SUNY Downstate IRB & Privacy Board

FORM 11-A5: Application for Expanded Access to Investigational Drug/Biologic for Treatment Use

(Version 06.30.2022)

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:

IMPORTANT NOTES & CONSIDERATIONS:

1) The terms expanded access, compassionate use, preapproval access, managed access programs, and treatment use are used interchangeably to refer to an investigational drug/biologic when the primary purpose is to diagnose, monitor, or treat a disease or condition rather than obtain any information that is generally derived from clinical trials (e.g., safety or effectiveness data).

2) This application is for non-emergency use. There are exceptions of certain emergencies where prior IRB approval is not required under applicable FDA regulations. In the case of "emergency use", among other things required by Policy IRB-01, the following are required: a) FDA authorization is required prior to use, and b) The IRB must be notified within 5 working days of the "emergency use" by using Form 20-B3, and c) follow all FDA requirements.

3) Because this is generally considered an option for treatment use, the standard requirements for typical IRB applications are generally waived and considered optional. Scientific Review Committee, Training documents, and Ancillary Reviews (except Pharmacy) are not required, unless subsequently requested by the IRB.

4) Conflict of Interest (COI) Disclosures are required for any clinicians who have a conflict of interest.

5) If any agreement must be signed prior to the release of the investigational agent to SUNY Downstate please contact Pre-Awards for guidance for funded projects or OCAS for non-funded projects.

6) Process any IRB Reliance agreements through the Downstate IRB.

A. Treatment 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. Clinical Investigator Name:

D. Degree: MD

E. Department/College:

F. Phone #:

G. E-mail: XXXXX@downstate.edu

H. PI Status: Downstate Faculty

I. Additional contact person (Name, E-mail, phone #, and role):

J. Funding Status:

- (●) Unfunded (Intramurally supported)
- ( ) Pending. REMINDER: Submit IRB amendment if funding is obtained.
- ( ) Fully funded (award issued)
- ( ) 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):

Section 2: Checklist of materials submited with the IRB application:

- [ ] IRB Approval Documentation (if approved by another IRB)
- [ ] IRB Reliance Agreement (if applicable)
- [x] FDA Form 1572
- [x] IND Letter from the Sponsor or FDA
- [ ] Investigator Brochure
- [ ] FDA Form 3926 (Request for IRB Chair approval in lieu of Full Board review)
- [x] Treatment Protocol/Plan (include IRB approved version if 1st box is checked)
- [x] Treatment Consent (include IRB approved version if 1st box is checked)
- [ ] Child Assent, when applicable (include IRB approved version if 1st box is checked)

- [ ] Other (describe):

- [ ] Check if requesting and exception to informed consent and describe reason below:

Section 3: Clinical staff:

A. REMINDER: Include all Clinical Investigators from Downstate and Kings County to be approved by this application on the IRBNet Registration Form.

B. Kings County Clinical Investigators who will prescribe the agent at Kings County:

C. Names of Clinical Investigators who have a Conflict of Interest for this activity.
(Anyone listed below must submit COI disclosures)

N/A

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

Section 4: Patient Enrollment and Monitoring:

A. Sites (choose all that apply):

- [x] University Hospital at Downstate
- [ ] NYC H+H, Kings County Hospital
- [ ] Online (remote consent)
- [ ] Other (describe):

- [ ] Check here, if any activities will take place in the Clinical & Translation Science Center (CTSC)

B. Estimated number of patients who will be given the drug/biologic:

C. Describe facility and equipment used to ensure adequate treatment of patients:

D. Describe the recruitment, screening, enrollment, and informed consent process:

E. Describe plans for monitoring the patients:

Section 5: Costs and Payments:

A. Will participants (or their insurance) be billed for any of the 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 project , b) amount for each visit, and c) estimated amount per calendar year):

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

Section 6: 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 Women, Pregnant Minors, or Fetuses
- ☐ 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
- ☐ Under-represented 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 project, including recruiting, enrolling, and obtaining informed consent:

5b. Are pregnant women excluded from prospective enrollment? ○ YES ◉ NO

If yes, explain reason for exclusion, including any safety, scientific, or regulatory reasons:

Section 7: Background Information:

Note: This section is OPTIONAL if the project is was approved by an External IRB

A. Name of investigational drug/biologic

B. Describe the condition or disease for this request:

C. Describe the eligibility (inclusion) criteria:

D. Describe the exclusion criteria:

E. Describe any potential direct benefits to patients:

F. Provide the reasons why alternative therapies are unsatisfactory:

G. What are the potential risks, discomforts, and adverse effects associated with the investigational drug/biologic?

H. What is length of treatment period?

I. If this is for an individual patient, describe the patient's condition and how the probable risk from the investigational drug/biologic is not greater than the probable risk from the disease or condition, based on the knowledge of the drug/biologic and patient's situation:

N/A - this is for multiple patients.

Section 8: Privacy, confidentiality and data security:

A. What will be done to ensure the privacy of the patient? (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 this activity; 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 data for this activity is 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 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 project, 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 project life cycle:

I. Methods to retain identifiable data at the end of the project 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 project?
- ☐ 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 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 9: Ancillary reviews:

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

- ☑ Downstate Research Pharmacy
- ☐ UHB Pathology Laboratories
- ☑ Institutional Biosafety Committee (IBC)
- ☐ Other (specify):

Provide the following information about the Drug/Biologic:

I. Is the investigation drug/biologic a controlled substance?

◯ Yes ◯ No

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 patents, 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 8: Additional information: