SUNY Downstate IRB & Privacy Board

FORM 11-A4: Application for Determination Letter (IRB Decision Aid) for "Not Research" "Not Human Research" or "Institution Not Engaged in Human Research"

(Version 08.08.2023)

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.

*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 for specific 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 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. 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 (i.e., when box A is checked in Section 4 on page 6 of this form) use terms such as "project, project staff, etc" rather than using terms such as "research, human research, study, investigator, etc when .*

C. Project Lead*: Degree:

**Note: Include the name of the local PI when seeking a "Not Engaged" determination for Downstate or Kings County activities involving multiple institutions).*

D. Department/College:

E. Phone #:

F. E-mail:

G. Position:

H. (Optional) Co-Lead and Degree:

I. (If Co-Lead is added): Co-Lead Department/College:

J. (If Co-Lead is added): Co-Lead Phone #:

K. (If Co-Lead is added): Co-Lead E-mail:

L. (If Co-Lead is added): Co-Lead Position:

M. (If Co-Lead is added): Explain the different roles and responsibilities of each Co-Lead and provide the rationale for using a multi-Lead approach:

N. Optional Contact (Name, E-mail, phone #, and role, i.e., Project Coordinator.)

O. Funding status:

- ◯ Unfunded (Intramurally supported by Downstate)
- ◯ Pending. ***REMINDER: Submit IRB amendment if funding is obtained.***
- ◯ Fully funded (award issued for sponsored research)
- ◯ Partially funded (if checked, explain below):

P. 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):

Q. Does this project support a multi-site study that has external IRB review for other site(s)?

◯ YES ◯ NO

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 investigators who are an **"Investigator for the purpose of COI reporting"**:

(Include the name of the Local PI if this is for a Not Engagement Request)

SELECT FROM DROP DOWN MENU

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

SELECT FROM DROP DOWN MENU

SECTION 3: GENERAL INFORMATION:

A. Documents included with this submission, as applicable:

- ☐ Project description/ Protocol
- ☐ External IRB approval letter
- ☐ Data collection tools/ List of data elements
- ☐ HIPAA Waiver
- ☐ Agreement (e.g., DUA, BAA, MTA, Data, Collaboration, Facility Use, etc.)
- ☐ Other documents (describe):

B. Is the activity an investigation of a drug, biologic, or medical device?

◯ NO ◯ YES

C. Is the activity a systematic investigation?

◯ NO ◯ YES

D. Is the project designed to develop or contribute to generalizable knowledge?

◯ NO ◯ YES

E. Is there any intent to publish findings or present at a meeting outside of the institution?

◯ NO ◯ YES

F. Will anyone listed on this application obtain information or biospecimens through an intervention or interaction with an individual?

◯ NO ◯ YES

G. Will anyone on listed on this application obtain, use, study, analyze, or generate identifiable private information or identifiable biospecimens?

◯ NO ◯ YES

H. Will anyone listed on this application intervene for research purposes with any research participant by manipulating the environment?

◯ NO ◯ YES

I. Will anyone listed on this application obtain informed consent from a research participant for research purposes?

◯ NO ◯ YES

J. Check if the activity involves obtaining, accessing, using, disclosing, or sharing any of the following:

At least one box must be checked. Check all applicable boxes.

- ☐ 1) Individually identifiable private information about a living individual.
- ☐ 2) Education records that can be linked to any living individual.
- ☐ 3) Protected Health Information (PHI) about any individual (living or deceased)
- ☐ 4) PHI from individuals who have been deceased for more than 50 years.
- ☐ 5) Data from deceased individuals without PHI.
- ☐ 6) PHI from individuals who have been deceased for less than 50 years with a Researcher Certification for PHI of Decedents.
- ☐ 7) Substance abuse information that can be linked to any individual (living or deceased).
- ☐ 8) Genetic information that can be linked to any individual (living or deceased).
- ☐ 9) HIV related information that can be linked to any individual (living or deceased).
- ☐ 10) Identifiable specimens (from any living individuals or any deceased individuals).
- ☐ 11) Use of human specimen(s) (including, coded, de-identified, or identifiable) to validate a medical device, diagnostic instrument, or laboratory test.
- ☐ 12) Specimens obtained from a producer or supplier (e.g., commercial cell line) that cannot be linked to an individual by the Investigators.
- ☐ 13) Use of a Limited Data Set protected by a Data Use Agreement (DUA) and investigators cannot readily identify the individuals about whom the data pertains and do not have access to the key to any codes to identify individuals.
- ☐ 14) De-identified materials.
- ☐ 15) Coded materials with process in place to prohibit release of code to staff or investigators.
- ☐ 16) Secondary data (e.g., data originally collected for another purpose).
- ☐ 17) None of the above.

K. Describe how the safety, rights, welfare, privacy, and confidentiality are ensured to protect the affected individuals:

L. Describe any risk mitigation strategies:

SECTION 4: DETERMINATION REQUESTED:

Check the determination requested (A, B, or C) below and respond to the questions, applicable for the request.

☐ **A. Not Research.** This project does not meet the definition of research as defined by applicable federal regulations.

NOTE: Skip section A if section B (page 11) or section C (page 16) is completed.

If A, check at least one specific reason(s) below and answer corresponding questions:

☐ 1) There is no intent to develop nor contribute to generalizable knowledge.

If checked, clarify the intent sof this project, including why there is no intent to!develop or contribute to generalizable knowledge.

Note: Usually the 2nd box is not checked, because most projects are systematic.

☐ 2) The activity is not a systematic investigation.

If checked, clarify the reason this activity is not a systematic investigation:

Additional information for item A:

If "Not Research" was checked above, please check the following when applicable to the activity and answer any relevant question below the item that was checked:

☐ 1) The activity is an Operations Activity or Healthcare Operations Activity (e.g., quality improvement activity) without any intent to develop or contribute to generalizable knowledge. If checked, answer the following:

Describe the operation activity:

If this is a quality improvement/assurance (QI/QA) activity, please describe the area of improvement that will help the institution from where the data are collected. Indicate N/A if this is NOT a QI/QA activity.

If this is a Resident Training activity, please describe or indicate N/A:

If checked, clarify the intent of this project, including why there is no intent to develop or contribute to generalizable knowledge.

☐ 2) The activity is a case report or case series involving up to three (3) individuals.

How may individuals will be involved?

☐ 3) The activity is an authorized operational activity in support of intelligence, homeland security, defense, or other national security missions.

Name of Agency:

Source of material(s):

Describe the nature of the operational activity and how it supports the above noted missions.

☐ 4) This activity does not involve human research as defined by Policy IRB-01 (e.g., no intent to develop nor contribute to generalizable knowledge). If checked, indicate type:

☐ Pilot activity

☐ Feasibility activity

☐ Evidence-based practice activity

☐ Training activity

☐ Educational activity

Describe the activity:

Clarify the intent of this project, including why there is no intent to develop nor contribute to generalizable knowledge:

☐ 5) This is a scholarly or journalistic activity which includes the collection and use of information that focuses directly on the specific individuals about whom the information is collected.

Indicate type(s):

- ☐ Oral history,
- ☐ Journalism
- ☐ Biography
- ☐ Literary criticism
- ☐ Legal research
- ☐ Historical scholarship
- ☐ Other, describe:

Describe the activity:

Describe the category of specific individuals (do not list names) about whom the information is collected:

Check at least one box below to confirm IRB approval is not required:

☐ The intent of this activity is NOT to form a hypothesis, draw conclusions, or generalize the findings

☐ This is not a systematic activity that is planned, orderly, and methodical

☐ 6) This is a public health surveillance activity.

Note: Do not choose this option for surveillance activities conducted to improve Downstate operations -- select Healthcare Operations activity (item 1, page 7) instead.

Name of public health authority:

Describe surveillance activity:

☐ 7) This activity is for the collection and analysis of information, biospecimens, by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

Name of criminal justice agency:

Describe source(s) of materials:

☐ 8)This is an authorized operational activity in support of intelligence, homeland security, defense, or other national security measure. Describe below:

☐ 9)The activity represents clinical care. Describe below:

☐ Check if this is an Off-Label Use of an FDA Approved Drug or Biologic

If checked, obtain Pharmacy Ancillary Review.

If checked, provide the name of the drug or biologic:

If checked, describe the off-label purpose:

☐ **B. Research-Not Human Subjects Research (Not Human Research).**

NOTE: Skip section B if section A (page 7) or section C (page 16) is completed.

This project meets the definition of research. It does not meet the definition of human (subjects) research, as defined by the Common Rule. The activity does not meet the definition of Clinical Investigation, as defined by the FDA.

If not checked, skip to Item C (page 16).

If B, check specific reason(s) below and answer corresponding questions:

☐ 1) The activity does **NOT** involve obtaining, accessing, using, disclosing, or sharing individual identifiable information or individual identifiable specimens or Protected Health Information (PHI).
If checked, describe the data, specimens, or other materials that will be used for the activity:

☐ 2) The activity involves data from deceased individuals without Protected Health Information (PHI).

If checked, describe the data, specimens, or other materials that will be used for the activity:

☐ 3) The activity involves Protected Health Information (PHI) from individuals who have been deceased for more than 50 years.

If checked, describe the data, specimens, or other materials that will be used for the activity:

How is it known the individuals have been deceased for more then 50 years?

☐ 4) The activity involves Protected Health Information (PHI) from deceased individuals with a Research Certification for PHI of Decedents.
If checked, describe the data, specimens, or other materials that will be used for the activity:

*Note: If box 4 is checked, include a copy of the Research Certification for PHI of Decedents, but **do not include the names** of the decedent(s) on the form submitted to the IRB. The names will be added later and securely stored with the research records).*

Additional information for item B:

If "**Research-Not Human Subjects Research (Not Human Research)"** was checked above, please check the following when applicable to the activity and answer any relevant question below the item that was checked:

☐ 1) The activity includes an Honest Broker activity.

If checked, provide the following:

Name of Honest Brokers, who are members of the Downstate workforce, who provide coded or de-identified materials to investigators:
NOTE: An Honest Broker may not be an author; but may be acknowledge in the publication.

What type of materials are provided by the Honest Broker:

☐ Data or Information (if checked, please describe below)

Type(s): ☐ Coded data/information

☐ De-identified data/information

☐ Specimens (if checked, please describe below):

Type(s): ☐ Coded specimens

☐ De-identified samples

☐ Leftover specimens (remnants of specimens collected for routine clinical care or analysis that would otherwise have been discarded). (if checked, please describe below):

Type(s): ☐ Coded leftover specimens

☐ De-identified left over specimens

☐ Please check to confirm all of the following are true:

- The honest brokers are members of the Downstate workforce and normally have access to the materials (information and/or specimens) as a part of their routine clinical duties.
- The honest brokers are not investigators for this project.
- Only the honest brokers (or future honest brokers approved by the IRB) may have access to identifiable information.
- Only the honest brokers can release the materials noted above.
- Only the honest brokers may have access to the key to the code that can identify the materials.
- HIPAA identifiers cannot be shared with the investigators.
- Any information shared cannot make the specimen source identifiable to the investigators or other individuals associated with the investigation, including a sponsor.

Note: Include the signed Application for Independent Honest Broker Agreement with the submission, which may be downloaded from Step 11 of the IRB Submissions website.

☐ 2) The project uses de-identified specimens to validate a medical device, diagnostic instrument, or laboratory test. *Note: the FDA uses enforcement discretion to not require informed consent for the use of de-identified specimens. See: FDA Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Specimens that are NOT Individually Identifiable.*

If checked, provide the following:

Source of specimens:

Will the study use specimens that were obtained from specimen repositories or leftover specimens that were previously collected for other research purposes?

☐ No ☐ Yes (If Yes, describe source below):

Check to confirm the following, as applicable to the project:

☐ This is a sponsored project. The sponsors will maintain written documentation outlined in the referenced FDA guidance. The sponsors of this study are aware that FDA may require additional clinical information in order to evaluate test results, as referenced in the above guidance. When choosing to follow the FDA guidance, they accept the risk that they may not be able to provide sufficient information to satisfy FDA's premarket review needs.

☐ An Honest Broker may obtain clinical information when needed and share coded or de-identified information with the investigators. The Honest Broker section is completed above.

☐ None of the above.

☐ 3) The activity involves the use of specimens obtained from a producer or supplier that cannot be linked to an individual by the investigators.

If checked, provide the name of the producer or supplier and describe the specimens obtained:

☐ Check box if an agreement is required and include draft with submission.

Note: Agreement must be fully executed before starting the activity.

☐ 4) The activity involves the use of a Limited Data Set protected with a Data Use Agreement (DUA) and investigators cannot readily identify the individuals about whom the data pertains and investigators do not have access to the key to any codes to identify the individuals. Include draft DUA with submission.
Note: The DUA must be fully executed prior to sharing the limited data set.

☐ 5) The activity involves the use of de-identified materials, not described above.

If checked, describe source of de-identified materials:

☐ 6) The activity involves the use of coded materials not described above, with a process in place to prohibit release of key to the code to the investigators.

If checked, describe source of the coded materials:

If checked, indicate the names of the individuals (who are NOT investigators) who hold the key to the code:

☐ **C. Research-Not Engaged (Institution Not Engaged in Human Research)**

NOTE: Skip section C if section A (page 7) or section B (page 11) is completed.

WARNING: Do not check C, if either of the following statements are true:

- *The institution submitting this application is the Primary Awardee on an HHS award (grant, contract, cooperative agreement) supporting the project described on this application, even if all of the human research activities are carried out by investigators from other institutions.*
- *Any individual listed on this application does any of the following activities for the purpose of the research described on this application:*
  - *intervenes with a research participant by performing invasive or noninvasive procedures,*
  - *intervenes with a research participant by manipulating the environment,*
  - *interacts with a research participant,*
  - *obtains informed consent from a research participant,*
  - *obtains identifiable private information,*
  - *obtains protected health information, or*
  - *obtains identifiable biological specimens*

☐ Before proceeding, check this box to confirm all of the above statements are false, and continue to next section below.

Note: If any of the above statements are true, then and do not complete section C. The institution is engaged in human research, when any of the above items are true

If C, check specific reason(s) below (items 1-14) and answer corresponding questions:

☐ 1) This activity represents a process referring others to a new study. If checked, describe the process that will be used to refer others to a new study:

How are referrals made to the engaged site?

☐ Clinical staff provide consent form and refer participant to engaged site to answer any questions about the research.

☐ Clinical staff refer their own patients to a new study.

☐ Staff refer patients unknown to them to the engaged site.

☐ Other (describe):

Note: If referring patients, include any of the applicable "Recruitment Authorization Form(s)" (Forms 8-14, 8-15, and/or 8-16), which can be downloaded from Step 8 of the IRB Electronic Submission Website.

☐ 2) The institution is involved in an activity that is limited to one or more activities listed in Section III (B) of the October 16, 2008 Guidance on Engagement of Institutions in Research.

If checked, describe non-engaged activities limited to those listed in the guidance:

☐ 3) The institution's workforce is involved in an activity that is limited to one or more activities listed in OHRP Correspondence on "Non-Engaged" Scenarios. If checked, describe non-engaged activities limited to those listed in the correspondence:

☐ 4) The Institution's workforce performs a service for investigators under the following conditions: a) the services performed do not merit professional recognition or publication privileges; b) the services performed are typically performed by those institutions for non-research purposes; and c) the institution's employees or agents do not administer any study intervention being tested or evaluated under the protocol. If checked, describe the service below:

☐ 5) The institution is not selected as a research site whose workforce

provides clinical trial-related medical services that are dictated by the protocol and would typically be performed as part of routine clinical monitoring and/or follow-up of participants enrolled at a study site by clinical trial investigators.

All of the conditions below are true:

- members of the workforce **do not** administer the study interventions being tested or evaluated under the protocol;
- the clinical trial-related medical services are typically provided by Downstate for clinical purposes;
- members of the workforce do not enroll participants or obtain the informed consent; and
- when appropriate, investigators from an institution engaged in the research retain responsibility for: i) overseeing protocol-related activities; and ii) ensuring appropriate arrangements are made for reporting protocol-related data to investigators at an engaged institution, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol.

If checked, describe the clinical trial-related medical services provided:

☐ 6) The institution was not initially selected as a research site; however, the workforce members administer the study interventions being tested or evaluated under the protocol limited to a one-time or short-term basis.
All of the conditions below are true:
a) an investigator from an institution engaged in the research determines that it would be in the participant's best interest to receive the study
interventions being tested or evaluated under the protocol;
b) members of the workforce do not enroll participants or obtain the informed consent;
c) investigators from the institution engaged in the research retain responsibility for
i) overseeing protocol-related activities;
ii) ensuring the study interventions are administered in accordance with the IRB-approved protocol; and
iii) ensuring appropriate arrangements are made for reporting protocol-related data to investigators at the engaged institution, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol; and an IRB designated on the engaged institution's FWA is informed that study interventions being tested or evaluated under the protocol have been administered at an institution not selected as a research site.

If checked, describe the short-term activities below:

☐ 7) Members of the institution's workforce ONLY do one or more of the following activities, as checked below:

- ☐ Inform prospective participants about the availability of the research.
- ☐ Provide prospective participants with information about the research (which may include a copy of the relevant informed consent document and other IRB approved materials) <u>but do not obtain participants' consent for the research nor act as representatives of the investigators.</u>
- ☐ Provide prospective participants with information about contacting investigators for information or enrollment.
- ☐ Seek or obtain the prospective participants' permission for investigators to contact them.

If any items are checked in item 7, describe the process for the above activities with the prospective participants and include any relevant documents:

☐ 8) The institution permits use of their facilities for interventions or interactions with participants by investigators from another institution.
Note: if checked, execute a Facilities Use Agreement when required.

If checked, describe activities to take place in facilities:

☐ 9) The institution's workforce **release** to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the participants of the research. All other institutional requirements must be satisfied before the information or specimens may be released.

If checked, describe information and/or materials to be released:

☐ 10) The institution's workforce obtains coded private information or coded specimens from another institution involved in the research that retains a link to individually identifying information; and the workforce are **unable** to readily ascertain the identity of the participants for whom the coded information or coded specimens pertain.

If checked, describe the information or specimens to be received:

☐ 11)The instituion's workforce access or utilize individually identifiable private information **only** while visiting an institution that is engaged in the research, **and** their research activities are overseen by the IRB of the institution that is engaged in the research. *CAUTION: Before selecting this as an option, consider whether an application for Exempt Research or Oversight from an External IRB is required.*

If checked, describe details below:

☐ 12)The instituion's workforce review identifiable private information for purposes of study auditing.

If checked, describe the study audit:

☐ 13)The instituion's workforce receive identifiable private information for purposes of satisfying U.S. Food and Drug Administration reporting requirements.

If checked, describe purpose and requirements:

☐ 14)The institution's workforce author a paper, journal article, or presentation describing human research study(ies). If checked, describe activities:

Section 5: 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. Does the European Union General Data Protection Regulation (EU GDPR) or Californian Consumer Privacy Act (CCPA)apply to this research? *(MUST SELECT AT LEAST ONE)*
- ☐ 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 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 6: 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 7: Additional information: