SUNY Downstate IRB & Privacy Board

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

(Version 05.26.2023)

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.

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". If a patient faces both a life threatening emergency and severely debilitating disease or condition and there is no time for IRB approval, follow the emergency use procedures outlined in Policy IRB-01 and notify the IRB within 5 working days of the "emergency use" by using Form 20-B3.

3) Because this application is for treatment use, most of the standard requirements for typical IRB applications are generally waived and considered optional, such as CMRC Review, most human research training, most ancillary reviews, most COI reporting, unless requested by the IRB. Pharmacy Ancillary review is required. HIPAA training is required by all Clinicians listed on the IRB application. Conflict of Interest (COI) Disclosures and COI training are ONLY required for any clinicians who have a conflict of interest. Dangerous Goods training is required for anyone who causes dangerous goods to be transported by a public carrier.

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:

E. Department/College:

F. Phone #:

G. E-mail:

H. Clinician Status: SELECT FROM DROP DOWN MENU

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)
- ☐ FDA Form 1572
- ☐ IND Letter from the Sponsor or FDA
- ☐ Investigator Brochure
- ☐ FDA Form 3926 (Request for IRB Chair approval in lieu of Full Board review)
- ☐ Treatment Protocol/Plan (include IRB approved version if 1st box is checked)
- ☐ 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):

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, or indicate "N/A".
(Anyone listed below must submit COI disclosures)

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):

- ☐ 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 patients (or their insurance) be billed for any of the procedures?

◉ NO ○ YES (describe):

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

◉ NO ○ YES (describe a) total range per patient 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 patients (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. Describe how the probable risk from the investigational drug/biologic is not greater than the probable risk from the disease or condition:

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

Section 8: 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 patient 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 patients, 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 patient (e.g., use of curtains, drapes, closed room)?

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 patient 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: