SUNY Downstate IRB & Privacy Board

FORM 11-A3: Application for Reviewing (External) IRB Oversight

(Version 04.27.2022)

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

(MUST use non-scientific lay language and eliminate or explain any scientific terms):

C. PI and Degree:

D. PI Department/College:

E. PI Phone #:

F. PI E-mail:

G. PI Status: Downstate Faculty

H. (Optional) Co-PI Name and Degree:

I. (If Co-PI is added): Co-PI Department/College:

J. (If Co-PI is added): Co-PI Phone #:

K. (If Co-PI is added): Co-PI E-mail:

L. (If Co-PI is added): Co-PI Status: NA -No Co-PI

M. (If Co-PI is added): Explain the different roles and responsibilities of each
Co-PI and provide the rationale for using a multi-PI approach:

N. Optional Contact (Name, E-mail, phone #, and role, i.e., Research Coordinator):

O. Specify type: Investigator initated research

P. Funding status:
- ○ Unfunded (Intramurally supported by Downstate)
- ○ Pending. REMINDER: Submit IRB amendment if funding is obtained.
- ◉ Fully funded (award issued for sponsored research)

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. ☐ Check if study is an "Applicable Clinical Trial (ACT)" and/or requires registration and reporting by the FDA, NIH, VA, ICMJE, or other entity and provide the following:

Provide NCT# for www.clinicaltrials.gov:

Responsible Party:

T. 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 ONLY investigators who are members of the Downstate workforce on the IRBNet Registration Form.

B. NOTE ABOUT EXTERNAL INVESTIGATORS: Kings County investigators may contact the Kings County Facility Research Coordinator for questions about the process to approve Kings County Investigators. Investigators from other sites should contact their IRB or Human Research Protections Office for guidance.

C. Name(s) of investigators who are an **"Investigator for the purpose of COI reporting"**:

(Always choose PI and Co-PI)

PI Only

D. Name(s) of investigators or coordinators who will aid the shipment of specimens, dangerous goods, or hazardous materials:

Only Research Coordinators listed below

Section 3: Review Type & Submission Checklist

☐ **A. (OPTIONAL) Initial Reliance Request**.
NOTE: This step may be submitted if the request to cede IRB review to a Reviewing (External) IRB has not yet been executed.
If checked, include the following:
- ☐ DRAFT IRB Reliance (Authorization) Agreement

☐ **B. (OPTIONAL) Administrative Pre-Review (may be required by Reviewing IRB)**

- ☐ Initial approval letter from Reviewing IRB (if issued)
- ☐ Continuing review approval letter from Reviewing IRB (if issued)
- ☐ FULLY EXECUTED IRB Reliance (Authorization) Agreement
- ☐ If applicable, documentation or forms provided by the Reviewing (External) IRB that the Downstate IRB is required to complete as part of its local review (e.g., "local context forms")
- ☐ IRBNet Registration Form

Include the following, as applicable to the request:
- ☐ Draft Informed Consent (include model template from sponsor)
- ☐ Draft HIPAA Authorization (stand alone document)
- ☐ Draft HIPAA Waiver
- ☐ Protocol (required to review consent materials)
- ☐ (OPTIONAL) Other pre-review materials submitted to Downstate IRB

☑ **C. Downstate Activation (final step)**
- ☐ FULLY EXECUTED IRB Reliance (Authorization) Agreement
- ☐ IRBNet Registration Form
- ☑ IRB approval letter
- ☐ Approved protocol

Include the following materials when approved by the Reviewing (External) IRB:
- ☑ Informed Consent Materials (including compound form with HIPAA Authorization)
- ☐ HIPAA Authorization (i.e., stand alone document)
- ☐ HIPAA Waiver
- ☑ IND Letter for investigational drug/biologic
- ☑ Investigator Brochure (IB) for clinical investigations
- ☑ Recruitment Materials (advertisements)

Note: Downstate representation on social media requires approval by Downstate Office of Communications and Marketing, after IRB approval.

Other applicable materials (describe below):
- ☑ FDA Form 1572 for Downstate Investigators
- ☐ Stand Alone HIPAA Authorization (required for studies involving PHI when approved by the NCI CIRB or other IRB not serving as a Privacy Board)
- ☐ OCAS Subject Recruitment Authorization Form(s), when applicable for the study.
- ☑ SUNY RF Payment Consent (or Waiver), when applicable for the study.
- ☐ (OPTIONAL) Other materials submitted to Downstate IRB

Section 4: Downstate Site Information

a) Describe the recruitment and enrollment process by the Downstate study team:

b) List sites where recruitment/enrollment will take place by Downstate investigators:

c) Check to indicate if any of the following research participants will be prospectively recruited/ enrolled by Downstate:

- ☐ Children. If checked, indicate age range:
- ☐ Children who are Wards (e.g., Foster Children)
- ☐ Emancipated Minors
- ☐ Married Minors
- ☐ Pregnant Minors
- ☐ Cognitively Impaired Adults
- ☐ Non-English-speaking Children, Adults, Parents, Legal Guardians, or Surrogates
- ☐ Fellows, Residents, or Students
- ☐ Employees or staff who are supervised by a study team member
- ☐ Fellows, Residents, or Students
- ☐ Other potentially vulnerable populations. If checked, describe:

d) Indicate whether the research involves any of the following at Downstate:

- ☐ Diagnostic (clinical) genetic testing
- ☐ Collection of information or specimens for future research
- ☐ Distribution (sharing) of information or specimens for future research
- ☐ Psychiatry notes
- ☐ Payment for research participation
- ☐ Future contact of research participants
- ☐ Disclosure of medical information or clinically relevant research results to

research participant or others
☐ Significant Financial Interest of an investigator
☐ EEA/EU General Data Protections
☐ NIH Certificate of Confidentiality
☑ Investigational New Drug (IND)
☐ Investigational Drug Exemption (IDE)
☐ Use of specimens for commercial profit
☐ Whole genome sequencing
☐ NIH genomic data sharing
☐ Research focus on American Indians, Alaskan Natives tribes, or indigenous people
☐ Other (describe, if checked):

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:

In- & Out- patients

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

Other (enter text here)

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

9AM to 5PM

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 5: 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. Physical safeguards for data security. Check all that apply.

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

C. Technical safeguards for data security. Check all that apply.

☒ 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. Internet and telehealth platforms. 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.

☒ 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 (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 6: 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 8: Additional information: