1) The study includes outreach and recruitment of individuals who are located in the European Economic Area (EEA), which is 28 EU member states and three additional countries (Liechtenstein, Iceland, and Norway),
- 2) The site seeking Downstate IRB approval is the site for a study involving the EEA and has the role of primary research site and/or lead investigator, or
- 3) The site seeking Downstate IRB approval collects and/or processes Personal Data (as defined by GDPR) in the EEA in connection with the study (including incidental collection of personal data on a mobile app while a research participant is travelling in the EEA).

DOWNSTATE REQUIREMENTS

MEDICAL RECORD DISCLOSURE

The following (or something similar) must be included when recruiting patients into a clinical trial involving an IND or IDE **or** when there is a Certificate of Confidentiality or when required by an external site (e.g., Kings County Hospital).

The researchers will file a copy of this consent in your medical record. The researchers will place a note in your medical record to let other healthcare providers know that you are participating in a clinical trial.

INCENTIVES, COMPENSATION AND REIMBURSEMENTS

All incentives, compensation and reimbursements must be fully disclosed within the consent form. For more information, refer to the [IRB Guidance for Recruitment, Referral, Screening, Advertising, and Incentives](#).

Whenever the research requires reporting to the Internal Revenue Service (IRS), this must be disclosed within the informed consent document.

Whenever the research requires collection of a social security number, this should be disclosed within the informed consent document.

SUNY RF PAYMENT FORM

When a participant accepts research payments (including travel reimbursement) of either 1) \$600 or more in a calendar year, or 2) more than \$100 per study visit, the SUNY RF Payment Consent Form must be used, unless a waiver is granted. A waiver may be requested for an exception for the use of the “SUNY RF Payment Consent” when all of the following are true: 1) total payments are less than \$600 per calendar year, AND 2) giving indirect payments (e.g., cash funds, gift card, pre-paid cards), AND 3) giving more than a \$100 per study visit. For more information, see Step 8 of the [IRB Electronic Submission Process website](#).

COMPANION (ANCILLARY) STUDIES

Some sponsors may want to require participants in treatment studies to participate in other research activities, such as a registry, data or specimen repository, or collection of specimens or genetic materials. Making such companion (ancillary) studies raise ethical issues and conflict with regulations pertaining to human research because 1) participation should not be mandatory but voluntary and 2) undue influence may be created if the participant is told that in order to participate in a study with a potential benefit (s)he must also participate in the companion study.

Participation in a companion study must be optional when the enrolling participants in an experimental treatment that might benefit the participant. Preferably, a separate consent form should be used for the companion study; however, the companion study could be described in a separate section within the main consent form, provided there are separate lines for the participant to initial if they agree to participate in the companion study.

A companion study may be mandatory under the following exceptions, with the understanding that eligible participants must agree to be in both the main study and companion study or be denied enrollment in the main study:

- Main study has no potential benefit to the research participants.
- Ancillary studies are necessary to answer the main research question.
- Participation is required by law (e.g., tumor registry, STD reporting).

OPTIONAL RESEARCH ACTIVITIES

Unless the primary purpose of the research is to store specimens or information for future research, such as in a repository for future studies, investigators must present the future use or disclosure of identifiable (or coded) information/specimens either as an optional provision to agree or disagree to participate in the future research or as a separate optional consent form. In general, the IRB does not permit “unspecified future use” when describing the future research

that involves PHI. 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. Be sure to clarify in the consent form that the future research is optional and that the decision about whether to participate in the future research will not affect their participation in the current research.

Include an optional authorization for future use within the consent form when PHI is involved in a treatment study. This requirement is based on the HIPAA rule that one cannot require future disclosures in research as a condition of participation in the current treatment study. A compound authorization must clearly differentiate between the conditioned and unconditioned components of the research and provide the participant with an opportunity to opt in or out of the research activities described in an unconditioned authorization. Alternatively, a separate consent form for the optional research may be used.

This provision is required based on Downstate's interpretation of the HIPAA Privacy Rule.

When applicable for the research, include options for the following:

- to request future contact to obtain or share information about genetic testing,
- sharing information/specimens for future research,
- future contact for other studies,
- release of medical information, or
- the use of coded specimens or coded information for future research.

For more information, see the template for informed consent at Step 8 of the [IRB Electronic Submission Process website](#)

PUBLISHING PHOTOGRAPHS OF THE FULL FACE

Written authorization is required to publish photographs of the full face of a research participant. The research participants must be given the option to include a full-face image with eyes either censored or uncensored.

CONFLICT OF INTEREST DISCLOSURES

MANAGEMENT PLANS

When there is a Conflict-of-Interest Committee (COIC) Management Plan (MP) approved by the COIC for an Investigator's Significant Financial Interest (SFI), and the COIC or the IRB require certain disclosures be included in the consent form these disclosures must be included in the consent. The specific language may be required by either the COIC or the IRB. Draft disclosure language is included in the consent template posted at Step 8 on the [IRB Electronic Submission Process website](#).

DISCLOSURE OF SITE FEES

When the study team provides fees to other sites (e.g., fees to review clinical records with treating clinicians to verify diagnosis), the fees provided to the clinic must be disclosed in the consent.

PREGNANT PARTNER AUTHORIZATION

With IRB approval, investigators may obtain consent from a pregnant woman to obtain information about her pregnancy when she is included in a study or when she is the partner of a research participant.

When a woman becomes pregnant in a study, her participation may need to end in order to minimize risk to a developing fetus. When an investigator wants to follow the pregnancy or outcomes of the pregnancy, the investigators must obtain IRB approval to obtain informed consent to collect this information.

If a partner of a research participant becomes pregnant and the investigator wants to follow the pregnancy or outcomes of the pregnancy, investigators must obtain informed consent of the pregnant partner to obtain information about her; however, the participant could provide parental permission (consent) to obtain outcomes of the child.

The consent for pregnancy follow-up may be included in the main consent form; however, a separate informed consent should be obtained when information is collected from a pregnant partner.

A Pregnancy Follow-Up Consent Form template is available at Step 8 on the [IRB Electronic Submission Process website](#).

DOWNSTATE RECOMMENDATIONS

The following are recommendations of the Downstate IRB:

CONSENT LOGO

Downstate does not require a site-specific logo on consent forms and/or recruitment documents; however, the suggested logo is included in the Downstate Informed Consent template. Consent form templates are available on the Downstate IRB website and are updated on a periodic basis. These templates are available at Step 8 at the [Downstate IRB Electronic Submission Process website](#).

READABILITY OF CONSENT FORMS

The following guidance is provided to improve the readability of the consent form:

- Investigators are encouraged to [test the readability within Microsoft Word](#).
- To the extent possible, explain technical, medical, and scientific concepts in lay terms that are understandable to someone who is educated to the **6th 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.
- Consider adding pictures, diagrams, tables, or charts if they will improve understanding.
- Avoid or minimize passive voice to the extent possible. Example of passive voice: “A summary of results will be sent to all study participants.” Example of active voice: “We will send you a summary of the results.”
- Write directly to the reader, as though you are explaining the facts in person. Write in the second person (“you”), not in the first person (“I”). Avoid the use of first-person pronouns (I, me, my, we, us, etc.).
- When applicable, change the title in header (e.g., PARENTAL PERMISSION, HEALTHY VOLUNTEER INFORMED CONSENT, etc.).
- Remove references to “NYC Health + Hospitals, Kings County” in the header and throughout the template form if they are not involved in the research.
- Use bold text and/or boxes around critical text for emphasis.

STATEMENTS FOR RECRUITING CHILDREN AND COGNITIVELY IMPAIRED ADULTS

Statements should be included within the informed consent document to clarify the meaning of “you” and “yours” when using the consent form for parental permission of a child or surrogate consent for an adult who does not have the capacity to provide consent.

Template language is included in the consent template in Step 8 on the [IRB Electronic Submission Process website](#). At the time of writing this guidance, the suggested language included in the template is provided below.

When requesting parent or legal guardian permission for a child, add the following or something similar (edit as needed, depending on the age range of the participants):

If you are providing permission for a child to be in the study, we want to be clear that the terms “you” and “your” mean your child (the participant) and we are asking your permission for your child to be in this study (consent). If he/she is older than 6, we will ask your child if he/she wants to be in the study (assent to express approval). If he/she is between 7-12 we will also ask your child to sign a special Assent Form to be in the study. If he/she is between 13-17, we will also ask your child to sign this form to be in the study (assent).

When obtaining consent from a surrogate for a cognitively impaired adult, add the following or something similar:

If you are deciding for another adult who cannot make their own decision to participate in the study or not, we want to be clear that the terms “you” and “your” mean that adult who cannot make his/her own decision. Please consider the wishes and beliefs or the best interests of this person. If this person (the participant) is able to get back their ability to make decisions for his/herself after you give your permission for him/her to be in the study, he/she will be asked to give his/her permission to participate (consent).

CONSENT FORM LANGUAGE FOR PREGNANCY TESTING IN MINORS

The Downstate IRB does not have standard language for pregnancy testing in minors; however, a female under 18 who becomes pregnant becomes emancipated. Results of pregnancy tests cannot be shared with the pregnant woman’s parents unless the pregnant woman provides permission to share the results. Suggested language may include the following or something similar:

Harms to unborn babies

The research study drug(s) can harm an unborn baby. Because of this, you should not become pregnant **[If appropriate include: or father a baby]** if you join this study. Females 12 years old and older in the study will have pregnancy tests before certain procedures.

If you join the study and have a positive pregnancy test, we would tell you about the test results. You must give your permission before the hospital can share the results with a parent or guardian. **[If appropriate include: If you have a positive pregnancy test, we would ask you to leave the study. This means that even if we did not tell your parent or guardian, they might find out you were pregnant.]**

HIV-RELATED INFORMATION

Downstate recommends (but does not require) including the following paragraph when researching HIV-related information as it may help ensure compliance with NY State regulations (NY PHL Section 2782(5)(a); NY PHL Section 2781(2)(e), 10 NYCRR 63.3(b)(5), 14 NYCRR 505.6(a)(ii)):

Recipients of HIV-related information may not re-disclose your HIV-related information without your authorization unless permitted to do so under federal or state law. You have a right to request a list of people who may receive or use your HIV-related information without authorization, as well as a list of any disclosures made pursuant to this research authorization. For more information about HIV confidentiality, call the New York State Department of Health HIV Confidentiality Hotline at 1-800-962-5065; for more information regarding federal privacy protection, call the Office for Civil Rights at 1-800-368-1019. You may also contact the NYS Division of Human Rights at 1-888-392-3644.

DISCLOSURE OF VIDEO OR VOICE RECORDINGS AND/OR PHOTOGRAPHS

When a study involves the use of video recordings, voice recordings or photographs, this should be disclosed in the informed consent document. Additional information should be provided to describe who will have access to these materials, how they will be stored securely, and the plans for destruction.

Template language is included in the consent template in Step 8 on the [IRB Electronic Submission Process website](#).

RESEARCH RELATED INJURY

Please see the suggested language in the Downstate Informed Consent template. Consent form templates are available on the Downstate IRB website and are updated on a periodic basis. These templates are available at Step 8 at the [Downstate IRB Electronic Submission Process website](#).

For an industry-sponsored study, it is best to compare the language from Downstate informed consent template regarding injuries to make sure it is consistent with the sponsor. This language may be altered with the assistance of the IRB and Sponsored Programs Administration to insure it is consistent with contractual obligations.

At time of this writing, the following language is suggested for disclosure of compensation for research related injuries for studies that are greater than minimal risk:

Who will pay for my medical care if participating in this research harms me?

It is important that you tell your study doctor if you feel that taking part in this study has injured you or caused you to become ill.

You will receive medical treatment if you are injured or become ill because of this study. Your doctor will explain the treatment options to you and tell you where you can get treatment.

Downstate [add others] makes no commitment to provide free medical care or payment for any unfavorable outcomes that result from your participation in this research. Medical services will be billed at the usual charge and will be your responsibility or that of your third-party payer, but you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research including Downstate [add others].

Include for industry sponsored research:

However, the Sponsor of this study will pay for the reasonable and necessary costs of medical care for research-related illness or injury where the illness or injury:

- results from this research study and not from a pre-existing medical condition, unless the condition was worsened by the study; and
- did not result from the negligence or misconduct of the study personnel, or their unjustified failure to follow the study protocol or instructions; and
- is directly related to the study drug or device or study procedure.

By accepting medical care or accepting payment for medical expenses, you are not waiving any of your legal rights.

For COVID-19 research which takes place during the COVID-19 pandemic, include the following:

Due to the coronavirus public health crisis (COVID-19), the federal government has issued an order that may limit your right to bring a claim if you are injured or harmed while participating in this COVID-19 clinical study. If the order applies to this study, it limits your right to bring a claim against the researchers, healthcare providers, and any study sponsor, manufacturer, and/or distributor involved with the study. However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. To find out more about this “Countermeasures Injury Compensation Program” go to <https://www.hrsa.gov/cicp/about/index.html> or call 1-855-266-2427

COSTS TO PARTICIPATE IN THE RESEARCH

Please see the suggested language in the Downstate Informed Consent template. Consent form templates are available on the Downstate IRB website and are updated on a periodic basis. These templates are available at Step 8 at the [Downstate IRB Electronic Submission Process website](#).

For an industry-sponsored study, it is best to compare the language from Downstate informed consent template and any additional costs to make sure it is consistent with the sponsor. This language may be altered with the assistance of the IRB and Sponsored Programs Administration to insure it is consistent with contractual obligations.

At time of this writing, the following language is suggested for disclosure of costs for participation in the research:

Are there any costs to participate?

If there are no foreseeable costs, this should be specified:

It does not cost anything to be in the study.

Describe any additional expenses that the participant will incur by taking part in the research. When applicable, include a discussion on transportation costs or loss of income for taking time off from work to be in a study.

For clinical trials or studies involving patient care, use the text:

Your insurance or third-party payer will be billed for any routine care in this study. The study team can explain your costs to you if your insurance does not pay. You will pay your usual co-payments or deductibles.

You will not be charged for ... **<include applicable investigational study drug, device, or biologic, unless this is covered by insurance (e.g., deemed or qualifying clinical trial with Medicare patients), and any other items.>**

[For studies involving greater than minimal risk, include the following:]

You or your insurance pay for the cost of treatment if you are injured.

If applicable, add:

You may request professional genetic counseling. You may have to pay for those additional services.

NAME AND SIGNATURE LINES

Below are the recommended names and signature lines for the informed consent document; however, suitable alternatives are acceptable provided they meet all applicable regulatory requirements.

Lines should be added for the Names for the following individuals, when applicable for the research (neither signature nor date are required):

- **Child under 13.**
- **Cognitively impaired adult.**

Lines should be added for the Names, Signatures, and Dates, as indicated below, when applicable for the research:

- **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.
- **Parent or Legal Guardian.** Required when enrolling a child, under the age of 18.
- **2nd Parent or Legal Guardian (if applicable).** Required for category 406 & 407 research.
- **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.
- **Married Minor.**

- **Pregnant Minor.**
- **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.
- **Adult Research Participant.** For adults who are 18 years of age or older.
- **Personal Representative (Legally Authorized Representative).** Required when obtaining surrogate consent for enrolling adults who are cognitively impaired.
- **Interpreter.** Required when there are plans to enroll participants with individuals who have Limited English Proficiency or communicate with sign language.
- **Witness.**
 - Required for the following situations:
 - When obtaining consent/permission from research participants, parents/guardians, or personal representatives with Limited English Proficiency.
 - When obtaining consent/permission from research participants, parents/guardians, or personal who understand English, but cannot read English.
 - When obtaining permission from the personal representative of a cognitively impaired adult.
 - A witness is recommended (not required) for clinical trials that involve investigational agent (e.g., drug, biologic, or device).
- **Impartial Witness.** Required for a Clinical Trial that follows ICH-GCP requirements when enrolling non-English reading research participants.

INFORMED CONSENT FOR PATIENTS WITH COVID-19

For considerations for obtaining informed consent from patients with COVID-19, please refer to the [Consolidated IRB Guidance Relate to COVID-19](#).

The above guidance and the informed consent template available at Step 8 on the [IRB Electronic Submission Process website](#) include information for documentation of remote consent and language to reduce liability of the institution when conducting COVID-19 research.

MODEL INFORMED CONSENT FORM FROM A SPONSOR, CRO, OR EXTERNAL IRB

The IRB may accept the model informed consent form that is created by a sponsor, Contract Research Organization (CRO), or External IRB. However, the IRB may require the use of the template HIPAA authorization language from Downstate informed consent template, unless the model consent form is within compliance of HIPAA regulations and local Downstate policy. For an industry-sponsored study, it is best to compare the language from Downstate informed consent template regarding injuries and any additional costs to make sure it is consistent with the

sponsor. This language may be altered with the assistance of the IRB and Sponsored Programs Administration to insure it is consistent with contractual obligations.

When a sponsored project is being conducted at multiple sites, the sponsoring company may require the use of their IRB approved informed consent for uniformity; however, Downstate IRB may recommend or require additional information to the informed consent, to ensure compliance with local laws and policy.

SINGLE VS. MULTIPLE CONSENT FORMS

A single informed consent document with HIPAA authorization (also known as a compound authorization) may cover uses and disclosures of PHI for multiple activities of a specific research study, including the collection and storage of tissues for that study and for disclosure of information pertaining to genetic studies.

A multiple consent form approach may be used when the research involves different research studies (e.g., where a research study collects information for the study itself and collects and stores PHI or specimens in a central repository for future research). However, the PI may choose to use a tiered consent approach to include options that allow a research participant to opt-in or opt-out of participation of specific research activities or for the future research of coded information or coded specimens. However, if the primary purpose of the study is to create a repository, the future research should be described within the section of the consent that describes the purpose of the research.

SOURCE RECORDS FOR FDA INVESTIGATIONS

For FDA regulated investigations, either a compliant electronic signature (see IRB Guidance on Data security) or the original signature must be obtained on the informed consent document and saved in the research records with other source documents.

DOCUMENTS FOR LIMITED ENGLISH PROFICIENCY

Downstate provides culturally and linguistically appropriate care and support to our patients in many languages, as determined and documented at the time of admission. The common preferred languages of our local community include English, Haitian Creole, Arabic, Spanish, Russian, Simplified Chinese, and Traditional Chinese. Individuals who do not speak English as their primary language and have a limited ability to read, speak, write, or understand English are considered to have a Limited English Proficiency (LEP).

In order to achieve equitable selection of research participants, it may be desirable to recruit and enroll the individuals who have LEP, particularly to make research available to those who may receive a prospect of direct therapeutic benefit. Recruitment of research participants with LEP is generally required, if the study holds the prospect of a direct therapeutic benefit to the research

participant, and the informed consent must be obtained in the research participant's preferred language.

This section describes a process to obtain effective (and document, when applicable) informed consent, LAR consent, parental permission, child assent, including applicable HIPAA research authorization for individuals who have a LEP and for those with low literacy and numeracy, physical challenges, or a religious objection to signing documents.

A LAR may provide consent in situations when the adult research participant is cognitively impaired, and the LAR consent process is approved by the IRB. The term LAR should not be confused to mean that a relative or close friend can provide consent for a participant who does not understand English. Assent of an adult research participant that is cognitively impaired must be obtained in the preferred language of the research participant. An interpreter must be available for a research participant with LEP or a LAR with LEP.

For a child with LEP, the pediatric assent must be obtained in his/her preferred language. Either the translated assent or the short form may be used, as approved by the IRB, and an interpreter must be available for the child. The signature of the child is only required on the Short Form or translated assent form if the IRB approved version of the English assent requires the child's signature. The IRB may determine that assent is not necessary or that assent may be waived in certain situations.

Informed consent, LAR consent, parental permission, and pediatric assent must be obtained in the preferred language of the individual, to help assure their understanding of the research including an explanation of scientific and medical terms. An interpreter must be available to an individual with LEP whenever there is a research interaction or intervention with him or her, including during times of recruitment, enrollment, obtaining consent. Investigators must carefully consider the ethical and legal ramifications for enrolling a participant when barriers exist. They must allow sufficient time for the Participant's voluntary decision and allow them to review the documents with others (e.g., family member, friend, clinician).

TRANSLATION AND CERTIFICATION OF WRITTEN RESEARCH MATERIALS

When recruiting and enrolling research participants with LEP, all applicable English documents must be approved by the IRB, prior to requesting translations into other languages, as the IRB may require modifications to the English document. Accuracy of translations can be accomplished in different ways depending on the service used to provide the translation and the type of document. In general, the following mechanisms are acceptable:

- **Back-translation:** After the document is translated into the foreign language, it is then translated back into English to determine accuracy of the original meaning. A certificate of translation and the English back-translation is provided.

- **Double translation:** With this method, two people translate the same documents and an arbitrator reviews both to determine any differences. Both translators sign the certificate of translation.
- **Other methods deemed appropriate by the IRB.**

For assistance, with translations, please contact Patient Relations Department, at (718) 270-1111.

The Sponsor is expected to pay fees related to translation of participant-facing English documents into other languages, (e.g., informed consent and parental permission documents including HIPAA research authorization language, recruitment materials, surveys, or other applicable materials requiring translation for non-English participants). Fees may range from about \$65-\$200 per page, depending on the language and service used. Fees for translation are coordinated through the PI. When anticipating the recruitment of those with LEP into a sponsored clinical trial, inform the Sponsored Programs Administration so they may negotiate translation fees during the CTA negotiations.

If a sponsor does not fund the translation, the Department should pay for the translation. The PI should plan for this in the research budget.

The Downstate IRB will fund the translation and certification of the short forms in the most common languages anticipated based on hospital statistics. These are available at Step 9 on the [IRB Electronic Submission website](#). If the translation and certificate is required for another language, the Department or sponsor is expected to pay the fees for this service; however, in an emergency or under extreme circumstances, Downstate IRB may consider the approval for the use of the English version of a short form to recruit a participant with LEP when a short form has not already been translated and certified.

All translations of written materials must be appropriately certified before submitting them to the IRB. Be mindful that the consent process begins with recruitment of potential participants; therefore, any advertising that targets individuals with a LEP, must be appropriately translated and certified.

DOCUMENTS FOR OBTAINING INFORMED CONSENT FROM AN INDIVIDUAL WITH LEP

There are three mechanisms for obtaining informed consent from an individual with LEP:

- The “**Long Form process**” involves the translation of the English version of the applicable Long Form.
- The “**Short Form process**” involves the use of the English Long Form and a translated Short Form.
- The “**Waiver of Documentation Process**” involves verbal consent when the IRB waives the requirement to obtain the signature of the participant.

LONG FORM

As applicable to the particular research, the “Long Form” is considered the consent form, parental/guardian permission form, or a pediatric assent document and includes the required HIPAA research authorization language when PHI is involved.

In general, written translation of the long forms is expected over the use of the short-form process when the research anticipates the enrollment of five or more research participants with limited English proficiency of the same language (e.g., 6 Spanish speaking participants) for the following types of research:

- Phase 0, 1, 1/2, 2, 2a, 2b, or 2/3 clinical investigations which are determined to be greater than minimal risk without any anticipated therapeutic benefit for the research participants;
- Other studies which are determined to be a minor increase over minimal risk, when there is no direct benefit to the research participant;
- Complex clinical trials; or
- When required by the sponsor.

For the long form process, submit the following for IRB approval:

- Submit long form in English, with applicable signature blocks.
- Submit recruitment materials, interview scripts, or other participant related documents (e.g., surveys, information cards, etc.) in English.

After the English versions are approved by the IRB, submit the following for IRB approval as an Amendment:

- IRB Application for Amendment.
- Translated versions of long form(s).
- Translated interview scripts or other participant related documents.
- Translated recruitment materials, if targeting a population in non-English.
- Certificate of translation(s) for all documents.
- The English back-translation, if obtained and a Word document that shows the comparison (e.g., marked-up, tracked changes, backline, comparison version) of the original English version (approved by the IRB) with the new English back-translation.

SHORT FORM

The short form process for obtaining informed consent must be used in conjunction with a **verbal interpretation** of either the IRB approved long form, **or** an IRB approved written summary of what will be said to the potential research participant.

In general, this process may be used, after IRB approval for the following situations:

- When the **written translation** of the long form is not required, as indicated above.
- When it is not possible to anticipate the primary languages of the research participants (or the parent, legal guardian, or personnel representative, as applicable).
- For research participants with apparent low literacy.
- To enroll a research participant **PRIOR** to the IRB approval of a translated long form, unless prohibited by a sponsor. *NOTE: In this situation, an amendment to translate the*

long Form MUST BE PROMPTLY submitted for IRB and once it is approved, the IRB stamped translated long form must be promptly provided to the research participant with LEP as an ongoing source of understandable information.

To obtain approval of the short form process for a study submit the following to the IRB:

- English version of the IRB approved long form(s). Be sure to include all required signatures, including interpreter, witness/impartial witness.
- A written summary of what will be said to the potential research participant (optional, to be used in lieu of using the long form)
- Translated recruitment materials, if targeting a population in non-English, along with certificate(s) of translation.
- Translated short forms in the anticipated languages. The fillable fields of the short forms are to be edited, prior to submission to the IRB, to include the title of the study and relevant contact information, which may be listed in English.
- Certificate of translation for short form if you are using a form that is not pre-certified by the IRB.

PROCESS FOR OBTAINING INFORMED CONSENT AND HIPAA RESEARCH AUTHORIZATION

TIP: Informed consent is a “PROCESS,” not just a FORM!!!

The “Process” is discussed in this section. See previous sections of this guidance and Policy IRB-01 for “Form” requirements.

Investigators must obtain informed consent and HIPAA research authorization, prior to enrolling a research participant into a study and/or conducting any procedures required by the protocol, unless waived by the IRB.

Individuals obtaining consent **MUST** be identified on the IRB application form.

Although the PI may delegate the responsibility for obtaining consent from research participants to other members of his/her research team, the PI retains ultimate responsibility for ensuring that each prospective participant is adequately informed about all aspects of the research and understands the information provided.

The consent process does not end with the formal signing of the consent document. Rather, it is an ongoing process that continues throughout the participation in the study. The investigators remain responsible for continued assessment of the research participant’s understanding of what is happening to him/her, his/her willingness to participate and for providing the research participant with any new information that may affect their willingness to participate.

It is the PI's responsibility to train and supervise the study personnel who are obtaining consent.

OBTAINING INFORMED CONSENT FROM THOSE WITH LEP

REMINDER: An impartial witness is required when enrolling those with LEP into a clinical trial that follows GCP standards.

INTERPRETER

When an interpreter is needed for UHB patients, follow UHB Policy PTBR-5: Language Services to Patients with Limited English Proficiency.

When research takes place at another location, the investigators must consult with the policy for the local site.

LONG FORM PROCESS

Prior to obtaining informed consent, the following steps are recommended:

- Gather the IRB approved stamped long form(s)
- Verify whether the interpreter is eligible to serve as the witness; otherwise, obtain another witness.
- Provide copies of the long form(s), and any IRB approved summary script, to the witness and interpreter so they can review in advance.

Signatures are required from the following individuals, when using the translated long form:

- Person authorizing the research, such as
 - Adult research participant with capacity to consent,
 - Parent or legal guardian, or
 - Personal representative (LAR)
- Witness (or Impartial Witness, when applicable)
- Interpreter, and the
- Investigator obtaining the informed consent.

SHORT FORM PROCESS

Prior to obtaining informed consent, the following steps are recommended:

- Gather the IRB approved documents: IRB stamped English long form(s), IRB stamped translated short form, and IRB stamped English written summary (if applicable).
- Provide copies of the above materials to the witness and interpreter so they can review in advance.
- Verify whether the interpreter is eligible to serve as the witness; otherwise, obtain another witness.
- Refer to the English short form, if needed.

Please refer to the table below for the required signatures for using the short form process. A “Yes” indicates the individual in the far-left column must sign the designated form in the vertical column.

<u>Who signs?</u>	<u>FORM TYPE</u>			
	<u>Translated Short Form</u>	<u>English Long Form</u>	<u>English Assent Form</u>	<u>English Written Summary Form</u>
Adult w/LEP (including Parent, Legal Guardian, or LAR)	Yes	Yes	Yes, if required by IRB. Usually, N/A.	Yes
Child w/LEP	Yes, if the IRB requires signature on the English assent form or on the English long form to document assent (typically when the child is between the ages 12-17)	Yes, if the IRB requires signature on the English long form to document assent (typically when the child is between the ages 12-17)	Yes, if the IRB requires signature on the English assent form (typically when the child is between the ages 7-11)	Yes, if the IRB requires signature on the English long form to document assent (typically when the child is between the ages 12-17)
Adult with low literacy or numeracy	Yes (May use English Short Form if preferred language is English)	Yes	Yes, if required by IRB. Usually, N/A.	Yes
Witness <i>Note: Must be an “impartial witness” for clinical investigations following GCP standards.</i>	Yes	Yes	Yes, if required by IRB.	Yes
Investigator obtaining consent	Yes	Yes	Yes, if required by IRB.	Yes
Interpreter	Yes	Yes	Yes, if required by IRB.	Yes

PROCESS WITH A WAIVER OF DOCUMENTATION OF INFORMED CONSENT

Prior to obtaining verbal informed consent, the following steps are recommended when the IRB waives documentation of informed consent (e.g., no signature required):

- Gather the IRB approved stamped information sheet.
- Verify whether the interpreter is eligible and can serve as the witness. If not, another person will be needed to serve as the witness.
- Provide copies of the information sheet to the witness and interpreter so they can review in advance.

Verbal consent is obtained without signatures in the presence of the witness with the assistance of the interpreter.

The signature of the witness, the interpreter, and the investigator obtaining the informed consent should be recorded on an enrollment master list of research participants.

OTHER ACCOMMODATIONS

Investigators should accommodate the specific needs of the study population or a specific individual on a case-by-case basis, some of which are described below. All accommodations must be approved by the IRB.

Although a competent person who does not read and write well can give informed consent, the investigator and IRB should consider whether any modifications to the informed consent process are necessary to ensure that the informed consent process is understandable.

For example, the investigator could use an audio or video tape of the contents of the consent form or a form with enlarged font, depending on the level of impairment of the visually impaired research participants. Other accommodations are described below.

The documentation of a written consent process must conform to all other requirements, including the signature of a witness (or impartial witness when required).

LOW LITERACY OR NUMERACY

For research participants with apparent low literacy or numeracy, oral presentation of the information contained in the consent form is especially important. When the elements of informed consent are presented orally to the individual, the IRB may consider approving the use of a short form and written summary, which includes a witness to the oral presentation of the informed consent who also signs the consent form.

BRAILLE

For blind research participants who read braille, the IRB may approve a consent document prepared in braille. To assure itself that a braille consent document is accurate; the IRB may

require a transcription into print text or review of the document by a qualified person who reads braille. If possible, the research participant will sign or make their mark on the braille consent.

AMERICAN SIGN LANGUAGE

For deaf research participants who are fluent in American Sign Language (ASL), the IRB may approve a consent process using approved ASL and the IRB-approved written consent form. When this process is approved, the individual authorized to consent prospective research participants must use a qualified interpreter fluent in ASL to conduct the consent process.

MAKING A MARK

Research participants, who cannot write or physically sign a document, can indicate their consent by "making his/her mark" (e.g., "X") on the consent form. In this situation, a note in the research record (e.g., participant's case history) should indicate the reason for the lack of a signature.

SIGNALING CONSENT

A person who is physically challenged (for example, physically unable to talk or write or has hearing or visual loss) can enroll in a research study if competent and able to signal consent. The research record and informed consent document must include a description of the specific means by which the prospective research participant communicated agreement to take part in the research and how questions were answered.

AUDIO OR VIDEO CONSENT

If the research participant is audio or video taped, his/her permission must be obtained to record them.

Adequate information security and confidentiality provisions must also be made.

RELIGIOUS OBJECTIONS FOR SIGNING DOCUMENTS

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

If a study team anticipates recruitment of individuals that may have a religious objection to signing an informed consent document and/or HIPAA research authorization, they may consider whether the research would qualify for a waiver of documentation of informed consent and/or a HIPAA Alteration.

Refer to additional IRB policies on waivers or consult with the IRB for additional information.

See also: “Signaling Consent.”

RE-OBTAINING THE CONSENT OF RESEARCH PARTICIPANTS

Consent may need to be re-obtained from research participants, not limited to the following reasons; however, each situation is reviewed by the IRB on a case-by-case basis:

- When modifications change the level of risk.
- When modifications might impact the research participants willingness to continue in the study.
- When children are enrolled in a repository or longitudinal study by obtaining the parent/legal guardian’s permission, their consent may need to be obtained when they turn 18.
 - If information is not gathered after the children become adults, re-consent may not be necessary.
 - If new specimens and information will be collected after they turn 18, the investigator should obtain their consent as adults for continued participation.
 - The IRB may consider waivers of informed consent of the adults who were enrolled as children, if applicable and justified.
- When a cognitively impaired adult research participant, initially enrolled by obtaining the LAR’s permission, has regained capacity to consent on his/her own behalf.
- When research participants are in a longitudinal study for an extended period of time, the IRB may require re-consent for a determined period of time (e.g., every 5 years).
- In certain cases, the IRB may approve the use of a short form process to enroll a participant in a clinical investigation involving an investigational agent (drug, biologic agent, or medical device), but require translation of the Long Form as soon as possible to provide additional information to the participant. Upon IRB approval of the amendment for the translated Long Form (consent), it must be provided to the research participant; however, the IRB may also require re-consent using the translated consent.
- Any time the IRB or sponsor requires re-consent using an IRB approved consent form.

The investigators must use the most recently IRB approved document when obtaining re-consent.

OTHER REQUIREMENTS

The informed consent requirements outlined in this guidance are not intended to preempt any applicable State, or local laws which require additional information to be disclosed for informed consent to be legally effective.

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

Other institutions may have additional requirements when multi-site research takes place.

WAIVER OF INFORMED CONSENT REQUIREMENTS AND/OR HIPAA WAIVERS

Waivers of the requirements of informed consent and HIPAA waivers are discussed in [Policy IRB-01](#). Forms used to request waivers are available in Step 8 on the [IRB Electronic Submission Process website](#).

Consider whether the research meets the criteria for the IRB to grant a request to waive any of the requirements of informed consent or HIPAA authorization or if it is impracticable to obtain. The regulatory criteria for granting waivers are outlined on the request forms in Step 8 on the [IRB Electronic Submission website](#).

A key regulatory criterion that must be met in order for the IRB to make a waiver determination is based on whether it is practicable to obtain consent/authorization, with an emphasis that it is impracticable to perform the research, and not just impracticable to obtain consent. Some common definitions of “practicable” include:

- 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 following tips were taken from recommendations by [The Secretary's Advisory Committee on Human Research Protections \(SACHRP\)](#) and may help determine whether it is impracticable to obtain consent:

- Scientific validity would be compromised if consent were required. Examples of this might include the following:
 - 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.
 - The participants 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 participant population and the research results may not be meaningful and lose statistical power.
 - The disclosure of the study purpose as part of the consent process would bias the research participants so that the results will not be meaningful.
- Ethical concerns would be raised if consent were required. For example:
 - 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.
 - There is a risk of inflicting psychological, social, or other harm by contacting individuals or families.

- There is a scientifically and ethically justifiable rationale why the research could not be conducted with a population from whom consent can be obtained.
- Practicability should not be determined solely by considerations of convenience, cost, or speed.

REFERENCES

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- 9 NYCRR Part 540- ESRA Amended Regulations, *May 7, 2003*
- [AAHRP Standards](#)
- Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care: A Roadmap for Hospitals. The Joint Commission. 2010.
- [Clinical Trial.gov website](#)
- [Downstate HIPAA Facsimile Cover Page](#)
- [Downstate Office of Compliance and Audit Services HIPAA Policy](#)
- [Downstate Policy HIPAA-28: Uses and Disclosures for Research Purposes](#)
- Downstate IRB Guidance for Full or Expedited Review
- [DOWNSTATE Policy IRB-01: Human Research Protections Program](#)
- FDA Guidance for informed consent
- [FDA Guidance for Investigator Responsibilities](#)
- [FDA Guidance on Exception from Informed Consent Requirements for Emergency Research](#)
- [FDA ICH Guidance Documents](#)
- [FDA Regulations \(21 CFR 11\): Electronic Records; Electronic Signatures](#)
- [FDA Website: Protection of Human Subjects; Informed Consent and Waiver of Informed Consent Requirements in Certain Emergency Research](#)
- [Health Information Privacy: Research](#)
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- [New York Mental Hygiene Law, Article 81](#)
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- New York State Technology Law Article 1- Electronic Signatures & Records Act (ESRA), *September 28, 1999 and amended August 6, 2002.*
- [New York State's Public Health Law 18: Access to Patient Records](#)
- [NIH Guidance: Protecting PHI in Research: Understanding the HIPAA Privacy Rule](#)
- [NY State Department of Health HIPAA Preemption Charts](#)
- [NYS 10 NYCRR Part 63 \(HIV/AIDS Testing, Reporting and Confidentiality of HIV-Related Information\)](#)
- [NYS 1-2.13 NY Estates Powers and Trusts Law](#)
- NYS Archives & Records Administration- Guidelines for the Legal Acceptance of Public Records in an Emerging Electronic Environment, *published 1998.*
- [NYS Civil Rights Law Section 79-L \(Confidentiality of genetic tests\)](#)
- [NYS DOH HIPAA Preemption Charts](#)
- NYS Office for Technology- ESRA Guidelines, *May 26, 2004*
- [OCR Health Information Technology for Economic and Clinical Health \(HITECH\) Act, enacted as part of the American Recovery and Reinvestment Act of 2009](#)
- Office of Human Research Protections’ Guidance [“Obtaining and Documenting Informed Consent of Research Participants Who Do Not Speak English”](#)
- [OHRP Guidance: Exculpatory language in Informed Consent \(1996\)](#)
- [OHRP Guidance: Exculpatory language in Informed Consent \(DRAFT November 7, 2011\)](#)
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- [OHRP Guidance: Informed Consent Requirements in Emergency Research](#), for Research not subject to FDA regulations
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AUTHORS

Nikol Celestine, BA, CIP
 Diann Johnson, MPH
 Kevin L. Nellis, MS, CIP

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 John M. Allen
 Enzo Bard

2015 IRB Policies and Procedures Manual (Draft)
 IRB Steering Committee
 Rebecca S. Twersky MD, MPH
 Richard Coico, MS, Ph.D.
 Shoshana Milstein, RHIA, CHP, CCS
 Phyllis Supino, EdD
 Stanley Friedman, MD
 Kathleen Powderly, Ph.D.
 Nicole McNair, MS
 Diann Johnson, MPH
 F. Lisa Murtha, Esq.

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