Local Context for Reviewing IRB

The SUNY Downstate Health Sciences University IRB (Downstate IRB) provides this guidance for reviewing (external) IRBs that have oversight of Downstate research through an IRB Reliance (authorization) Agreement (IRA).

This guidance provides a brief overview of the process for Downstate investigators who wish to use an External IRB. For more information, please contact the SUNY Downstate IRB at IRB@downstate.edu

KEY POINTS:

- This guidance document summarizes the local requirements of Downstate for a reviewing IRB that has oversight of Downstate research through an IRB reliance (authorization) agreement.
- This guidance was developed based on questions submitted to the Downstate IRB from various reviewing IRB and may not cover every local concern.
- This document focuses on requirements that go beyond the federal requirements for IRB approval, with a focus on NY State regulations and Downstate policy and recommendations.
- The Downstate PI must submit an "Application for External IRB Oversight" to the Downstate IRB. This form is available at Step 11 on the Downstate IRB Submissions Website.
    - Prior to submitting a study to the reviewing IRB, the Downstate PI may require a Pre-Review of materials to ensure local context requirements are met. This optional step is strongly encouraged, but not required. However, the pre-review must be submitted to the Downstate IRB, when required by the reviewing IRB, and the Downstate IRB can issue a preliminary letter to indicate it meets all local research context requirements or list any pending requirements.
    - Before the research can begin at Downstate, the Downstate IRB must activate the external IRB approval. The Downstate IRB will verify all local research context requirements.
- 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 additional information see the Downstate IRB Guidance: Obtaining Legally Effective Informed Consent and HIPAA Research Authorization.
- All policies and guidance referenced in this guidance are available on the Downstate IRB Policies and Guidance website.

CONTENTS

INSTUTIONAL INFORMATION

The table below provides some basic information about SUNY Downstate.

Institution Legal Name:	SUNY Health Science Center at Brooklyn
Address:	450 Clarkson Ave, Box 1284 Brooklyn, NY, 11203 (USA)
Other Names:	• Downstate Medical Center • State University of NY (SUNY) Health Science Center at Brooklyn
Components Listed on FWA	• SUNY Downstate Medical Center • University Hospital of Brooklyn • College of Medicine • College of Health Related Professions • College of Nursing • School of Graduate Studies • School of Public Health • SUNY-Long Island College Hospital • Research Foundation for SUNY-Downstate Medical Center • Research Foundation SUNY Downstate Health Sciences University • SUNY Downstate Health Sciences University
Downstate is subject to the following state laws:	New York
Federalwide Assurance (FWA) #:	FWA00003624
IRB Registry Number(s)	IORG0000064; IRB00011521; IRB00012854
AAHRPP accreditation:	No
Requirements to serve as reviewing IRB for Downstate.	Must enter into an IRB Reliance Agreement with Downstate. Must have an FWA registered with OHRP, unless operating a stand-alone IRB (commercial IRB). Must have OHRP IRB Registration. Must have at least one of the following: 1) AAHRPP accreditation 2) Member of SMART IRB 3) Recent FDA or OHRP inspection 4) Recent quality audit
Downstate IRB Board specialties:	Nephrology, Dermatology, Physiology, Pharmacology, Medicine, Endocrinology, Pediatrics, Cardiology, Pediatric Endocrinology, Pediatric Infectious Diseases,

	Psychiatry, Nursing, Infectious Disease, Reproductive Endocrinology, Pediatric Endocrinology, Physical Therapy, Occupational Therapy, Hematology, Oncology, Pulmonary Medicine, Anesthesiology, Critical Care Medicine
HIPAA Covered Enity	Yes
IRB Chair	Clinton Brown, MD Clinton.Brown@downstate.edu (718) 270-1729
Administrative contact:	Kevin Nellis Executive Director, Human Research Protections and Quality Assurance (718) 613-8461 Kevin.Nellis@downstate.edu
Alternate contact	IRB@Downstate.edu (718) 613-8480
IRB Website:	https://research.downstate.edu/irb/electronic-submission.html

APPLICABILITY OF REGULATIONS

Downstate 'unchecked' the box on our FWA.

Downstate certifies to the NYS Department of Health that Downstate research follows federal regulations (Common Rule, FDA, or HIPAA) for research. The Common Rule applies to federally funded, supported, or conducted research. We apply the Common Rule (Part A) to all research that is not regulated by FDA or HIPAA.

Downstate may apply the federal requirements of the categorical vulnerable populations (Children, Pregnant Women, Neonates, and Prisoners) regardless of funding or support or where the research is conducted.

Downstate applies NY State regulatory requirements to human research, as applicable to the research.

Downstate applies other foreign, state, or local regulations, when applicable to the study.

Downstate applies any applicable requirements of 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), including the requirement tribal IRB approval, when required by a tribe.

NY STATE REGULATIONS FOR REVIEWING IRB CONSIDERATION

When applicable, in addition to Federal regulations, research conducted at SUNY Downstate is subject to the following:

- New York Codes, Rules and Regulations, Title 14, Department of Mental Hygiene, Part 527, Rights of Patients
- New York Mental Hygiene Law, Article 81
- New York State Public Health Law, Article 24A –Protection of Human Research Participants
- New York State's Public Health Law 18: Access to Patient Records
- New York's Family Health Care Decisions Act (FHCDA) (Public Health Law §29-CC)
- NY State Department of Health HIPPA 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 Civil Rights Law Section 79-L (Confidentiality of genetic tests)
- NYC Department of Education IRB
- NYS DOH HIPAA Preemption Charts

OVERSEEING THE CONDUCT OF RESEARCH AT DOWNSTATE

The following is a summary of the research oversight at Downstate:

- The Department Chairs and Deans are responsible for making sure the research is conducted properly and that adequate resources are available.
- The IRB office a review the local IRB Application to make sure all local policy, HIPAA, and
  information security requirements are met.
- The Privacy Officer is responsible for Downstate Privacy policies and is available to consult with the Downstate IRB. The Privacy Officer is notified of any privacy concerns that arise during the research.
- The Data Security Officer is consulted, before final approval is issued at the local level, if there are any information security concerns. The Data Security Officer He would be notified of any information security concerns that arise during the research.
- The IO is notified of any serious or continuing non-compliance, or unanticipated problems involving risks to research participants or others. The Downstate IRB assists the IO when reporting reportable events to OHRP and FDA. The Director, Sponsored Programs Administration is responsible for reporting reportable events to Funding Agencies, when appropriate.

DOWNSTATE INVESTIGATIONS, AUDITS, AND FINDINGS

There are no investigations, audits, or findings (e.g., OHRP, FDA, or local audits) over the past three years that would be relevant to the conduct of new human research proposed at Downstate.

IDENTIFICATION AND MANAGEMENT OF POTENTIAL UNANTICIPATED PROBLEMS AND/OR SERIOUS OR CONTINUING NON-COMPLIANCE

The principal investigator, Downstate IRB, and institution typically become aware of the event directly from the PI or the IRB may learn of an event from a research participant or from information received about a particular research participant or research activity. The PI must report the event to the reviewing IRB.

When the reviewing IRB reviews an internal event and reports findings back to the PI, the PI must notify the Downstate IRB. These reports will be tracked by the Downstate IRB.

POST IRB APPROVAL MONITORING

The Downstate IRB may request or conduct for cause and not for cause research audits or request these be done through the Office of Compliance and Audit Services (OCAS). OCAS has developed a new audit program and will conduct not for cause audits as needed or when requested. The Downstate IRB Office Staff conduct audits with input from OCAS.

The Research Foundation (Central Office located in Albany NY) completes internal audits of the Downstate IRB and investigators on a periodic basis.

COMMUNITY AND CULTURAL DIFFERENCES

In general, the Downstate community has a positive attitude towards the conduct of research.

The Downstate IRB has not noted any community or cultural differences for the local population of research participants that the relying (external) IRB should consider. Downstate serves a very diverse population in the Brooklyn and NYC area.

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.

STUDY PARTICIPANTS CONCERNS

The PI includes the IRB contact (external, local, or both as required by the reviewing IRB) on the approved consent form. Study participants can contact the IRB at any time.

AGE OF MAJORITY

The age of majority for NY state is 18.

AGE OF ASSENT

In general, if a child is between 7-12, the Downstate IRB generally requires a child to sign a separate Assent Form to be in the study. For children between 13-17, the Downstate IRB generally uses the consent form/parental permission form to document assent by including the signature of a child.

When requesting parent or legal guardian permission for a child, the Downstate IRB recommends adding the following or something similar (edit as needed, depending on the age range of the participants) to the parental permission form:

> **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).

RESEARCH INVOLVING CHILDREN (MINORS)

The following is general guidance for the external IRB to consider when enrolling children in the research:

- The age of majority is 18 years in the State of New York. In general, anyone under 18 is a child.
- An emancipated minor is defined as either a person 16 years or older and living independently from his/ her parents or a minor who is a parent him/herself.

- Additional protections must be in place when enrolling a Ward. It is the general expectation of the DMC IRB that an Independent Consent Monitor be present during the enrollment process and sign this consent; however, the external IRB must determine this for each study.
- In general, the external IRB makes their determination as to whether parental consent is required for research depending on whether the research is about clinical procedures for which parents do not have to provide consent under NY state laws.
    - For example, if the research involves clinical treatment for which parental consent is not required (e.g., HIV or STD treatment) then parental consent would not necessarily be required for the research.
    - However, if the research does not involve a clinical treatment (e.g., "survey" on HIV or STD), then either parental consent is required, or the IRB could grant a waiver of parental consent along with requiring an Independent Consent Monitor as an additional protection.
    - When waving parental consent, the Downstate IRB recommends having an Independent Consent Monitor.

CONSENT FORM APPROVED BY A REVIEWING IRB

In general, the Downstate IRB conducts an administrative review of the consent form approved by the reviewing IRB may; however, the Downstate IRB may request modifications or make recommendations to the consent based on this guidance or request an addendum consent. Any request made of the Downstate IRB must be approved by the reviewing IRB before the change is made.

The Downstate IRB will stamp consent forms if the reviewing IRB does not stamp them.

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 additional information see the Downstate IRB Guidance: Obtaining Legally Effective Informed Consent and HIPAA Research Authorization.

HIPAA AUTHORIZATIONS

The Downstate IRB will accept the approval of HIPAA authorization language approved by the reviewing IRB; however, Downstate will confirm all required elements are included in the document.

The Downstate IRB permits the use of compound authorizations (HIPAA language included in the consent form) or stand-alone documents.

The Downstate IRB serves as a privacy board and will approve a HIPAA authorization language for studies when the reviewing IRB does not serve as a privacy board.

HIPAA WAIVERS FOR REVIEW OF MEDICAL RECORDS FOR RECRUITMENT PURPOSES

The HIPAA Privacy and Security Rule applies to research involving Protected Health Information (PHI) at Downstate.

Downstate requires approval of a waiver of authorization under HIPAA for review of medical records to identify eligible research participants if the potential participants are not seen as patients by the investigators.

CONSENT PROCESS FOR IMPAIRED DECISION-MAKING CAPACITY

For the purposes of Downstate Policy IRB-01, a *legally authorized representative (LAR, personal representative or legally empowered representative or surrogate)* is an individual, judicial, or other body authorized under applicable law to provide consent on behalf of an adult prospective research participant for the research participation of an adult who is cognitively impaired and unable to provide consent. A *LAR* is an individual authorized to provide permission on behalf of a prospective research participant to be involved in the research.

Base the designation of a *LAR* in individual cases on the presence or absence of a power of attorney, living will, or health care proxy (as above).

The informed consent process must comply with institutional policy. For research at Downstate, this includes Policy CONS-01. Only one person from the list below, from the class of highest in priority may authorize the research when persons in prior classes are not reasonably available. The surrogate must be willing and competent to act. The person who is designated may designate another person on the list to be surrogate, as long as no one in the class higher in priority objects. However, if one surrogate does not provide consent, the investigator must honor that decision and not seek consent from another surrogate on the list.

- Healthcare Agent (legal guardian) with authority to provide consent to healthcare decisions (highest priority)
- Guardian authorized to decide about health care, pursuant to Article 81 of the NYS Mental Hygiene law
- Spouse or domestic partner (provided there is no legal separation)
- Adult child (son or daughter)
- Parent
- Adult sibling (brother or sister)

- Close adult friend (must be 18 years or older and present a signed statement of relationship to a patient/participant) (lowest priority)

DOWNSTATE CONSENT FORM 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:

> 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 participant 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 participant 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.

USE OF SHORT FORMS FOR NON-ENGLISH SPEAKING INDIVIDUALS

The Downstate IRB permits the use of the Downstate Short Forms or the Short Forms and approved by the reviewing IRB. The Downstate Short forms are available at Step 8 on the IRB Electronic Submission Process website.

For additional information see the Downstate IRB Guidance: Obtaining Legally Effective Informed Consent and HIPAA Research Authorization.

TRANSLATION OF CONSENT FORMS FOR NON-ENGLISH SPEAKING INDIVIDUALS

The Downstate IRB permits the use translated consent forms for non-English speaking individuals.

For additional information see the Downstate IRB Guidance: Obtaining Legally Effective Informed Consent and HIPAA Research Authorization.

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.]

CONSENT FORM LANGUAGE FOR 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.

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.

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.

QUALIFICATIONS OF DOWNSTATE INVESTIGATORS AND STUDY STAFF

A Downstate Department Chair or Dean must sign the submission to the Downstate IRB to approve the PI to take part in the research at Downstate and that the investigators on the local IRB application are qualified to do the research. The Downstate IRB will confirm the qualifications of the Investigators and Study Staff during the administrative review process. If an IRB administrator needs assistance with determining an investigators qualification, (s)he will consult with the Dean, Department Chair, Credentialing Office, IRB Chair, IRB Vice Chair, or experienced Downstate IRB members. In addition, the Administrative Staff of the IRB will review the submission to verify all training is up to date and COI disclosures are approved.

CONFLICTS OF INTERESTS

Downstate investigators must comply with Downstate conflict of interest (COI) policies. The Downstate Financial COI Committee will determine if there is a relevant individual or institutional conflict of interest and will develop a management plan (MP) to ensure management or elimination of any COI or significant financial interests (SFI), including any necessary COI disclosures within the informed consent document. The Downstate IRB will confirm all local requirements are met before activating a study at Downstate. If there are any SFI or MP in place, these will be shared with the relying (external) IRB.

For more information about the Downstate COI process, please see Step 6 at the Downstate IRB Electronic Submission Process website.

REQUIRED TRAINING

Downstate investigators must complete all required training before the research is activated at Downstate. For more information about the Downstate training requirements, please see Step 6 at the Downstate IRB Electronic Submission Process website.

DRUG AND DEVICE STORAGE

Study drugs are managed by the Downstate Research Pharmacy. Any study that involve drugs must undergo ancillary review by the Downstate Research Pharmacy.

Medical devices are not managed centrally at Downstate. The Downstate PI should provide study-specific information about plans for storage, handling, and dispensing of medical devices.

RESEARCH INVOLVING NYC PUBLIC SCHOOLS

Any research conducted within the NYC Public Schools is subject to approval by the NYC Department of Education IRB. For more information see:
http://schools.nyc.gov/Accountability/data/DataRequests.htm

RESEARCH RECORD RETENTION AND DESTRUCTION

Downstate investigators must consult with FDA regulations, State Retention Policies, Downstate guidance and their departmental policies for additional information. If research records are part of a legal hold or audit, hold the records until the hold is lifted or they are no longer needed for an audit. Downstate investigators must consult the SUNY Downstate Office of General Counsel or the group performing an audit if there are any questions. The SUNY Downstate Office of General Counsel will notify the Department or IRB of any litigation holds and follow-up when records are

no longer subject to a legal hold. Research records and specimens must be securely stored in accordance with the research procedures.

Records may not be destroyed that may have important historical value. Before destroying any research record, list the records on a Records Management Certificate of Destruction form and obtain approval by the Records Management Officer or Designee. Research records and specimens may not be destroyed unless in conformity with Downstate policies, and when applicable other requirements of sponsors or external research sites.

In general, research retention periods follow, but may differ depending on the details of the study. Some of the minimum retention periods are provided below; however, it is recommended all research records be retained securely for up to ten (10) years (including the minimum requirements indicated below),when practicable:

- Securely maintain records relating to a specific research activity, including research records collected by investigators for at least three (3) years after completion of the research. This minimum retention period applies regardless of enrollment of any research participants.
- Securely maintain records, if the research is FDA regulated, for at least two (2) years after approval of the investigational agent by FDA; if it is not approved, records should be retained at least two years after the study is terminated and FDA is notified. However, the FDA requirements for record retention differ and the individual pharmaceutical or device manufacturing companies sponsoring the research may have their own policies on record retention to which the investigators may be subject. Consult with the sponsor before destroying any records.
- Securely maintain the research participants' signed HIPAA Research Authorization forms (or informed consent documents containing the HIPAA authorization) for a minimum of six (6) years after such authorization last was in effect.
- Securely maintain records concerning controlled substance research for five (5) years after completion of the study.
- When research takes place an external site, the PI must follow the longer specified retention period of either the external site or Downstate. For additional information, refer to the Guidance for Retention and Destruction of IRB Records.

CONSENT LANGUAGE TO BE USED AROUND MANDATORY REPORTING TO AUTHORITIES

When applicable to the research, the suggested language for mandatory reporting to health authorities, includes the following:

The research team may share your Protected Health Information as required by law, for example, to:

- Comply with a court ordered subpoena, ***[CAUTION: remove this bullet if there is a Certificate of Confidentiality for this study)]***
- Report suspected child abuse or neglect,
- Report certain communicable diseases,
- Report a possible threat or harm to yourself or others, or
- Comply with other laws.

This should be included with the disclosure for a Certificate of Confidentiality and when otherwise applicable.

DOWNSTATE PROCEDURES FOR REQUESTING AN EXTERNAL IRB REVIEW AND APPROVAL

Below are the key steps for a Downstate PI to follow when seeking reliance on an external IRB. The key steps noted below correspond to the steps on the Downstate IRB Electronic Submission website for more details.

- Step 4a: Determine which investigators are member of the Downstate Workforce. The IRB Reliance Agreement established with the external (reviewing) IRB is only applicable to investigators who are members of the Downstate workforce.
- Step 5: Determine which IRB to use. Downstate has established a master agreement to use the services of the WIRB Copernicus Group (WCG) IRB as the preferred IRB for 1) Industry Sponsored clinical investigations, and 2) Federally funded non-exempt human research which requires a Single IRB (sIRB) when Downstate is the primary awardee for a multi-site study. As required by the agreement, Downstate will make every reasonable effort to use the WCG IRB except in situations where a sponsor requires the use of another independent IRB or when the research has oversight by the NCI Central IRB.
- Step 6: All Downstate investigators must complete the training and conflict of interest disclosures required by Downstate.
- Step 8: Develop the consent materials. Be sure to edit the model consent document developed by the main study site to include any edited fields that are permissible by the reviewing IRB. The Downstate IRB will assist in the Downstate investigators to ensure the Downstate consent form meets the local requirements and ensure the draft consent documents are acceptable. The Downstate PI must share these materials in IRBNet and request a "Pre-Review" (see step 11 below).
    - Be sure to review the Downstate IRB Guidance: "Obtaining Legally Effective Informed Consent and HIPAA Research Authorization."
        - This document includes important requirements required by NY State and by Downstate, including the following topics, which may be unique to Downstate:
            - HIPAA authorization language
            - NYS genetic testing disclosures

        - Disclosure of psychotherapy notes
        - Medical record disclosures
        - SUNY RF Payment form
        - Companion (ancillary) studies
        - Optional research activities
        - Publishing photographs of the full face
        - Conflict of interest disclosures
        - Pregnant partner authorization
      - The external (reviewing) IRB may limit that can be changed in the model consent form, such as contact information for the local study team, costs that differ for Downstate, Downstate's language regarding the availability of and compensation for research-related injury.
      - The external (reviewing) IRB may prefer an addendum be added to the model consent form; however, such an addendum must be approved by external (reviewing) IRB and activated by the Downstate IRB.
    - If the external (reviewing) IRB does not serve as a Privacy Board, the Downstate IRB or Downstate Privacy Officer will review HIPAA instruments (i.e., authorizations, waivers, DUAs, BAAs, etc.)
- Step 9: Develop Short Forms, if applicable.
    - SUNY Downstate serves patients with limited English proficiency (LEP). For more information, please refer to the IRB guidance: "Obtaining Legally Effective Informed Consent and HIPAA Research Authorization."
    - Develop any necessary Short Forms for recruitment of those with limited English proficiency. The Downstate IRB will activate either the Downstate Short Forms or any other Short Forms approved by the external (reviewing) IRB.
- Step 11: The Downstate PI must submit an "Application for External IRB Oversight" to the Downstate IRB. This form is available at Step 11 on the Downstate IRB Submissions Website.
    - The "Application for External IRB Oversight" is designed to be flexible and can be used to request one or more of the following depending on the stage of the submission:
      - Reliance Request
      - Pre-Review
      - Downstate Activation
    - When developing the IRB application materials, be sure the submission is consistent with Downstate policy and guidance to ensure the requirements, expectations and limitations of the Downstate IRB are followed. The following materials are available on the Downstate IRB Policy and Guidance website:
      - Policy IRB-01
      - Information Security Guidance
      - Recruitment, Referral, Screening, Advertising, and Incentives
- Step 12: Upload all materials in IRBNet.
- Step 14-16: Obtain all required ancillary reviews, including Department Chair or Dean approval, and submit the application in IRBNet.

- Prior to submitting a study to the reviewing IRB, the Downstate PI or the external (reviewing) IRB may require a Pre-Review of materials to ensure local context requirements are met.
- The Downstate IRB can issue a preliminary letter to indicate it meets all local research context requirements or list any pending requirements.
- Before the research can begin at Downstate, the Downstate IRB must activate the external IRB approval. The Downstate IRB will verify all local research context requirements.
- The external IRB determines the expiration date of IRB approval. If the Downstate IRB receives a notice of approval of continuing review, yet not all of the investigators have updated their local training or conflict of interest requirements, the delinquent investigators cannot participate in the research, until they meet all of the local pending requirements.

AMENDMENTS

The Downstate IRB will conduct an administrative review and acknowledge amendments approved by the reviewing IRB. The Downstate IRB will confirm all local requirements are met.

If a reviewing IRB does not require an amendment for study stuff, the Downstate IRB will process such amendments. The Downstate IRB will confirm all local requirements are met, including verification of all required training and conflict of interest disclosures.

CONTINUING REVIEW

The Downstate investigators must submit their progress reports for continued approval to the reviewing IRB. Once approved, the investigators must submit the Downstate IRB Application for Progress Report (Continuing Review) for External IRB Oversight. The Downstate IRB will confirm all local requirements are met and activate the continuation of the study at Downstate.

REFERENCES

- 21 CFR 50, 56, 312, & 812
- 45 CFR 46
- Downstate IRB Guidance
- Downstate Policy IRB-01

AUTHOR

Kevin L. Nellis, MS
Executive Director, Human Research Protections and Quality Improvement

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