

SUNY Downstate Ancillary Review

FORM 7b: Application for Ancillary Review of Unfunded Clinical Research

(Pilot Version 10.24.2024)

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 completed form to the Downstate IRB using IRBNet.

Note: For more detailed instructions on how to fill and digitally sign IRB Forms, see: [IRB Submission Tip #2](#).

Complete Section 1-4 of this form and submit to IRB in IRBNet with study submission 1) whenever it is requested by the Downstate IRB or Downstate Leadership or 2) for any unfunded (intramurally supported) clinical research, including any unfunded research that meets one of the regulatory definitions for a [Clinical Trial](#).

Attach a Research Budget indicating: all participating physician and/or staff time; supplies, drugs, and/or devices; procedures completed – and the source of each.

Section 1: General Information:

- A. IRBNet #:
- B. Protocol Title:
- C. PI Name and Degree
- D. PI Department/College

Section 2: Resources:

Reminder: Be sure to include all resources in attached budget.

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|--|-----|----|
| A. University Hospital at Downstate Staff, Equipment, or Space | Yes | No |
| B. Downstate Health Physicians (UPB) Staff, Equipment, or Space | Yes | No |
| C. Downstate College/School Staff, Students, Equipment, or Space | Yes | No |
| D. Research Foundation Staff, Equipment, or Space | Yes | No |
| E. Research Volunteers: | Yes | No |
| F. Investigational Drug/Biologic | Yes | No |
| G. FDA Approved Drug/Biologic | Yes | No |
| H. Investigational Medical Device | Yes | No |
| I. FDA Approved Medical Device | Yes | No |
| J. Other Resources (If yes, describe below) | Yes | No |

Section 3: Additional information:

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Section 3: Additional information (continued):

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Business Associates Agreement (BAA)
Confidentiality Agreement (CA)
Data Use Agreement (DUA)
Data Agreement (DA)
Clinical Trials Agreement (CTA)
Facilities Use Agreement (FUA)
Material Transfer Agreement (MTA)
Non Disclosure Agreement (NDA)

No Agreements
Other (describe below)

Section 4: Principal Investigator Attestation:

By signing this form, I attest the information on this form and the attached budget are accurate and complete to the best of my knowledge.

Section 5: Approvals: (IRB will forward to CMO, UHD, RF, as applicable)

A. University Hospital at Downstate, Chief Medical Officer

B. Downstate Health Physicians (DHP/UPB), when using DHP/UPB resources

C. Research Foundation, when using RF resources