SUNY Downstate IRB & Privacy Board

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

(Version 07.26.2023)

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.*

Note: *Whenever possible use the WCG IRB for oversight; however, see* ***Step 5*** *on the IRB Electronic Submission Process website to determine which other Reviewing (external) IRB may be used. This form is submitted to the Downstate IRB after the Reviewing IRB approves a study in order to activate it at Downstate. This form may also be used for "pre-review" requests (e.g., to verify informed consent and/or local requirements), prior to or during the Reviewing IRB process.*

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

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: SELECT FROM DROP DOWN MENU

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: SELECT FROM DROP DOWN MENU (IF APPLICABLE)

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 IRB Amendment when 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): *(Consult Downstate IRB Fee Schedule for guidance).*

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 other relevant details about the funding for the IRB to consider or check box if N/A: ☐

Section 2: Study staff:

A. *REMINDER:* Include ONLY investigators and study staff 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)

SELECT FROM DROP DOWN MENU

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

SELECT FROM DROP DOWN MENU, IF APPLICABLE

Section 3: Review Type & Submission Checklist

Check the name of the Reviewing IRB:

☐ *WCG IRB ☐ *BRANY IRB ☐ *NCI CIRB ☐ Other (describe below):

NOTE: Master Agreements are in place with Downstate.

☐ **A. (IF APPLICABLE) Initial Reliance Request.**

NOTE: Check box A, when establishing a new IRB Reliance Agreement to cede IRB review that is not executed via the SMART IRB Online Reliance System nor through the IReX Online Reliance System.

☐ Check if a DRAFT paper based IRB Reliance Agreement is included with the submission.

☐ Additional Information:
(or enter "N/A")

☐ **B. (OPTIONAL) Administrative Pre-Review** *(May be required be the Reviewing IRB, Sponsor, CRO, Local PI, or Main Site)*

- ☐ Draft Informed Consent (include model template from sponsor)
- ☐ Draft HIPAA Authorization (stand alone document)
- ☐ Draft HIPAA Waiver
- ☐ Protocol (required to review consent materials)
- ☐ Recruitment materials (advertisements) (see note in /Section C below)
- ☐ Other pre-review materials submitted to Downstate IRB (if checked, describe below):

☐ **C. (FINAL STEP) Downstate Activation**

Include ONLY the following Reviewing (External) IRB approved materials:

- ☐ Executed IRB Reliance Agreement (if not yet on file with Downstate IRB Office)
- ☐ IRB approval letter
- ☐ Approved protocol
- ☐ Informed Consent Materials (including compound form with HIPAA Authorization)
- ☐ HIPAA Authorization (i.e., stand alone document)
- ☐ HIPAA Waiver
- ☐ IND Letter (required when using investigational drug/biologic)
- ☐ Investigator Brochure (IB) for clinical investigations
- ☐ Recruitment materials (advertisements)

  Note: The IRB will forward social media ads to the Office Communications and Marketing for review. For additional guidance see IRB Guidance: /Recruitment, Referral and Screening of Research Participants, Advertising, & Incentives.

- ☐ FDA Form 1572 for Downstate Investigators
- ☐ OCAS Subject Recruitment Authorization Form(s), when applicable for the study
- ☐ SUNY RF Payment Consent, when applicable for the study.
- ☐ Other materials (OPTIONAL); if checked, describe below:

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 who report to the study team
- ☐ 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 participants or others

☐ Significant Financial Interest of an investigator
☐ 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):

Note: Items checked in item (d) above may require specific disclosures within the consent document. Consult the Downstate IRB guidance (i.e.,consent template, local research context), as needed.

Section 5: Drugs/Biologics used at a Downstate site:

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:
SELECT FROM DROP DOWN MENU (OR ENTER TEXT)

III. Days of the week for participant recruitment/enrollment:
SELECT FROM DROP DOWN MENU (OR ENTER TEXT)

IV. Business hours of the day will participants be enrolled or recruited?
SELECT FROM DROP DOWN MENU (OR ENTER TEXT)

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 6: 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 authori ation.*

☐ 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 authori ation:*

☐ 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 unauthori ed 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 7: 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 8: Additional information: