

SUNY Downstate IRB & Privacy Board

FORM 20-B2A: Application for Amendment

(Version 11.23.2021)

Instructions: 1) Open form in Adobe Reader. 2) Use Fill & Sign tool to complete. 3) Confirm any preformatted fields are correct. 4) Save file. 5) Submit completed form to IRB.

Note: Free Adobe Reader available at: www.adobe.com

Section 1: General Information:

A. IRBNet Number:

B. Protocol Title:

C. Does this submission include staff change(s): NO YES

If yes, include Form 20-B2B

D. PI* Name and Degree

**Note: Provide "Principal Clinician" for HUD for clinical use and expanded access projects.*

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

F. Does this amendment come at the request of the sponsor? NO YES

If yes, include supporting documentation.

G. Check type of proposed change(s)

REMINDER: Attach revised documents and documents with tracked changes when possible.

IRBNet Registration Form

Funding source or status

Number of research participants

Recruitment methods, advertisements, reimbursement, or compensation.

Study sites

Protocol or abstract

Consent, Assent, Parental Permission, Information Sheet, HIPAA Authorization, Consent

Addendum, SUNY RF Consent, or other similar documents

Waiver of Informed Consent requirements, HIPPA Waiver, or other similar documents

Investigator Brochure

Changes required by ancillary review

Transition research to the 2018 Common Rule

Changes already made to eliminate apparent immediate hazard

Changes to eliminate or minimize COVID-19 hazards

Other, describe:

Section 2: List previously approved documents to be discontinued with this submission:

Section 3: Summary of Proposed Changes

REMINDER: If documents require amended changes, submit an "Application for Amendment" form.

A. Why are the changes are needed?

B. Summary of proposed changes:

C. Check if N/A; otherwise, indicate the impact of these changes on the research participants:

Section 4: Additional information (optional):