**Local Research Context Guide for External IRB Review**

|  |
| --- |
| **The SUNY Downstate Medical Center (DMC) IRB provides this guidance for external IRBs that are reviewing research at DMC. For more information, please contact the SUNY DMC IRB at 718-613-8461 or** **IRB@downstate.edu****KEY POINTS:*** The PI at SUNY DMC must complete an [“Application for External IRB Oversight”](http://research.downstate.edu/irb/irb-electronic-submissions.html) form and submit it to the SUNY DMC IRB.
* Before the research can begin, the SUNY DMC IRB must acknowledge the external IRB approval.The DMC IRB will verify all local research context requirements.
* If required by the External IRB, the DMC IRB can issue a preliminary letter to indicate it meets all local research context requirements or list any pending requirements.
* All required financial conflict of interest disclosures and applicable management plans for significant financial interests must be complete.
* All required human research protections training must be complete.
* The PI must address all NY state regulations and requirements.
* The PI must complete Downstate Medical Center ancillary reviews when applicable.
* For additional information consult with [Policy IRB-01](http://research.downstate.edu/irb/irb-policies.html).

For any additional information on the NYC H+H, Kings County Medical Center (KCHC) process please contact one of the [KCHC Facility Research Coordinators](http://research.downstate.edu/irb/irb-electronic-submissions.html). |

Contents

[Request to Use an External IRB or sIRB for Multi-Site Research Projects 2](#_Toc10706367)

[Procedures for Requesting an External IRB Review and Approval 3](#_Toc10706368)

[DMC Acknowledgement Process After External IRB Approval 4](#_Toc10706369)

[Additional Protections Required By The DMC IRB when using an external irb (including SIRB). 5](#_Toc10706370)

[Cooperative Research Review (Single IRB Review of Federally Funded or Federally Conducted Study) 7](#_Toc10706371)

[SUNY DMC IRB Application to Use an External IRB 8](#_Toc10706372)

[Research Involving the Kings County Hospital Center (NYC Health + Hospital) 8](#_Toc10706373)

[NY State Regulations 8](#_Toc10706374)

[Financial Conflict of Interest Committee 9](#_Toc10706375)

[Training Requirements 9](#_Toc10706376)

[Ancillary Reviews by Downstate Medical Center 9](#_Toc10706377)

[Research Participants with Limited English Proficiency (LEP) 12](#_Toc10706378)

[Research Involving Children (Minors) 12](#_Toc10706379)

[Research Involving NYC Public Schools 13](#_Toc10706380)

[Legally Authorized Representative (LAR) or Surrogate 13](#_Toc10706381)

[HIPAA Authorization Language 14](#_Toc10706382)

[Genetics Testing 14](#_Toc10706383)

[Specimen or Information Storage For Future Research 14](#_Toc10706384)

[HIV Testing 14](#_Toc10706385)

[Obtianing Video, Audio , or Images 15](#_Toc10706386)

[Informed Consent/HIPAA Authorization Signature Lines 15](#_Toc10706387)

[Possible DMC IRB Actions 15](#_Toc10706388)

[Acknowledgement 15](#_Toc10706389)

[Acknowledgement Pending External IRB Approval 15](#_Toc10706390)

[Suspension or Termination 16](#_Toc10706391)

[References 16](#_Toc10706392)

[Author 16](#_Toc10706393)

[Review and Approval History 16](#_Toc10706394)

# Request to Use an External IRB or sIRB for Multi-Site Research Projects

An external IRB is any IRB other than the DMC IRB that reviews and approves a multi-site research project that includes DMC. This can be a Central IRB, a Commercial IRB, a Main Study Site IRB, or a Single IRB; however, the DMC IRB may be required to establish an IRB Authorization (Reliance) Agreement with the external IRB. The DMC IRB must acknowledge external IRB approval, and confirm the study meets any local research context requirements, before the research may begin at DMC.

Any external IRB that oversees DMC research must enter into an IRB Reliance (Authorization) Agreement with SUNY DMC for all FDA regulated or federally funded research. At the time of this writing, the SUNY DMC has entered into IRB Reliance (Authorization) Agreement with the following IRBs:

* [National Cancer Center Central IRB (1, 2, 3, & 4)](https://www.ncicirb.org/)
* [Biomedical Research Alliance of New York (BRANY) IRB](https://www.brany.com/irb-services/)
* [SMART IRB](https://smartirb.org/)

*Note: Contact the IRB for other sites not listed above.*

Unless the DMC IRB refers review to an external IRB, **DO NOT** use an external IRB for any research involving any of the following:

* DMC as a single research site; or
* Research previously disapproved by the DMC IRB.

*Note: Research that takes place at NYC H+H, Kings County and Downstate is not considered a single site for the purpose of this guidance.*

When using an external IRB, the research team must follow the procedures, policies, directives, and practices of the external IRB, the DMC, the IRB Authorization (Reliance) Agreement, and the sponsor.

The PI and research staff must comply with the determinations and requirements of the both the external IRB and the DMC IRB. DMC is responsible for ensuring compliance with the IRB’s requirements at the DMC.

Each institution involved in the multi-site project is responsible for ensuring compliance at their site. Research staff from external sites must consult their own institutional policies to determine if other requirements apply.

## Procedures for Requesting an External IRB Review and Approval

|  |
| --- |
| **IMPORTANT:** When requesting the review and approval of human research by an external IRB, the PI must complete the required external IRB Application (according to the guidance and directions of the external IRB). In addition, the PI MUST also submit the DMC IRB’s “Application for External IRB Oversight.”  |

|  |
| --- |
| **CAUTION:** The DMC often collaborates with employees from NYC H + H, Kings County. If employees from NYC H + H, Kings County are included as investigators on a **federally funded** **study**, please **use the BRANY IRB** or **The SMART IRB** online reliance system, or collaborate with NYC H + H, Kings County to establish an IRB Reliance (Authorization) Agreement with the External IRB and NYC H + H, Kings County. |

|  |
| --- |
| **TIP:** While waiting for approval of the external IRB application, one may wish to begin the submission to the DMC IRB to ensure the research meets all local requirements by submitting the DMC IRB’s “Request to Use an External IRB Application.” In particular, please ensure completion of the following on a timely basis: 1) Ancillary reviews, if required 2) Training 3) Conflict of Interest (COI) disclosures. |

The IRB Office will forward the IRB Reliance Agreement to the Institutional Official (IO) for signature. The DMC IRB will acknowledge the approval of the external IRB’s approval once it has certified that the research meets all local research context requirements, including all local training and conflict of interest requirements. In general, the DMC IRB will not require changes to the research approved by the external IRB; however, the DMC IRB may require or recommend changes or an addendum for submission to the external IRB for approval.

The external IRB must approve the research and the DMC IRB must acknowledge the external IRB approval before any research activities at the DMC site may begin. The PI or IRB may provide the external IRB with this “[Local Research Context for External IRB](http://research.downstate.edu/irb/irb-policies.html)” guidance document, to clarify DMC requirements.

The external IRB determines the expiration date of IRB approval.

All required ancillary reviews must take place before the research may begin.

If required by the External IRB, the DMC IRB can issue a preliminary letter to indicate it meets all local research context requirements or list any pending requirements.

If the DMC 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.

### DMC Acknowledgement Process After External IRB Approval

Before acknowledging the external IRB approval, the DMC will confirm:

* An IRB Authorization (Reliance) Agreement, when required, has been fully executed between DMC (and a separate agreement with the NYC H+H, Kings County Hospital Center, if applicable, which also must be approved by the NYC H+H IO) and the external IRB,

*Note: When the external IRB and DMC agree to apportion IRB review responsibilities, the external IRB should have written procedures describing how it implements its responsibilities under the agreement or this can be included in the reliance agreement.*

* All required ancillary reviews are complete or the DMC IRB may indicate the research cannot begin until the required ancillary review is complete,
* All required training is complete, and
* All required conflict of interest disclosures are complete and approved.

In order for the DMC IRB to accept the review of an external IRB, the PI must provide information about the external IRB to demonstrate it meets the following criteria:

1. Unless it is an IRB organization, the institution must maintain a Federalwide Assurance (FWA) approved by the OHRP.
2. The IRB must maintain an active registration with OHRP.
3. **The IRB must be:**
	1. **AAHRPP accredited,**
	2. **be a member of the SMART IRB reliance system, or**
	3. **it must have undergone or initiated an assessment of the quality of the IRB within five years (e.g., participation in OHRP’s Quality Assessment Program, internal audit, FDA inspection, ORHP inspection, or equivalent approach).**

*Note: The DMC IRB may request documentation to support item 3c, above.*

1. The external IRB must provide a point of contact for communication with the DMC IRB.
2. Information on how the external IRB intends to communicate with the investigators and the DMC IRB.
3. For FDA regulated research, provide a description of the external IRB’s ability to evaluate the institution’s ability to participate in the study (e.g., whether the institution has medical services appropriate for the complexity of the study).

### Additional Protections Required By The DMC IRB when using an external irb (including SIRB).

In general, an External IRB serves as a Privacy Board to approve HIPAA authorizations or HIPAA waivers, under the HIPAA regulations. If an External IRB does not serve as a Privacy Board, such as the NCI CIRB, it does not have the authority to approve HIPAA authorizations, HIPAA waivers, or other HIPAA documents (e.g., Data Use Agreements, Business Associate Agreements) or review HIPAA researcher certifications (e.g., Preparatory to Research, PHI for Decedents). When an external IRB does not have the authority to approve any HIPAA documents, the DMC IRB must approve any HIPAA documents.

If boilerplate language or addendum documents are required to be added to the informed consent or information sheet documents by the DMC IRB, the external IRB must also approve of the additional requirements.

DMC leadership and the DMC IRB reserve the right to place enrollment on hold, suspend or terminate the research activity or request additional protections at the DMC site at any time. At such time, the DMC IRB or Institutional Official will promptly notify the external IRB of these actions; however, the PI may also be required to notify the external IRB, within the external IRB’s specified reporting deadlines.

Promptly submit any amendments requested by the DMC IRB to the external IRB, within the timeframe requested by the DMC IRB and follow-up with the DMC IRB, based on the response from the external IRB determination:

1. If the external IRB issues a disapproval, the PI must report the findings, including the reasons for the disapproval to the DMC IRB **within 5 days.** The DMC IRB, IRB Chair, Vice Chair, or IO will determine whether the research may continue at DMC.
2. If the external IRB issues an **approval**, report the findings to the DMC IRB **within 30 days,** for DMC IRB acknowledgement prior to starting the research.

Although a study is under the primary jurisdiction of the external IRB, the following also apply:

* When requested by the DMC IRB, submit progress reports for continuing review and/or IRB notices or letters from the external IRB to the DMC IRB for local acknowledgement. This request may take place at the time of initial local research context review or may be required throughout the duration of the entire study, or on a case-by-case request.
* When the external IRB requires continuing review:
	+ The research may continue, once the external IRB approves the continuation; however, maintain the IRB approval letter in the research record so that it is readily available to the DMC IRB.
	+ If requested by the DMC IRB, as noted above, the DMC PI must complete an abbreviated continuing review (progress) report for the DMC IRB; however, the DMC IRB review will focus on local research context.
* Whenever there are changes to materials that require an IRB stamp prior to use (as required by Policy IRB-01) and the external IRB does not provide a stamp, submit a request to the DMC IRB to request to stamp the materials. This request can be in the form or an amendment or it can take place during the initial review of local research context.
* Whenever there are changes to the local study site personnel, submit an IRB amendment to the DMC IRB. When adding research staff, please indicate whether the new research staff are *investigators for the purposes of COI* as defined by the DMC COI policy. New study site personnel may not participate in the research until the DMC IRB acknowledges the addition of study staff.
* Either the External IRB or the DMC IRB may require, conduct, or request post approval monitoring or audits.

In addition to the reporting requirements of the external IRB, **immediately** report the following events to the DMC IRB:

* Any privacy breach that occurs at DMC.

*Note: Immediately report this event to the DMC Privacy Officer, as well.*

* Any information security breach that occurs at DMC.

*Note: Immediately report this to the DMC Data Security Officer, as well.*

* Any event involving the death of a research participant from the DMC site, when the death is related, probably related, or possibly related to participation in the research.
* Whenever there is a discovery of the incarceration of a research participant from the DMC site, if any research interventions must take place while under incarceration.
* Any event that occurs at DMC that requires mandated reporting to a State or Federal Department or Agency, including:
	+ Suspension or termination of IRB approval of research
	+ Unanticipated problems involving risks to research participants or others
	+ Serious or continuing non-compliance

### Cooperative Research Review (Single IRB Review of Federally Funded or Federally Conducted Study)

Cooperative research projects are those projects that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of research participants and for complying with federal regulations.

[NIH Policy](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-076.html) requires the use of a single IRB (sIRB) for multi-site research for all human research covered by a grant application on or after January 25, 2018.

When the DMC is engages in federally funded cooperative (multi-site) research with other sites, DMC must rely upon approval by an sIRB for that portion of the research that is conducted in the United States, by January 20, 2020.

In general, the Federal department or agency supporting or conducting a research project identifies the sIRB to oversee the research. A lead institution may propose the sIRB, subject to the acceptance of the Federal department or agency supporting the research.

At present, the DMC IRB does not have the capacity to serve as a sIRB; therefore, when the research requires a sIRB, follow the process for using an External IRB. Contact the DMC IRB if seeking recommendations for another sIRB.

***NOTE: Investigators applying for an NIH grant requiring sIRB review, should include the sIRB fees in the budget. Be mindful that it is not known if other federal departments or agencies will allow for sIRB fees in the budget of their grants, which must be implemented by January 20, 2020. For additional information, please consult with the federal department or agency funding the research.***

For certain research, more than single IRB review may be required by law (e.g., tribal law passed by the official governing body of a Native American or Alaska Native tribe, research for which any federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate).

# SUNY DMC IRB Application to Use an External IRB

The PI at SUNY DMC must complete an [“Application for External IRB Oversight”](http://research.downstate.edu/irb/irb-electronic-submissions.html) ” form and submit it to the SUNY DMC IRB. Before the research can begin, the SUNY DMC IRB must acknowledge the external IRB approval. The SUNY DMC acknowledges the approval of the external IRB, after verifying local research context requirements. The following materials must be submitted with the application:

Before acknowledging the external IRB approval, the DMC IRB will confirm:

* An IRB Authorization (Reliance) Agreement has been fully executed for any research that is federally funded or supported, or when required by the External IRB between SUNY Downstate Medical Center (and Kings County Hospital Center, if applicable)
* All required ancillary reviews are complete
* All required training is complete
* All required Conflict of Interest disclosures are complete and approved

# Research Involving the Kings County Hospital Center (NYC Health + Hospital)

The SUNY Downstate Medical Center often collaborates with NYC Health + Hospital (NYC H+H), Kings County Hospital Center (KCHC) and many of the DMC faculty are clinicians at KCHC.

If employees from KCHC are included as investigators, making KCHC engaged in human research, please contact KCHC to determine requirements of establishing an IRB Authorization (Reliance) Agreement between the KCHC and the external IRB and obtain the IO signature on the agreement, when such is required.

For any additional information on the NYC H+H, Kings County Medical Center (KCHC) process please contact one of the [KCHC Facility Research Coordinators](http://research.downstate.edu/irb/irb-electronic-submissions.html)

# NY State Regulations

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

* [New York Codes, Rules and Regulations, Title 14, Department of Mental Hygiene, Part 527, Rights of Patients](https://www.omh.ny.gov/omhweb/policy_and_regulations/)
* [New York Mental Hygiene Law, Article 81](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwjwycbpkJnMAhUJyj4KHT7bCe0QFggdMAA&url=http%3A%2F%2Fwww.nycourts.gov%2Fip%2Fgfs%2FArticle_81_Law_2008.pdf&usg=AFQjCNGmFr_gaA9epXmzFloU15Dx64xxzg&sig2=qSaQIg4wUbezAn7tvoMMLQ)
* [New York State Public Health Law, Article 24A –Protection of Human Research Participants](https://www.nysenate.gov/legislation/laws/PBH/A24-A) [[1]](#footnote-2)
* [New York State's Public Health Law 18: Access to Patient Records](http://www.douglasandlondon.com/docs/New-York-State-Public-Health-Law-18.pdf)
* [New York’s Family Health Care Decisions Act (FHCDA) (Public Health Law §29-CC)](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=5&ved=0ahUKEwi66OqIlJnMAhVLeT4KHTdOA2AQFgg7MAQ&url=https%3A%2F%2Fwww.health.ny.gov%2Fdiseases%2Faids%2Fproviders%2Fregulations%2Ffhcda%2Fai_fact_sheet.htm&usg=AFQjCNG7kzcFNmDCA1qa5g5VW7b21L9gjQ&sig2=dyxkL-ZTSjxcoErVnoF5eg&cad=rja)
* [NY State Department of Health HIPPA Preemption Charts](http://www.health.ny.gov/regulations/hipaa/preemption_charts.htm)
* [NYS 10 NYCRR Part 63 (HIV/AIDS Testing, Reporting and Confidentiality of HIV-Related Information](http://www.health.ny.gov/professionals/ems/pdf/srgpart63.pdf)
* [NYS 1-2.13 NY Estates Powers and Trusts Law](http://www.nysl.nysed.gov/libdev/excerpts/ept11-23.htm)
* [NYS Civil Rights Law Section 79-L (Confidentiality of genetic tests)](http://codes.findlaw.com/ny/civil-rights-law/cvr-sect-79-l.html)
* [NYC Department of Education IRB](http://text.nycenet.edu/Accountability/data/DataRequests.htm)
* [NYS DOH HIPAA Preemption Charts](http://www.health.ny.gov/regulations/hipaa/preemption_charts.htm)

# Financial Conflict of Interest Committee

The SUNY DMC IRB will check COI disclosures. The SUNY DMC fCOI Committee reviews Significant Financial Interests and implements Management Plans when required prior to final local IRB acknowledgement of External IRB approval.

For more information, see the [“Training and COI Disclosure” guidance](http://research.downstate.edu/irb/irb-training.html).

# Training Requirements

The SUNY DMC IRB will check all training requirements:

* CITI training (all investigators)
* HIPAA training (all investigators)
* Conflict of Interest (COI) Training (required by PI and all investigators deemed by the PI to be “Investigators for the purposes of COI”)
* Dangerous Goods Shipping Certification (required by individuals who are involved with shipping specimens, infectious substances, biological or hazardous substances

For specific details, please refer to the [SUNY Downstate IRB Training website](http://research.downstate.edu/irb/irb-training.html).

# Ancillary Reviews by Downstate Medical Center

Ancillary reviews by various departments or committees may be required, depending on the nature of the study. At the discretion of the IRB, the IRB may consult with others or require ancillary review of a research application at any time.

Examples of Ancillary Reviews may include Scientific Review Committee, Institutional Biosafety Committee, Pharmacy, and Pathology. To determine if such a review is required, consult the IRB website, contact the DMC IRB, or refer to the policies of the above committees or departments.

Ancillary reviews by various departments or committees may be required as an administrative process for Downstate policy or at the discretion of the IRB for any human research protection concern. Examples of Ancillary Reviews may include Scientific Review Committee (SRC), Institutional Biosafety Committee (IBC), Radiation Safety, Radiology, Pharmacy, and UHB Pathology.

To determine if an ancillary review is required prior to IRB approval of a specific project, other than noted below, please consult the IRB website, contact the IRB, or refer to the policies of the above committees or departments. When an external IRB is used, the DMC IRB requires the following ancillary reviews in advance of granting IRB approval for the specific conditions noted below:

* **Downstate Department Chair or Dean Review:**
* **Scientific (or Scholarly) Review** is required prior to External IRB approval of the following types of research projects:
	+ The following types of studies must undergo SR by the SUNY Downstate Cancer Program/Institute SRC, regardless of level of IRB review (e.g., full board, expedited, exempt, external IRB review):
* Any cancer-related study involving the prospective enrollment of research participants at SUNY Downstate.
* Prospective studies of tissue and/or body fluids with a scientific hypothesis related to cancer.
* Studies in which the eligibility criteria requires a cancer diagnosis regardless if the study’s focus is cancer or not.
* All interventional studies involving cancer prevention.
* Research that includes individuals with cancer, individuals at risk for cancer, or individuals in a study involving a specific cancer focus (e.g., program evaluations, quality of life, and health education).
* **Downstate Institutional Biosafety Committee (IBC) review and or** [**Novel and Exceptional and Research Advisory Committee (NExTRAC)**](https://osp.od.nih.gov/biosafety-biosecurity-and-emerging-biotechnology/) **[formally the NIH Recombinant DNA Advisory Committee (RAC)] review** is required prior to IRB approval for any study that involves human gene therapy or any deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules into one or more human research participants.

*Note: IBC approval may be required for other activities, prior to starting the research. Refer to IBC policy or IRB guidance on the IRB application or IRB website for additional details.*

**UHB pathology review** is required prior to IRB approval when patient material obtained for research will affect the clinical care of a patient (e.g., if the research proposes a surgical sample is divided for research and clinical purposes), as determined on a case by case basis by either the IRB or UHB Pathology.

*Note: UHB pathology approval may be required for other activities, prior to starting the research. Refer to UHB policy or IRB guidance on the IRB application or IRB website for additional details.*

* **Downstate Pharmacy Review** is required prior to IRB approval for clinical investigations at Downstate that involves an IND.

*Note: Downstate Pharmacy reviews for other studies involving a drug, including biologic can take place after IRB approval. Refer to Downstate Pharmacy policy or IRB guidance on the IRB application or IRB website for additional details.*

* **Any ancillary review required by the IRB not otherwise noted above** when the IRB determines there is a human research protection concern that requires the ancillary review. Examples may include the following:
	+ The IRB may request Radiology review or Radiation Safety review for concerns with the risk or level of radiation exposure of a research participant.
	+ The IRB may request a Biostatical review for a study with possible design flaws or concerns with the data analysis plan.
	+ The IRB may request a consultant review the study when there is not sufficient expertise on the IRB to evaluate the study.
	+ The IRB may request review by the Privacy Officer or Data Security Officer to address any concerns with HIPAA regulations, GDPR regulations, privacy, confidentiality, or information security.
	+ The IRB may request an ethics consult regarding the research proposal.
	+ The IRB may request IBC review for any biosafety concern.
	+ The IRB may request biomedical engineering review for any equipment used in the research, if there is a safety concern or unknown risk of using the equipment.

*Note: For more information on Downstate information security requirements, please see:* [*IRB Guidance: DATA SECURITY*](http://research.downstate.edu/irb/irb-policies.html)*.*

In general, when an ancillary review is required in advance of IRB approval and still pending, the IRB issues a conditional approval letter. The IRB grants final approval after receiving documentation of ancillary approval. However, any changes required by the ancillary review must also undergo IRB amendment review and approval.

When an ancillary review is NOT required prior to IRB approval, the investigator must document approval of any pending required ancillary review within the research record prior to starting the research or enrolling any research participants, as applicable. The IRB will provide a copy of the approval letter to the corresponding department or committee that should complete the ancillary review. If an ancillary reviewer requires or recommends any modifications to the previously IRB approved research, any such modification must be subsequently approved through an IRB amendment, prior to implementation of changes. If desired, by the PI or sponsor, the PI may submit a copy of the documentation of ancillary approval not requiring any modifications to the IRB for the IRB to acknowledge; however, this is not a requirement of Policy IRB-01.

# Research Participants with Limited English Proficiency (LEP)

The SUNY DMC serves many patients with limited English proficiency (LEP). For more information, please refer to the IRB guidance: [“Obtaining Legally Effective Informed Consent and HIPAA Research Authorization.”](http://research.downstate.edu/irb/irb-policies.html)

When applicable, the external IRB may approve either their own Short Forms or the [Short Forms posted on the DMC IRB website](http://research.downstate.edu/irb/irb-electronic-submissions.html).

# 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 monitor as an additional protection.
	+ When waving parental consent, the DMC IRB recommends having an Independent Consent Monitor.

# 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>

# Legally Authorized Representative (LAR) or Surrogate

For the purposes of 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)

# HIPAA Authorization Language

The SUNY DMC IRB encourages the use of HIPAA Authorization Language within the Informed Consent Document, also known as a compound authorization. If needed, the external IRB may adopt the language provided in the [DMC IRB Informed Consent template](http://research.downstate.edu/irb/irb-electronic-submissions.html).

# Genetics Testing

Under [NYS Civil Rights Law Section 79-L (Confidentiality of genetic tests)](http://codes.findlaw.com/ny/civil-rights-law/cvr-sect-79-l.html), researchers must ask permission to contact a research participant in the future to obtain or share information related to diagnostic genetic testing. If needed, the external IRB may adopt the language provided in the [DMC IRB Informed Consent template](http://research.downstate.edu/irb/irb-electronic-submissions.html).

# Specimen or Information Storage For Future Research

If samples or identifiable (or coded) data are stored for future research purposes, including for genetic testing, the informed consent document must state how long the samples will be stored. If needed, the external IRB may adopt the language provided in the [DMC IRB Informed Consent template](http://research.downstate.edu/irb/irb-electronic-submissions.html).

If identifiers might be removed from the identifiable private information or identifiable specimens and after such removal, the information or specimens could be used for future research studies or distributed to another investigator for future research studies or distributed to another investigator without obtaining additional informed consent (or an LAR). However, the informed consent process **must** obtain the permission to share coded materials with other investigators. The consent must ask permission to use or share coded information or coded specimens for future research studies and provide more information about this. Investigator can only use or share coded material obtained from a current research if the participants provide their permission to do so. Investigators cannot share the key to the code with future researchers; therefore, the researchers doing future research cannot identify the research participants. When this approach is taken, the research participants must be given the optional authorization for future research, as required under the HIPAA regulations. Please see the [DMC informed consent template](http://research.downstate.edu/irb/irb-electronic-submissions.html) for suggested language for this purpose.

# HIV Testing

*Recommend (not require) including the following paragraph within the informed consent document 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.

# Obtianing Video, Audio , or Images

Under DMC policy, obtaining video, audio, or images from research participants must be disclosed within the informed consent document. If needed, the external IRB may adopt the language provided in the [DMC IRB Informed Consent template](http://research.downstate.edu/irb/irb-electronic-submissions.html).

# Informed Consent/HIPAA Authorization Signature Lines

The external IRB will determine the appropriate signature lines and attestations for informed consent and HIPAA research authorization. If needed, the external IRB may adopt the language provided at the end of the [DMC IRB Informed Consent template](http://research.downstate.edu/irb/irb-electronic-submissions.html).

# Possible DMC IRB Actions

The IRB enters the following possible IRB Actions or Approvals in the IRB application and submission system, which are included within the IRB letter.

## Acknowledgement

The IRB may acknowledge the receipt of the submitted materials. No additional actions are usually required, unless specified in the IRB letter.

The IRB may issue this type of letter to acknowledge an external IRB approval, once the DMC IRB confirms it meets all local research context requirements.

## Acknowledgement Pending External IRB Approval

When an External IRB request local research context review, prior to issuing approval, the DMC IRB Office will review and confirm the study meets all local research context requirements. When the study meets all local requirements, the DMC IRB will issue a letter to acknowledge but indicate external IRB is pending.

Once the PI submits a follow-up submission to the DMC IRB with the External IRB approval letter, the DMC IRB will issue a final acknowledgment.

## Suspension or Termination

The IRB will acknowledge a notice for study is suspension or termination by someone other than the IRB. If the IRB suspends or terminates IRB approval, the letter will state such actions.

The IRB will consider any actions required to protect any research participants in the study.

# References

* + [21 CFR 50, 56, 312, & 812](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm)
	+ [45 CFR 46](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/revised-common-rule-regulatory-text/index.html)
	+ [IRB-01 policy](http://research.downstate.edu/irb/irb-policies.html)

# Author

Kevin L. Nellis, MS, CIP

# Review and Approval History

Original Issue Date: 10.13.2016

Supersedes: 10.13.2016, 03.21.2017, 07.21.2018

Revision Date: 01.23.2019

|  |  |  |  |
| --- | --- | --- | --- |
| **Date** **Reviewed & Approved** | **Revision Required** | **Responsible Staff Name and Title** | **Comments** |
| Yes | No |
| 10.13.2016 |  | X | Kevin L. Nellis, MS, CIP, Executive Director, Human Research Protections and Quality Improvement |  |
| 03.21.2017 | X |  | Kevin L. Nellis, MS, CIP, Executive Director, Human Research Protections and Quality Improvement |  |
| 07.21.2018 | X |  | Kevin L. Nellis, MS, CIP, Executive Director, Human Research Protections and Quality Improvement |  |
| 01.23.2019 | X |  | Kevin L. Nellis, MS, CIP, Executive Director, Human Research Protections and Quality Improvement | Updated to be consistent with revised Policy IRB-01, effective 1.21.2019. |
| 04.09.2019 | X |  | Kevin L. Nellis, MS, CIP, Executive Director, Human Research Protections and Quality Improvement | Updated to reflect new process for NCI CIRB approvals and a few other minor changes, effective 04.09.2019. |
| 06.06.2019 | X |  | Kevin L. Nellis, MS, CIP, Executive Director, Human Research Protections and Quality Improvement | Major updates include 1) changing the OCAS ‘requirement’ of HIV language to ‘recommending’ the language within the informed consent and 2) updating change in RAC to NExTRAC. Other minor edits made to emphasize the process of acknowledging external IRB approvals. |

1. *: The SUNY DMC voluntarily applies 45 CFR 46 and all subparts to all research; therefore, NY Article 24A does not apply. Please note there are anticipated changes to NYS Article 24A, which may affect the implementation of the Federal Common Rule once these changes go into effect.*  [↑](#footnote-ref-2)