

## SUNY Downstate IRB & Privacy Board

### FORM 11-10: Application For Downstate Workforce Activation of Exempt Research or IRB Determinations (Not Research, Not Human Research, or Downstate Not Engaged) Approved by an (External) Reviewing IRB

(Pilot Version 01.13.2024)

**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.

**NOTES:** 1) Do NOT use this form for human research activities that qualifies for Expedited or Full Board review. 2) This form is typically used when an investigator has a joint role or appointment with Downstate or when a Downstate student or trainee is conducting activities at their employer's institution and seeks approval by their institution's IRB or HRPP for multi-site activities which includes Downstate 3) Downstate does NOT require an IRB Reliance Agreement to activate exemptions or determinations submitted with this application form; however, the external IRB may require one. 4) For more detailed instructions on how to fill and digitally sign IRB Forms, see: [IRB Submission Tip #2](#).

**CAUTION:** If the research or activity 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 or Project Title:

B. Non-Scientific (Lay Person) Abstract

(Please describe the project using lay language. Scientific and technical terms must be avoided or explained.)

C. Name of Downstate (local)  
PI/Project Lead & Degree:

D. Department/College:

E. Phone #:

F. E-mail:

G. PI Status (if applicable, or  
choose N/A for Project Lead):

Provide information about the External Overall PI/Project Lead for the study/activity who was approved by the External/Reviewing IRB::

H. Name of Overall PI/Project Lead and Degree:

I. Institution:

J. Phone #:

K. E-mail:

L. Name of External IRB:

M. IRB E-mail:

N. IRB Phone #:

O. Is the External Overall PI/Project Lead a member of the Downstate Workforce?

YES            NO (if No is checked, do not list them on the IRBNet Registration Form)

P. Provide any additional information about the determination by the External IRB, if applicable (optional)

Q. Additional contact person (Name, E-mail, phone #, and role, e.g., Coordinator):

R. Is this considered an "Investigator Initiated" Project?    Yes            No            N/A

S. 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):

T. 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 3: External IRB Approval or IRB Determination for the Downstate Workforce:**

A. Indicate type of approval/determination for the activities conducted by the Downstate Workforce:

Exempt Research Approval by the Downstate workforce

Determined that Downstate activities are "Not Research"

Determined that Downstate activities are "Not Human (Subjects) Research"

Determined that Downstate is "Not Engaged in Human (subjects) Research"

B. Indicate type of activities conducted by the Downstate workforce:

Access to identifiable data/specimens  
(including coded data/specimens IF they have access to the key to the code).

Interactions with research participants.

Obtaining informed consent from research participants.

Study interventions with research participants.

None of the above.

C. Fully describe the activities conducted by the Downstate workforce and include the specific details for the items checked in item B (above).

**Section 3: Study /Project staff:**

**A. REMINDER:** Include ONLY investigators, study staff, and project 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. For Exempt studies that are Federally funded or FDA regulated, provide the Name(s) of investigators who are an “Investigator for the purpose of COI reporting”:**  
(Always choose PI)

**D. Name(s) of anyone in the Downstate workforce who will aid the shipment of specimens, dangerous goods, or hazardous materials:**

**E . Name(s) of anyone in the Downstate workforce who will provide evidence of training required and confirmed by the External IRB rather than completing the Downstate CITI training requirements (or indicate N/A):**

**NOTES:**

- 1) *If NA is selected, complete all Downstate CITI training requirements.*
- 2) *If the External IRB training is used, attach all training certificates approved by the External IRB.*
- 3) *Reminder: All other applicable training is required for the Downstate workforce. Downstate HIPAA training is required for all investigators conducting Exempt Research. Downstate HIPAA training is required for all workforce members who have access to PHI under an IRB Determination.*

## **Section 4: 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. (OPTIONAL) Initial Reliance Request (IF REQUIRED BY EXTERNAL IRB).**

*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 by the Reviewing IRB, Sponsor, CRO, Local PI, or Main Site)*

Draft Informed Consent/Information Sheet (include model template from sponsor)

Draft HIPAA Authorization (stand alone document)

Draft HIPAA Waiver

Protocol (required to review consent form or information 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:*

IRB approval/determination letter

IRB Approved protocol

Informed Consent Materials (including compound form with HIPAA Authorization)

HIPAA Authorization (i.e., stand alone document)

HIPAA Waiver

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](#).*

OCAS Subject Recruitment Authorization Form(s), when applicable for the study

SUNY RF Payment Consent, when applicable for the study (must be approved by the External IRB)

Other materials (OPTIONAL); if checked, describe below:

## Section 5: Downstate Site Information

a) Describe the recruitment and enrollment process by the Downstate workforce, or indicate "N/A":

b) List the sites where recruitment/enrollment will take place by the Downstate workforce, or indicate "N/A":

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:

None of the above

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):

None of the above

*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 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 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 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 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: Provide any details requested of the Downstate IRB by the External IRB (optional):**

**Section 9: Additional information (optional):**