SUNY Downstate Medical Center
Institutional Review Board
Registration Form for DMC/IRB Review

- ☐ **Investigational Drugs**
- ☐ **Approved Drugs**
- ☐ **Devices**

I. Project Personnel

Name: **Role:**

Phone: **Email:**

DMC Status:

Department:

Interaction with subjects? ☐ Yes ☐ No

II. Research Funding

Funding Sources:

- ☐ Internal Funds Only
- ☐ External Funds Only
- ☐ Both Internal and External Funds
- ☐ Seeking funding
- ☐ No Internal or External Funds Required

Grant Sponsor	**Grant Status**	**RF #**

Grant Title:

Significant Financial Interest:

Do any investigators listed above, or members of their immediate families, have a significant (personal) financial interest (e.g., consulting fees, honoraria, ownership) in the sponsoring company (if funded)?

- ☐ Yes *(Detail required in the Application for Expedited or Full DMC/IRB Review.)*
- ☐ No
- ☐ Not Applicable: Not Externally Funded

Interest in Commercial Success:

Do any investigators listed above, or members of their immediate families, have a vested personal interest in the future commercial success of the drug, device, etc under study (e.g., was involved in discovery, patent, licensing, IND/IDE filings etc.)?

- ☐ Yes *(See COI section of the DMC/IRB Investigators Policies and Procedures for required consent form language.)*
- ☐ No

III. Project Information

Campus Study Locations:

- ☐ Downstate Medical Center (not including hospital locations)
- ☐ University Hospital
- ☐ University Hospital at Long Island College Hospital
- ☐ University Hospital at Bay Ridge
- ☐ University Hospital Satellite Clinics
- ☐ Kings County Hospital Center
  (Provide HHC/KCHC with study information through the HHC REASON system.)
- ☐ Veterans Administration Brooklyn
- ☐ Other:

Investigator initiated? ☐ Yes ☐ No

Activities conducted at another institution? ☐ Yes ☐ No *(Skip to Section IV.)*

Participating institution(s), FWA numbers, and role(s):

Multi-center clinical trial? ☐ Yes ☐ No

DMC is lead institution? ☐ Yes ☐ No

Note that *if DMC is the lead institution,* IRBNet must be used by all sites to keep them informed of study-related current information (protocols, amendments, consent documents, IRB status). The Principal Investigator will comply with this requirement:

☐ Yes ☐ No ☐ DMC is not lead.

IV. Subject Information

Special Populations:

- ☐ Children (0-17 years old)
- ☐ Women
- ☐ Pregnant women/fetuses

- ☐ Non-viable/questionably viable neonates *[note that viable neonates are considered children]*
- ☐ Minorities *[including American Indians, Alaskan Native, Asian, Native Hawaiian, Pacific Islander, Black [not of Hispanic origin] and Hispanic]*
- ☐ Cognitively-impaired adults
- ☐ Non-English speakers *[required, if the study holds the prospect of direct therapeutic benefit to the subject]*
- ☐ Any investigators named on this form, or relatives/subordinates/students thereof
- ☐ Prisoners
- ☐ Elderly
- ☐ Students
- ☐ None of the above populations will be included.

Obtaining informed consent (and/or permission/assent)?

- ☐ YES, I will be obtaining documented, informed consent/permission/assent.
- ☐ YES, but I will be requesting a waiver from the documentation of consent/permission/assent in the Application for Expedited or Full DMC/IRB Review.
- ☐ NO, I will be requesting a waiver from the requirement of informed consent/permission/assent for this study in the Application for Expedited or Full DMC/IRB Review.

Research involves collection of health information?

- ☐ NO
- ☐ YES, but data are de-identified or constitute a limited data set.
- ☐ YES, subjects' authorization will be obtained, or a waiver of authorization will be requested in the Application for Expedited or Full DMC/IRB Review.

V. Drugs and Devices

Drugs or biologics used for research purposes in this study? ☐ Yes ☐ No

Use of devices (instruments, implants, *in vitro* reagents, etc.)? ☐ Yes ☐ No

VI. Investigational/Off-Label Use of Drugs and Biologics N/A ☐

Use of drugs or biologics NOT FDA approved? ☐ Yes ☐ No

For each agent listed, upload the associated Investigator Brochure provided by the sponsor/manufacturer and evidence of the IND/BB-IND #, if not specifically referenced in the sponsor's Investigator Brochure or Protocol.

Trade Name: **Generic:**

IND/BB-IND #: **IND Holder:**

If the DMC investigator is the holder of the IND/BB-IND, will the investigator comply with the applicable FDA regulations and will the investigators ensure that the research is conducted according to the signed agreement and approved protocol?

☐ Yes ☐ No ☐ The DMC Investigator is not the holder of the IND/BB-IND.

If no IND/BB-IND number, justify the use of the drug or biologic:

Difference from approved indication (if being used off-label)?

VII. FDA-Approved Drugs and Biologics N/A ☐

Drugs or biologics FDA-approved and used according to label? ☐ Yes ☐ No

For each agent listed, upload the associated package insert provided by the sponsor/manufacturer.

Trade Name	Generic Name

VIII. Medical Devices N/A ☐

Medical devices used? ☐ Yes ☐ No

For each device listed, upload the associated Investigator Device Brochure (for all experimental, non-FDA approved devices) or the Product Package Material (for all FDA-approved devices, whether used as approved by FDA, or being used "off-label"). Evidence of any cited IDE#'s must be uploaded as well, if not provided in a sponsor protocol or brochure.

Trade Name: **Generic:**

IDE #: **IDE Holder:**

FDA-approved device? ☐ Yes ☐ No

If the DMC investigator is the holder of the IDE, will the investigator comply with the applicable FDA regulations and will the investigators ensure that the research is conducted according to the signed agreement and approved protocol?

☐ Yes ☐ No ☐ The DMC Investigator is not the holder of the IDE.

Device risk?

- ☐ Significant Risk
- ☐ Non-Significant Risk
- ☐ Not Applicable: Device is approved by the FDA

Off-label use?

- ☐ Yes
- ☐ No
- ☐ Not Applicable: Experimental Device

If no IDE number and device is not approved or is being used off-label, justify use:

IX. Radiation Exposure

Exposure to radiation? ☐ Yes ☐ No

Forms of radiation that will be involved:

- ☐ Diagnostic X-Rays
- ☐ Radiation Therapy
- ☐ Radioisotopes
- ☐ Other:

Amounts and schedule of administration:

INSTRUCTIONS TO RESEARCHERS

Review the contents of this form for accuracy and completeness before submitting this package to the appropriate committee(s).

Next Steps: Once you have clicked Save and Exit below, you must continue constructing your project package to completion.

If you are submitting a new project in IRBNet:

- Complete the "Application for Expedited or Full IRB Review", located in the IRB Office Forms and Templates Library in IRBNet.
- Continue adding documents for your submission, in accordance with the requirements outlined in the IRB Submission Requirements for New, First Time Submissions, also available in your Forms and Templates Library.
- Obtain appropriate electronic signatures and SUBMIT the package to the IRB office, in accordance with the Instructions for DMC or KCHC Investigators.

If you are submitting continuing review materials into IRBNet and you have not previously submitted a copy of this electronic Registration Form for your study:

- Complete the continuing review application appropriate for your study (i.e., either "Application for Continued IRB Approval" or "Application for Five Year Continued IRB Approval"), located in the IRB Office Forms and Templates Library in IRBNet.
- Continue adding documents for your submission, in accordance with the requirements outlined in the IRB Submission Requirements for Continuing Reviews (Regular and Five-Year) also available in your Forms and Templates Library.
- Obtain appropriate signatures and SUBMIT the package to the IRB office, in accordance with the Instructions for DMC or KCHC Investigators.

SUBMISSIONS TO THE DOWNSTATE IRB OFFICE THAT DO NOT INCLUDE THE REGISTRATION FORM, THE APPROPRIATE APPLICATION, DEPARTMENT CHAIR ELECTRONIC SIGNATURE, AND ALL OTHER REQUIRED MATERIALS WILL BE CONSIDERED INCOMPLETE AND WILL NOT BE FORWARDED TO THE IRB FOR ACTION. If you have any questions, please contact

the Institutional Review Board Office at 718-813-8480 or the Office of Scientific Affairs at 718-270-2680.