

## SUNY Downstate IRB & Privacy Board

### FORM 11-A2: Application for Full Board or Expedited Review

(Version 05.18.2023)

**Instructions:** 1) Download and save the PDF fillable IRB Form to your desktop. 2) Open Adobe Acrobat Reader ([software available for free](#)). 3) Navigate to "Tools." 4) Click on "Fill & Sign." 5) Click "select a file" to open the form that was saved on desktop. 6) Complete form and confirm any preformatted fields are correct. 7) Save the file to your desktop with appropriate name. 8) Submit completed form to the Downstate IRB using IRBNet.

**Note:** For more detailed instructions on how to fill and digitally sign IRB Forms, see: [IRB Submission Tip #2](#).

**WARNING:** Do not use this form to submit research to the Downstate IRB that requires "**sIRB review**" nor for research that is "**Industry Sponsored**". For more information see **Step 5** on the [IRB Electronic Submission Process website](#).

**CAUTION:** If the research requires Downstate to comply with GDPR or other foreign regulations, contact the IRB Office for guidance before submitting the application for review.

#### **Section 1: General Information:**

A. Protocol Title:

B. Non-Scientific (Lay Person) Abstract

(Please describe the project using lay language. Scientific and technical terms must be avoided or explained.)

C. PI Name and Degree:

D. PI Department/  
College:

E. PI Phone #:

F. PI E-mail:

G. PI Status:

When applicable, include information about a Co-PI (optional) below:

H. If applicable, Co-PI Name and Degree:

I. If applicable, Co-PI Department/College:

J. If applicable, Co-PI Phone #:

K. If applicable, Co-PI E-mail:

L. If applicable, Co-PI Status:

M. If applicable, explain the different roles and responsibilities of each Co-PI and provide rationale for using a multi-PI approach:

N. Additional contact person (Name, E-mail, phone #, and role, e.g., Research Coordinator):

O. Is this considered an "Investigator Initiated" Project?      Yes              No              N/A

P. Funding status:              Unfunded (Intramurally supported)  
   Pending. **REMINDER: Submit an IRB amendment if funding is obtained.**  
   Fully funded (award issued for sponsored research)  
   Partially funded (If checked, explain below):

Q. Funding source (**check at least one**):

Unfunded (Intramurally supported by Downstate). Comments (optional):

NYC H + H, Kings County departmental funds, equipment, resources, or labor.

Industry sponsor: **DO NOT USE THIS FORM** *Note: Step 5 & Step 11 on the Electronic IRB Website for more information.*

Federal Department/Agency sponsor and award #:

*REMINDER: Do not use this form for federally funded studies which require sIRB review.*

Inbound subcontract. Specify funding entity and date of anticipated funding:

Other or non-industry sponsor (specify):

R. Provide other relevant details about the funding for the IRB to consider or check N/A:

**Section 2: Study staff:** For guidance on **IIA** and **IRA**, see Step 5 of the IRB submission website.

**A. REMINDER:** Include ALL study staff to be approved by the Downstate IRB on the IRBNet Registration Form. All study staff who are members of the Downstate workforce must be listed must be included on the IRBNet Registration Form.

**B. Kings County investigators** who are NOT part of the Downstate workforce:

**C. External Investigators** with an **Individual Investigator Agreement (IIA):**

**D. External Investigators** obtaining oversight from the Downstate IRB through an **IRB Reliance Agreement (IRA):**

**E. Name(s) of investigators** who are an **“Investigator for the purpose of COI reporting”**:  
(Always choose PI and Co-PI)

**F. Name(s) of investigators and/or study staff** who will aid the shipment of specimens, dangerous goods, or hazardous materials:

**Section 3: Research sites (choose all that apply):**

SUNY Downstate  
NYC H+H, Kings County  
Online (web-based research)  
Other sites (describe):

Check here, if research will take place in the Clinical & Translation Science Center (CTSC)

**Section 4: Costs and payments:**

A. Will participants (or their insurance) be billed for any of the research procedures?

NO YES (if yes, describe and justify):

B. Will participants receive any reimbursement, remuneration, compensation, or gifts for their participation? *Reminder: Include Form 8-12, if over \$100 per study visit or \$600 or more per calendar year.*

NO YES (if yes, describe a) total range per participant for entire study, b) amount for each visit, and c) estimated amount per calendar year):

C. (Optional) Provide any additional information regarding costs and payments:

**Section 5: Check if prospectively enrolling any of the possibly vulnerable populations:**

Children or Neonates. If checked, indicate age range:

Children who are Wards (e.g., Foster Children)

Human embryos

Emancipated Minors

Married Minors

Pregnant People or Fetuses

Research participants whose sexual partners may become pregnant during the research

Cognitively Impaired Adults

Individuals with physical or mental disabilities

Non-English-speaking participants (if checked, provide anticipated # below):

Arabic

Russian

Chinese (Simplified)

Spanish

Chinese (Traditional)

Other (describe language and #):

Haitian Creole

Employees, Students, Residents, or Fellows who are subordinate to the investigative staff

Patients recruited by their own providers.

Economically or educationally disadvantaged

Study staff or investigators named on this application

Economically or socially disadvantaged

Terminally ill or very sick

Underrepresented populations.

People of diverse backgrounds

Institutionalized persons (prisons, nursing homes, or mental health facilities)

Other potentially vulnerable populations. If checked, describe:

5a. For the populations checked above, describe the strategies used to minimize the possibility of undue influence or coercion as it relates to the implementation of the study, including recruiting, enrolling, and obtaining informed consent:

5b. Check any box below as applicable to the research (or choose none of the above as a response):

Prospective exclusion of pregnant people from research that involves an intervention upon the body (e.g., drug, biologic, medical device, physical intervention, etc.). **Submit Form 11-8**

Prospective enrollment of research participants of childbearing potential who require contraception to be included in the research. **Submit Form 11-8**

Prospective enrollment of pregnant people (and their fetus/es) that involves an intervention upon the body (e.g., drug, biologic, medical device, physical intervention, etc.). **Submit Form 11-9**

Prospective enrollment of research participants whose sexual partners may become pregnant AND the research may cause possible risk to the sexual partner, fetus, or neonate. **Submit Form 11-8**

Plans to study outcomes of unexpected pregnancies of research participants or the sexual partners of research participants. **Submit Form 11-8**

None of the above

**Section 6: Check if the research involves any of the following:**

(Include information in protocol or provide separate attachments, as applicable)

NIH Clinical Trial ([as defined by NIH](#))

[Qualifying/Deemed Clinical Trial under the CMS regulations](#)

Downstate Investigator Initiated [Applicable Clinical Trial \(ACT\)](#), if checked provide:

a) NCT# **AND** b) Name of Responsible Party:

Sponsor Initiated [Applicable Clinical Trial \(ACT\)](#), if checked provide:

a) NCT# **OR** b) Anticipated date of registration:

Implantable medical device, if checked provide a) storage location, b) how device use is tracked, c) how unused devices are returned or destroyed :

Sponsor directly issues compensation or travel reimbursement (not in RF budget)

RF issues payments from research budget for compensation or travel reimbursement

Advertisements, Fliers, Printed Ads, Radio or TV Scripts

Recruitment by social media/Internet (Facebook, Instagram, Twitter, social apps, etc)

Recruitment e-mails, letters, or written scripts for verbal presentation

Deception research

Radiology or imaging procedures

Specimens

Specimen transport on public courier

Specimen processing by UHB Pathology

Use of biospecimens for commercial profit

Diagnostic (clinical) genetic testing

Whole genome sequencing

NIH genomic data sharing

Access to medical information or protected health information (PHI)

Disclosure of medical information, PHI, or clinically relevant research results

Distribution (sharing) of information or specimens for future research

Future Contact of research participants

Psychiatry Notes

Comparative effectiveness research

CRISPR, Gene editing, gene therapy, stem cells, or xenografts

Significant Financial Interest of an investigator

NIH Certificate of Confidentiality

Investigational New Drug (IND)

Investigational Device Exemption (IDE)

Use of specimens for commercial profit

Research focus on American Indians, Alaskan Natives tribes, or indigenous people (do not check if there may be incidental involvement)

**Section 7: Describe the recruitment and enrollment process for research overseen by the Downstate IRB:**



*Note: The upper space on this page was intentionally left blank.*

**Section 8: Drugs/Biologics used at a Downstate site:**

e. Drugs/Biologics:

I. Does this study involve any drugs or biologics at Downstate?

No    Yes    *If yes, request Research Pharmacist ancillary Review  
If no, skip to next Section.*

(a). If yes to above, does this study involve any controlled substances?

Yes    No

(b). If controlled substances are involved, indicate schedule:

Schedule III-V (Attach copy of Class 4 Researcher License)

Schedule II (Attach copy of Class 4 Researcher License)

Schedule I (Attach copy of Class 7 Research/Instructional License)

*Note: Please provide a copy of any other applicable Licenses for review by the IRB and Pharmacy.*

II. Types of patients that will be involved in the study:

III. Days of the week for participant recruitment/enrollment:

IV. Business hours of the day will participants be enrolled or recruited?

V. How much time (hours) does the Pharmacy have from randomization/enrollment to drug administration?

VI. Drug formulation:

Injectable            Oral            Topical

Other, specify:

VII. If intravenous, for how many hours is the product stable once prepared?

VIII. Who can randomize a patient into the study?

PI      Sub-I/Co-I      Study coordinator      Pharmacist

Other, specify:

IX. Who can receive drug treatment assignment via IVRS/IWRS?

PI      Sub-I/Co-I      Study coordinator      Pharmacist

Other, specify:

X. What is the Downstate enrollment goal (i.e., number of research participants, consistent with all IRB related materials)?

XI. Anticipated quantity of drug (number of kits) shipped to site (if known):

XII. Size (dimensions) of kits (if known):

XIII. (Optional) additional Information for Pharmacy:

## **Section 9: Privacy, confidentiality and data security:**

A. What will be done to ensure the privacy of the research participant? (e.g., use of curtains, drapes, closed room)      Check box if N/A (i.e. data only studies).

B. Check the "physical" safeguard in place to secure the data for this study:

- Controlled access.  Locks.  Fire suppression.  Alarms.
- Sensitive documents will not be kept in plain view on desk, computer, fax machines and copiers.
- Simulated data will be used for training purposes.
- Confidential or secure information will be discarded in accordance with policy (e.g., Shred-It program, computer/electronic waste procedures, etc.). Confidential or secure information will NOT be discarded in a waste receptacle or recycling bin.
- Password protection/screen locks will be enabled with established automatic security timeout or auto locks after no more than 15 minutes of inactivity.
- Other (describe):

C. Check the technical safeguards for data security that apply to this study.

- All investigators and study staff who are members of the Downstate workforce will use a "downstate.edu" e-mail address.
- Store data on Downstate approved network drive.
- Back-up data on Downstate approved server or other alternative location.
- Transmit Electronic Protected Health Information (EPHI), Electronic Confidential Information (ECI), or Electronic Sensitive Information (ESI) with technical security controls. *If checked, please attach supporting documentation.*
- EPHI, ECI, or ESI resides in centralized secure location (e.g., behind Downstate firewall, encrypted device. If checked, describe Location/Device:

- Downstate MS OneDrive (Cannot be used for EPHI)
- EPHI, ECI, or ESI on cloud drive approved and documented by the Downstate Data Security Officer. *If checked, please attach supporting documentation.*
- EPHI, ECI, or ESI is NOT stored on a local computer hard drive, non-encrypted laptop, or non-encrypted mobile device.
- Mobile devices provided to IT for enrollment into the Mobile Device Management (MDM) platform.
- Messages sent within Downstate's network (from one Downstate.edu e-mailaccount to another) and are automatically secured.

Emails containing EPHI, ECI, or ESI that are sent outside of Downstate's network (including forwarding or replying to external emails) MUST be encrypted.

*Note: The simplest way to encrypt an email message using the Downstate MS Outlook program is to enter "Confidential" without quote anywhere in the message subject.*

Mobile devices connected to a Downstate network are encrypted.

Downstate and Non-Downstate owned mobile devices (e.g., laptops, notebook, tablets, cell phones, smart phones, USB connected thumb drives, portable storage device, etc.) are used for research; however, they DO NOT contain EPHI, ECI, or ESI.

Mobile devices are encrypted with a validated Federal Information Processing Standard (FIPS 140-2) or other encryption algorithms or protocols approved by Downstate policy (see HIS-13). **If checked, please attach supporting documentation.**

Data repository, data warehouse, file server and/or database that stores research data in compliance with Downstate policies. **If checked, please attach supporting documentation.**

To ensure data security when in transit, data entry or file transfers containing EPHI, EPHI and ECI) or ESI are sent to an external site via a HTTPS secured website, encrypted e-mail, or via a secure file transfer, Secure File Transfer (SFTP), Virtual Private Networks (VPN), or via other methods approved by the DMC Information Security Officer. **If checked, please attach supporting documentation.**

USB drives or other removable storage devices are NOT USED for long-term storage of EPHI, ECI, or ESI.

Other (describe):

D. If Internet, app, cloud-based, and/or telehealth platforms is/are used, check all that apply.

- MS One Drive for de-identified data *(no PHI;no sensitive nor confidential data).*
- MS Forms for de-identified data *(no PHI;no sensitive nor confidential data).*
- Google Forms for de-identified data *(no PHI;no sensitive nor confidential data).*
- SharePoint for de-identified data *(no PHI;no sensitive nor confidential data).*
- Qualtrics for de-identified data *(no PHI;no sensitive nor confidential data).*
- Fax transmissions for de-identified data *(no PHI;no sensitive nor confidential data).*
- Fax transmissions using secure fax machine with Downstate approved HIPAA Facsimile Cover Page *(may be used to transmit PHI)*
- REDCap hosted by Downstate *(may be used for PHI). Caution: The REDCap system hosted at Downstate cannot be used for e-signatures for FDA Clinical Investigations.*

REDCap hosted by another site (no PHI, no confidential nor sensitive information).

REDCap hosted by another site with sharing of PHI nor confidential nor sensitive information. *If checked, describe the platform below and provide applicable supporting documentation (e.g., BAA between platform and other site, HIPAA compliance statement, and/ or other supporting agreements, etc) and include applicable disclosures in the HIPAA authorization.*

Zoom *(no PHI;no sensitive nor confidential data).*

MS Teams hosted by Downstate *(OK for PHI; BAA on file with Privacy Officer).*

Docu-Sign *(no PHI;no sensitive nor confidential data).*

Doxy.Me hosted by Downstate *(OK for PHI; BAA on file with Privacy Officer).*

Other platform *(no PHI;no sensitive nor confidential data).* If checked describe platform and how it will be used in the research:

Other HIPAA compliant platform (e.g., Zoom for Healthcare) hosted at another site (e.g., collaborating site, sponsor, CRO) specifically for this study. *If checked, describe the platform below and provide applicable supporting documentation (e.g., BAA between platform and other site, HIPAA compliance statement, and/ or other supporting agreements, etc) and include applicable disclosures in the HIPAA authorization:*

Social Media platform (i.e., Facebook, Instagram, Ticktok, dating apps)  
(if checked, describe below and provide copy of terms of service):

Other (describe below and **attach any applicable supporting documentation**):

E. Administrative safeguards for data security. Check all that apply.

**THIS BOX MUST BE CHECKED.** All research staff will follow general SUNY Downstate and SUNY RF policies and guidance for administrative safeguards (*i.e., password protections, not sharing credentials, not re-using passwords across different media, not using someone else's password, removing access to study personnel who are no longer part of the research team, apply disciplinary actions for unauthorized activities, report suspected violations, do not retaliate toward nor harass employees who in good faith report suspected violations, report lost or stolen mobile devices*).

Other administrative safeguards for data security (if checked, describe below):

F. Describe plans for sharing **de-identified** (or coded) data/specimens; or indicate "N/A":

G. Describe any additional plans and protections (not otherwise described above) for sharing **PHI, confidential data, sensitive data, or identifiable specimens**; or indicate "N/A":

H. Describe the methods that will be used to **destroy** identifiable data/specimens at the end of the research life cycle; or indicate "N/A":

I. Describe the methods to **retain** data/specimens at the end of the research life cycle, including Include whether and how data/specimens will be stripped of identifiers or coded; or indicate "N/A".

J. Do the [European Union General Data Protection Regulation \(EU GDPR\)](#), the [Californian Consumer Privacy Act \(CCPA\)](#) or other foreign regulations apply to local research activities?

Yes

No

If yes, describe:

K. Required agreements:      Check if there are no agreements

- Data Agreements
- Data Use Agreements (DUA) for research involving limited data sets
- Business Associate Agreements (BAA)
- Material Transfer Agreements (MTA)
- Confidentiality agreements
- Confidentiality and Non-Disclosure Agreements (CDA/NDAs)
- Clinical Trial Agreement (CTA) (DO NOT ATTACH)

Other (describe):

**Section 10: Ancillary reviews:**      Check if N/A

*Check box if ancillary review is required, as outlined on the IRB submission website (Step 14 & 15):*

- UHB PATHOLOGY LABORATORIES
- INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)
- OTHER DEPARTMENT OR COLLEGE (OUTSIDE PI LOCATION)
- RADIOLOGY
- RADIATION SAFETY
- OTHER (SPECIFY):

**Section 11: Additional information:**