SUNY Downstate IRB & Privacy Board

FORM 20-B4: Application for Continuing Review/Check-In/Closure/Re-Activation

(Version 09.17.2021)

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. PI* Name and Degree

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

E. PI Department/College

F. PI Status Downstate Faculty

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 NA -No Co-PI

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

Section 2: Review Type & Status:

A. Review Type: SELECT TYPE FROM DROP DOWN MENU BELOW

B. If closing or re-activating a study, state reason:

C. Select study status: SELECT OPTION FROM DROP DOWN MENU BELOW

D. ☐ Check if study relies on oversight of an external IRB & include their determination letter. (sIRB, Central IRB, Commercial IRB, WCGIRB, ADVARRA, BRANY, NCI-CIRB, etc)

E. ☐ Check if the analysis of identifiable private information is complete

Section 3: Indicate whether any of the following have not yet been reported to this IRB:

REMINDER: Include any applicable Amendment or Reportable Event Form with this submission.

YES	NO	
○	◉	1. Changes in the project, including changes to status or source of funding.
○	◉	2. Changes to the protocol, consent, or materials seen by those enrolled.
○	◉	3. Changes implemented without prior IRB approval/activation.
○	◉	4. Scientific publications, safety reports, interim findings, multi-center trial reports, interim safety analysis, or any similar reports relevant to the study risk or design.
○	◉	5. New or change in risks, potential benefits, or risk-benefit relationship.
○	◉	6. Complaints from study participants, patients, research staff, or others.
○	◉	7. Change in laws, regulations, or policy that impact the project.
○	◉	8. Unreported reportable events, including unrelated SAEs or minor protocol deviations.
○	◉	9. Government notice of study hold, suspension, termination, or warning.
○	◉	10. FDA Form 483 in the past 5 years.
○	◉	11. FDA warning letter regarding this study.
○	◉	12. Use of the HUD/HDE for "off label" purpose.
○	◉	13. HUD/HDE malfunction.
○	◉	14. Change in stock or patent position with a clinician using an HUD on this project.
○	◉	15. Notice of disqualification, denial, revocation, suspension, reduction, limitation, probation, non-renewal, relinquishment, sanction, fine, or notice of disciplinary action of an investigator or study staff member regarding any of the following: clinical privileges at any site, DEA license, certification, medical license, faculty appointment, privileges, society memberships, etc.
○	◉	16. Changes to study staff.
○	◉	17. Errors with consent process, study procedures, or administration of a drug, biologic, or medical device.

If Yes to any of the above items (1-17), please summarize and describe any trends or patterns. *NOTE: Unless confidential or sensitive, submit relevant supporting documentation, reports, correspondence, publications, etc.*

Section 4: Study staff: For guidance on **IIA** and **IRA**, see Step 5 of the IRB submission website.

NOTE: SKIP THIS SECTION FOR CLOSURE REPORTS

Reminder: Request an amendment to add or remove Study staff if applicable.

A. Include an IRBNet Registration Form with submission, listing all current investigators, including the Downstate workforce. Investigators who are not part of the Downstate workforce must also be specified below (items B, C, & D).

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)

PI Only

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

N/A (None)

Section 5: Research sites approved by the IRB (choose all that apply):

- [x] SUNY Downstate
  - [ ] Including Clinical & Translation Science Center (CTSC)
- [ ] NYC H+H, Kings County
- [ ] Online (web-based research)
- [ ] Other sites (describe):

Section 6: Preliminary Reporting:

A. Is this project an "Applicable Clinical Trial (ACT)" and/or requires registration and reporting by the FDA, NIH, VA, ICMJE, or other entity? (•) NO ( ) YES

A1. If YES, provide NCT# for www.clinicaltrials.gov:

A2. If YES, indicate Responsible Party: IF YES, SELECT FROM MENU OR ENTER TEXT

B. [x] Check box if N/A; otherwise, provide a summary of all reportable events during this approval period, and describe any trends or patterns:

C. [x] Check box if N/A; otherwise, provide any preliminary results from the project:

D. If the study was previously approved by the **full board**, indicate if any of the following apply:

- ( ) Enrollment is permanently closed, all participants have completed all research-related interventions, and the research remains active only for long-term follow-up of participants
- ( ) No participants are enrolled yet and no additional risks have been identified
- ( ) The remaining research activities are limited to data analysis
- ( ) This study was not previously approved by the full board
- (•) None of the above.

***SINCE STUDY STARTUP:**

E. *Number approved to be in the research *(include screening)*:

F. *Number enrolled *(i.e., via consent/authorization, surveys, focus groups):*

G. *Number included, not otherwise enrolled *(i.e., via charts, data):*

H. *Number of screening failures *(Enter 0 if protocol does not involve screening):* 0

I. *Number who withdrew/stopped participation on their own *(do not count screen failures):* 0

J. *Number of participants withdrawn by the PI before reaching the study end point: 0

K. *Summarize the reasons the participants withdrew and/or were withdrawn:

Section 7: Additional information (optional):

Section 8: Ancillary reviews: ☑ Check if N/A

Check applicable box(es) below when 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)
- ☐ OTHER (Specify):