SUNY Downstate IRB & Privacy Board

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

(Version 02.02.2022)

Instructions: 1) Open form in Adobe Reader. 2) Use Fill & Sign tool to complete. 3) Confirm any preformatted fields are correct. 4) Save file. 5) Submit completed form to IRB.

Note: Free Adobe Reader available at: www.adobe.com

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: Downstate Faculty

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: NA -No Co-PI

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. Specify type of research: Investigator initated research

P. Funding status:

- ○ Unfunded (Intramurally supported)
- ○ Pending. REMINDER: Submit 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 and award #:

☐ Federal Department/Agency sponsor and award #:

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

☐ Other (specify):

R. ☑ Check if study is industry sponsored and/or requires sIRB review. Describe the IRB fees that are included in the budget as approved by the sponsor (or justify why there are no IRB fees):

S. Provide the following information for projects submitted during the COVID-19 pandemic:

1. Compelling reason to initiate new research:

2. Explain how the benefits of the research outweigh the risks of exposure of research participants and others (e.g., investigators, staff, family members of research participants) to COVID-19:

3. Procedures to mitigate the risk of COVID-19:

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.

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)

PI Only

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

N/A (None)

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 (describe):

B. Will participants receive any reimbursement, remuneration, compensation, or gifts for their participation?

◉ NO ○ 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 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
  - ☐ Chinese (Simplified)
  - ☐ Chinese (Traditional)
  - ☐ Haitian Creole
  - ☐ Russian
  - ☐ Spanish
  - ☐ Other (describe language and #):
- ☐ 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:

Not applicable

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

Not applicable

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

Not applicable

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 licy (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 account 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 and/or telehealth platforms are used, check all that apply.

☐ MS One Drive for de-identified data (Cannot be used for EPHI).
☐ MS Forms for de-identified data (Cannot be used for EPHI).
☐ Google Forms for de-identified data (Cannot be used for EPHI).
☐ SharePoint for de-identified data (Cannot be used for EPHI).
☐ Qualtrics for de-identified data (Cannot be used for EPHI).
☐ Fax transmissions (no EPHI).
☐ Fax transmissions using secure fax machine with Downstate approved HIPAA Facsimile Cover Page.
☐ REDCap hosted by Downstate (approved for EPHI).
Note: The REDCap system hosted at Downstate is HIPAA compliant; however, there is no documentation in place for 21 CFR Part 11 certification (therefore e-consent via REDCap cannot be used for FDA regulated clinical investigations).
☐ REDCap hosted by another site; however, EPHI, ECI, and ESI are NOT shared on REDCap.
☐ REDCap hosted by another site with sharing of EPHI, ECI, or ESI approved and documented by the Downstate Data Security Officer. If checked, please attach supporting documentation.
☐ Zoom without EPHI.
☐ Zoom (temporary) with EPHI. *May be used with PHI during the COVID-19 health crisis during discretion period of the COVID-19 health crisis as outlined by the Office of Civil Rights (OCR) Notification of Enforcement Discretion for Telehealth.*
☐ Docu-Sign without EPHI.
☐ Docu-Sign with Downstate BAA for EPHI. If checked, please attach BAA.
☐ Doxy.Me hosted by Downstate (approved for PHI). BAA on file with Downstate.

☐ FDA COVID MyStudies App. *Permitted e-consent for clinical investigations that occur during the COVID public health emergency.*
☐ Other platforms described in the OCR Notification of Enforcement Discretion for Telehealth may be used during the discretion period of the COVID-19 health crisis, when approved by the Downstate IRB, Privacy Officer, and Information Security Officer. If checked, please attach supporting documentation. Describe:

☐ Social Media platform (describe):

☐ Other (describe below and attach 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, no re-using passwords across different media, no 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 or harass employees who in good faith report suspected violations, report lost or stolen mobile devices).
■ Other administrative safeguards for data security (describe):

F. Plans for sharing de-identified data:

G. Plans and protections (not described above) for sharing EPHI, ECI, or ESI:

H. Methods to destroy identifiable data at the end of the research life cycle:

I. Methods to retain identifiable data at the end of the research life cycle. Include whether and how data will be stripped of identifiers:

J. Does the European Union General Data Protection Regulation (EU GDPR) or Californian Consumer Privacy Act (CCPA) apply to this research?
- ☐ EU GDPR – required EU GDPR informed consent disclosures included.
- ☐ CCPA – required CCPA informed consent disclosures included.
- ■ None of the above

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)
- ☐ OTHER (Specify):

Section 11: Additional information: