SUNYDownstate IRB & Privacy Board

FORM 11-A4Q: Application for an IRB Determination of "NOT Research" or "NOT Human Research" for a Quality Improvement, Quality Assurance, Performance Improvement, or Evidence Based Practice Activity.

(Pilot Version 06.03.2024)

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 the completed form to the Downstate IRB using IRBNet.

*Notes: 1) For more detailed instructions on how to fill and digitally sign IRB Forms, see: IRB Submission Tip #2. 2) See IRB submission Tip #5 or relevant tips on completing this form. 3) A Project Lead is not required to have "PI Status" and may e-sign the IRBNet submission as "other signatory" 4) For additional guidance, consult Downstate Policy IRB-01, in the Section titled "Determining Whether IRB Approval is Required." 5) Submit completed form in IRBNet, as described in **Step 12** on the IRB Submission website.*

***CAUTION:** If the activity requires Downstate to comply with European Union General Data Protection Regulation (EU GDPR) or other foreign regulations, contact the IRB Office for guidance before submitting the application for review.*

Section 1: General Information:

A. Title of Project or Activity:

B. Description of Project or Activity:

(MUST use non-scientific lay language and eliminate or explain any scientific terms):

***Caution:** When requesting a "not research" determination please use terms such as "project, project staff, etc" rather than using terms such as "research, human research, study, investigator, etc. However, the terms "research", "study", and "investigator", may be used for "research" which is "not human research". See page 4 of this form for clarification.*

C. Project Lead: Earned Degree:

If student, list anticipated degree in program of study:

D. Department/College:

E. Phone #:

F. E-mail:

G. Position:

If the Project Lead is a Student, provide Faculty Mentor information below:
Reminder: Faculty Mentors must e-sign submission in IRBNet.

H. Faculty Mentor and Degree:
(Required for Student Project Lead; otherwise indicate N/A)

I. Faculty Mentor Department/College:

J. Faculty Mentor Phone #:

K. Faculty Mentor E-mail:

L. Faculty Mentor Position:

M. Does Downstate receive extramural funding (e.g., grant, sponsor support, industry funding, non-profit funding, non-SUNY award) for this activity?

◯ NO ◯ YES If yes, describe:

N. Does this project support a multi-site project that has or will require external IRB approval or determination from another site?

◯ NO ◯ YES If yes, describe:

O. Type of activity (multiple options may be selected):

☐ Quality Improvement (QI)
☐ Quality Assurance (QA)
☐ Performance Improvement (PI)
☐ Evidence Based Practice (EBP)
☐ Other (describe):

Section 2: Project Staff:

A. REMINDER: Include ONLY project staff who are members of the Downstate, UPB, and/or Kings County workforce on the IRBNet Registration Form.

B. NOTE ABOUT EXTERNAL PROJECT STAFF: Project staff from other sites should contact their IRB or Human Research Protections Office for guidance.

C. Name(s) of staff who will aid the shipment of specimens, dangerous goods, or hazardous materials (or indicate N/A):

Section 3: Project Materials for IRB Submission (check items submitted):

- ☐ Project description (or Protocol) (REQUIRED, unless fully described in in item B, Section 1 of this form) *It is recommended that the project description (or protocol) include the following: 1) Short background on the importance of the project, 2) Full description of activities, 4) How and where it will be conducted, 5) Time line, 6) What data will be accessed and/or collected, 7) Whether the project team has access to or is recording identifiable information, 8) What will be done with the data, 9) Describe any data sharing between multiple sites and whether the data will be identifiable or protected health information. Caution: It is best to share de-identified or coded data between sites.*
- ☐ Data collection tool(s), e.g., survey, data collection tool, spreadsheet, REDCap Form (or list of data elements) (REQUIRED to determine if identifiable data or PHI is involved in the activity)
- ☐ Independent Honest Broker Assurance (Form11-A7) (if applicable, based on project design)
- ☐ Information Sheet (or Consent Form) (generally expected for projects with prospective interactions)
- ☐ Information Sheet for a Child (or Assent Form) (generally expected for projects with prospective interactions with children ages 7-12)
- ☐ HIPAA Authorization (generally not needed for QI/QA/PI activities; however, include, if applicable, based on the design of projects which include PHI which are not healthcare operations activities)
- ☐ HIPAA Waiver (generally not needed for QI/QA/PI activities; however, include, if applicable, based on the design of projects which include PHI which are not healthcare operations activities)
- ☐ Recruitment materials (Fliers, Advertisement, Recruitment E-mail/letters, etc), as applicable, based on the design of activities which are not healthcare operations)
- ☐ Agreement(s) [e.g., Data Use Agreement (DUA), Business Associates Agreement (BAA), Materials Transfer Agreement (MTA), Data Agreement (DA), Collaboration, Facility Use, Non-Disclosure Agreements (NDA), etc.] as applicable, based on HIPAA regulations, data provider, or requirements of an external collaborator]. A draft agreement may be included if it is not yet fully executed. Include additional details for item K in Section 6 (page 8).
- ☐ Other documents included with submission(describe below):

SECTION 4: REGULATORY INFORMATION:

A. Does the activity use a systematic approach? (e.g., planned, orderly, or methodical)

◯ **NO** ◯ **YES**

If NO is checked, please clarify the reason this activity does NOT use a systematic approach:

B. Is the project designed to develop or contribute to generalizable knowledge beyond the unit, institution, organization, or network under evaluation?

◯ **NO** ◯ **YES**

Describe each of the following to assist the IRB in making a regulatory determination:

1) Area (unit, department, college, school, institution, organization, network, etc) **under review that will benefit from this project:**

2) Practice, policy, or activity under review:

3) Population under evaluation (patients, students, employees, public, etc):

4) Most significant goals, objectives, reports, outcomes, changes, or improvements, that are expected:

5) If "No" was checked for item B, explain why there is no intent to develop or contribute to generalizable knowledge beyond the area and population under evaluation.

C. Will anyone obtain and use, study, or analyze information (data) or specimens through an intervention or interaction with a living individual about whom this activity pertains? (e.g., interview, survey, focus group, physical procedures, environmental manipulation, direct contact, communication, collecting samples, obtaining vital signs, evaluating psychotherapy or behavioral interventions, etc)

◯ NO ◯ YES

D. Will identifiable private information, identifiable (bio) specimens, or Protected Health Information (PHI) be obtained, used, analyzed, or generated for this activity?

◯ NO ◯ YES

NOTES REGARDING DETERMINATIONS:

*If NO to A **OR** B, this activity is "NOT RESEARCH".*

If Yes to A & B, and NO to C & D, this activity is considered "RESEARCH, BUT NOT HUMAN RESEARCH".

If Yes to A & B, and YES to C or D, this activity is human (subjects) research and therefore this form cannot be used.

Section 5: Privacy, confidentiality and data security:

A. What will be done to ensure the privacy of any project participants? (e.g., use of curtains, drapes, closed room) ☐ Check box if N/A (i.e. data only studies).

B. Check the "physical" safeguard(s) in place to secure the data:

☐ 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 project 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 the 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 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:

☐ 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, Tiktok, 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 Downstate 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 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 project life cycle; or indicate "N/A":

I. Describe the methods to **retain** data/specimens at the end of the project 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) or Californian Consumer Privacy Act (CCPA)or other foreign regulations apply to this activity?

EU GDPR – required EU GDPR informed consent disclosures included.
CCPA – required CCPA informed consent disclosures included.

☐ Foreign regulations. If checked, describe:
☐ None of the above

K. Required agreements: ☐ Check if there are no agreements

Data Agreements
Data Use Agreements (DUA) for activities 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 6: Ancillary reviews:

☐ Check if there are no ancillary review requirements (N/A)

Check box(es) below to indicate the type(s) of ancillary review(s) 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 7: Publications or Presentations

Are there any plans to publish or present the findings of this activity?

◯ YES ◯ NO

If yes, based on the information provided on page 5, indicate the type of disclaimer that will be included in all publications or presentations:

◯ This project was determined to be "research" but not "not human (subjects) research" by the SUNY Downstate Health Sciences University IRB & Privacy Board.

◯ This project was determined to be "not research" by the SUNY Downstate Health Sciences University IRB & Privacy Board.

◯ Other (specify below):

Section 8: Additional information: