

SUNY Downstate IRB & Privacy Board

FORM 20-B2B: Application for Amendment - STAFF CHANGES ONLY

(Version 09.01.2021)

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. Indicate type of change(s): Adding staff Removing staff

D. PI* Name and Degree

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

E. PI Department/College

F. PI Status

When applicable, include information about a **Co-PI (optional) below:

***Note: If more than one Co-PI, attach separate sheet with the additional information*

G. If applicable, Co-PI Name and Degree:

H. If applicable, Co-PI Department/College:

I. If applicable, Co-PI Status

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

Section 3: Study staff: For guidance on **IIA** and **IRA**, see Step 5 of the IRB submission website.

REMINDER: Include ALL study staff to be approved by the Downstate IRB on IRBNet Registration Form.

A. ADDING Investigators who are members of the **Downstate Workforce**:

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

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

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

E. ADDING Name(s) of investigators who are an “**Investigator for the purpose of COI reporting**”: *(NOTE: Always include any NEW PI/Co-PI)*

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

Section 4: List the names of those who are no longer a part of the study team:

Section 5: Summary of Proposed Changes

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

A. Why are the changes needed?

B. What are the responsibilities of each new study team member?

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

Section 6: Additional information (optional):