SUNY Downstate IRB & Privacy Board

FORM 11-A1: Application for Exempt Review

(Version 05.18.2023)

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.

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

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 an IRB amendment if 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 or non-industry sponsor (specify):

R. Provide other relevant details about the funding for the IRB to consider or check N/A: ☐

Section 2: Study staff: For guidance on **IIA** and **IRA**, see Step 5 of the IRB submission website.

A. REMINDER: Include ALL study staff to be approved by the Downstate IRB on the IRBNet Registration Form. All study staff who are members of the Downstate workforce must be listed must be included on the IRBNet Registration Form.

B. Kings County investigators who are NOT part of the Downstate workforce:

C. External Investigators with an **Individual Investigator Agreement (IIA):**

D. External Investigators obtaining oversight from the Downstate IRB through an **IRB Reliance Agreement (IRA):**

E. 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

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

SELECT FROM DROP DOWN MENU

Section 3: Research sites (choose all that apply):

- ☐ SUNY Downstate
- ☐ NYC H+H, Kings County
- ☐ Online (web-based research)
- ☐ Other sites (describe):

☐ Check here, if research will take place in the Clinical & Translation Science Center (CTSC)

Section 4: Costs and payments:

A. Will participants (or their insurance) be billed for any of the research procedures?

◉ NO ○ YES (if yes, describe and justify):

B. Will participants receive any reimbursement, remuneration, compensation, or gifts for their participation? *Reminder: Include Form 8-12, if over $100 per study visit or $600 or more per calendar year.*

◉ NO ○ YES (if yes, describe a) total range per participant for entire study, b) amount for each visit, and c) estimated amount per calendar year):

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

Section 5: Check if prospectively enrolling any of the possibly vulnerable populations:

☐ N/A. Check N/A if the research does not involve an interaction nor an intervention (i.e., chart review)

☐ 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 study, including recruiting, enrolling, and obtaining informed consent:

5b. For studies with prospective enrollment, are pregnant individuals excluded:

◯ Yes ◯ NO ◉ N/A [no enrollment (i.e., chart review)]

5b(i). If yes, explain reason for exclusion, including any safety, scientific, or regulatory reasons:

Section 6: Check if the research involves any of the following:

(Include information in protocol or provide separate attachments, as applicable)

- ☐ NIH Clinical Trial (as defined by NIH)
- ☐ Sponsor directly issues compensation or travel reimbursement (not in RF budget)
- ☐ RF issues payment from research budget for compensation or travel reimbursement
- ☐ Advertisements, Fliers, Printed Ads, Radio or TV Scripts
- ☐ Recruitment by social media/Internet (Facebook, Instagram, Twitter, social apps, etc)
- ☐ Recruitment e-mails, letters, or written scripts for verbal presentation
- ☐ Deception research
- ☐ Radiology images
- ☐ Access to medical information or protected health information (PHI)
- ☐ Disclosure of medical information, PHI, or clinically relevant research results
- ☐ Distribution (sharing) of information or specimens for future research
- ☐ Future Contact of research participants
- ☐ Psychiatry Notes
- ☐ Comparative effectiveness research
- ☐ Significant Financial Interest of an investigator
- ☐ NIH Certificate of Confidentiality
- ☐ Research focus on American Indians, Alaskan Natives tribes, or indigenous people (do not check if there may be incidental involvement)

Section 7: Describe the prospective recruitment and enrollment process for research overseen by the Downstate IRB:

☐ Check if N/A [no enrollment (i.e., chart review)]

Section 8: Exemption Request

Check the permissible category or categories below. To be exempt, no non-exempt activities can be involved. All the research activities must be covered by one or more categories to qualify for exempt review. For additional guidance, see OHRP Decision Charts.

☑ Check to confirm prisoners are not intentionally recruited or enrolled in this research.

☐ Category 1: **Educational Practices**

If Category 1 is checked, answer the following:

A. Describe the established or commonly accepted educational setting where the research is conducted:

B. Describe the normal educational practice involved in the research:

C. Reasons this activity is not likely to adversely impact the students' opportunity to learn required educational content:

D. Reasons this this activity is not likely to adversely impact the assessment of educators who provide instruction:

☐ Category 2 (select as applicable):

- ☐ **Educational tests (cognitive, diagnostic, aptitude, achievement)**
- ☐ **Surveys, interview procedures, or focus groups**
- ☐ **Observations of public behavior (including visual or auditory recording)**

If Category 2 is checked, answer the following:

A. Children (under 18 years old) are:

- ☐ Included
- ☐ Excluded

B. Check the type of activities which are permissible under this category:

☐ The information obtained is recorded in a manner that the identity of the ADULT participants CANNOT readily be ascertained, directly or indirectly through identifies linked to the participants.

☐ The information obtained is recorded in a manner that the identity of the CHILD participants CANNOT readily be ascertained, directly or indirectly through identifies linked to the participants AND the research involves EDUCATIONAL TESTS or OBSERVATION OF

PUBLIC BEHAVIOR AND the INVESTIGATORS DO NOT PARTICIPATE in the activities being observed.

☐ Disclosure of the participants' responses outside the research would not reasonably place ADULTS at risk of liability nor be damaging to the participants' financial standing, employability, educational advancement, or reputation.

☐ Disclosure of the participants' responses outside the research would not reasonably place CHILDREN at risk of liability nor be damaging to the participants financial standing, employability, educational advancement, or reputation AND the research applies to EDUCATIONAL TESTS or OBSERVATION OF PUBLIC BEHAVIOR AND the INVESTIGATORS DO NOT PARTICIPATE in the activities being observed.

☐ Identifiable information is obtained from ADULTS and information security measures are in place as described below (Section 9).

(Optional) comments regarding above selection(s):

☐ Category 3: **Benign behavioral interventions with ADULTS.**

If Category 3 is checked, answer the following:

A. Age range (≥18 years of age) of the adult participants:

B. Describe the process for obtaining the participants' prospective agreement to the intervention and information collection:

C. Check the type of activities which are permissible under this category:

☐ The information obtained is recorded in such a manner that participants cannot be identified, directly or through identifiers linked to the participants

☐ Any disclosure of the human research participants' responses outside the research could not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement or reputation.

☐ Information obtained is recorded in such a manner that human research participants can be identified, directly or through identifiers linked to the participants and provisions to protect the privacy of research participants and for maintaining the confidentiality of the data are described below (Section 6).

(Optional) comments regarding above selection(s):

D. Describe the benign behavioral intervention(s):

E. Describe the process for information collection:

F. Information collection:
☐ Verbal or written responses (including data entry)
☐ Audiovisual recording

G. ☐ Check box to attest a) the benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, and not likely to have a significant adverse lasting impact on research participants; and b) there is no reason to think the research participants will find the interventions offensive or embarrassing.
(Optional) comments regarding above attestation:

H. Does this research involve deceiving the research participants regarding the nature or purposes of the research? ☐ No ☐ Yes *IF YES, include a written research participant agreement to prospectively authorize the deception and inform the research participant that he or she will be unaware of or misled regarding the nature or purposes of the research.*

☐ Category 4: **Secondary use of information or specimens.** *Note: The information/specimens were collected for another initial activity and the research activities must meet one or more of the specific criteria below.*

A. Check the permissible activities planned for this exemption:
☐ Publicly available identifiable private information
☐ Publicly available identifiable specimens
☐ Information (including information about specimens) that is recorded by investigators in such a manner that the identity of the research participants cannot readily be ascertained (recorded information does not include HIPAA identifiers), and the investigators will not attempt to contact or re-identify research participants.
☐ The research involves only the collection or analysis of Protected Health Information (PHI) from a HIPAA covered entity (such as medical records or lab results). *NOTES: a) include the applicable HIPAA Waiver or HIPAA Authorization; b) this subcategory doesn't apply to the collection and/or physical analysis of identifiable specimens, but may apply to using information about specimens*
☐ The research is conducted on behalf of the federal department or agency using government-generated or government-collected information obtained for non research purposes.

B. Describe the sources (i.e., Healthbridge, department database, medical records, prior project, public repository) for the original information and/or specimens):

C. Were any of these materials originally obtained for research purposes? YES ☐ NO ☐

D. Was informed consent obtained for the original collection of the materials? YES ☐ NO ☐

If YES to D, include copy(ies) of the consent document(s) related to the prior activity(ies) to confirm there are no prohibitions for using the materials in this secondary research project.

☐ Category 5: **Public benefit or service programs.**

If Category 5 is checked, answer the following:

i. Which Federal Department or Agency approved or will approve this research or demonstration project?

ii. Provide a brief description on how the research is designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including the following: a) procedures for obtaining benefits or services under those programs b) possible changes in or alternatives to those programs or procedures, or c) possible changes in methods or levels of payment for the benefits or services under those public benefit or service programs:

iii. Does this project include waivers of mandatory requirements under the Social Security Act?
☐ Yes ☐ No ☐ N/A

iv. The Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving research participants. Provide the link to the website or describe the manner which supports this provision (include available supporting documentation):

☐ Category 6: **Taste and food quality evaluation and consumer acceptance studies.**

If Category 6 is checked, indicate the permissible type of study:

☐ Wholesome foods without additives are consumed

☐ Food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe AND the following agency determined the food ingredient is safe or approved for consumption (attach supporting documentation):

- ☐ Food and Drug Administration
- ☐ Environmental Protection Agency
- ☐ Food Safety and Inspection Service of the U.S. Department of Agriculture

Section 9: 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 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 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 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: