

# Application for New Study

## Instructions: PDF Version

This format is designed for those who wish to print the form and complete it with a typewriter. If you would prefer to complete the form on a computer, please choose a different format.

If you need additional room to answer any questions, attach a separate page.

If you have any questions, contact the IRB Office at 718-270-2680.

## Submission Checklist:

Before you submit this form, ensure that all study staff have completed the IRB training requirements.

In your submission to the IRB, please include the following:

- \_\_\_\_\_ New Study Form
- \_\_\_\_\_ Abstract
- \_\_\_\_\_ Consent Form – See IRB Consent Form Template and Sample Consent Form
- \_\_\_\_\_ Assent Form. (Required if you are planning to enroll participants age 7-12.) See IRB Assent Form Template.
- \_\_\_\_\_ Complete Protocol. This may be a sponsor’s protocol or a protocol submitted to FDA or NIH. For small surveys or chart reviews, a brief description and survey instrument or data collection sheet may be sufficient. Contact the IRB Office.
- \_\_\_\_\_ Investigator’s Brochure (if applicable)
- \_\_\_\_\_ List of additional study staff, FDA Form 1572, or NIH “Key Personnel” section (if applicable)

**Protocol #:**

SUNY Health Science Center at Brooklyn  
Kings County Hospital Center  
Institutional Review Board

**Application for New Study**

**GENERAL INFORMATION**

<b>Principal Investigator:</b> (must be HSCB faculty)	<b>Dept:</b>	<b>Box:</b>
<b>Co-Investigator:</b>	<b>Dept:</b>	<b>Box:</b>
<b>Co-Investigator:</b>	<b>Dept:</b>	<b>Box:</b>

**Additional Study Staff Authorized to Conduct Consent Interview:**

Append list of additional staff if necessary. Please provide a copy of FDA Form 1572 or NIH application section “Key Personnel” (NIH Form 398 p2), if applicable.

**How should we contact you?**

<b>Name (if not PI):</b>	<b>Email:</b>
<b>Ph:</b>	<b>Cell:</b>
<b>Fax:</b>	<b>Page:</b>

<b>Protocol Title:</b>
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**1) Is this sponsored research?**  
 No  Yes **If yes, sponsor’s name and protocol #:**

**2) Where will the study be conducted?**  
 University Hospital of Brooklyn  
 Kings County Hospital Center (Administrative approval required. Use form HHC 641)  
 Other, **Please specify.**

**3) Does the study involve any drugs, devices, or biologics not approved by the FDA or used for a new indication?**  
 No  
 Yes **If yes, provide IND/IDE# or explain why IND/IDE not necessary.**



**BIOLOGICAL SPECIMENS**

**9) Does the study make use of biological specimens (e.g. blood or tissue samples)?**

No  Yes **If no, skip to “Privacy and Confidentiality.”**

**10) Are the specimens,**

To be obtained in the future.

**If in future, will the specimens be**

Taken for research purposes only

Excess material from clinical samples

From an existing collection.

**If existing, was consent originally obtained? For what purposes?**

**11) Will the specimens be**

Fully anonymous (i.e. not carry any identifiable information, such as name, ID#, code)

Linked to individually identifiable information (e.g. name, ID#, code)

**If linked, might the study yield clinically relevant information?**

No  Yes **If yes, under what circumstances will participants be contacted?**

**12) Will the specimens be preserved for other research?**

No  Yes **If yes, please explain what, why, and by whom.**

**PRIVACY AND CONFIDENTIALITY**

**13) What will be done to protect participants’ privacy and confidentiality? (e.g. data access, storage, and coding)**

## PARTICIPANTS

**14) How many people will participate in the study?**

At the locations listed above:

At all sites:

**15) Who is eligible to participate?**

Age Range:

Sex:  Male  Female

**16) Do you want approval to enroll members of any of the following groups?**

- Minors (If minors 7-12 will be enrolled, provide assent form)
- Pregnant women
- Prisoners
- Decisionally-impaired Persons

**For any checked boxes, please provide justification and any additional protections.**

**17) Does the study specifically target OR exclude any of the following groups: either sex, pregnant women, racial/ethnic minorities, non-English speakers, students, employees, persons who are institutionalized, or economically/educationally disadvantaged? If so, please identify and explain.**

## RECRUITMENT AND CONSENT

**18) How will potential participants be identified, contacted, and recruited? (Please attach any proposed advertising, e.g. flyers, radio ads – these may also be submitted as amendments.)**

**19) How will consent be obtained and documented? Will any information be withheld from participants? If you are requesting a waiver of consent or documentation, please justify.**

## COSTS AND PAYMENTS

**20) Will participants (or their insurance) be billed for any of the procedures?**

No  Yes **If yes, which procedures?**

**21) Will participants receive any reimbursement or remuneration for their participation?**

No  Yes **If yes, how much and for what?**

**22) Are there any procedures to compensate participants for study related injury?**

No  Yes **If yes, please describe.**

### SIGNATURES:

Principal Investigator certifies that the study will be conducted in accordance with federal regulations and SUNY HSCB/KCHC policy.

Department Chairs certify that the study is scientifically sound and that there are sufficient departmental resources, financial and otherwise, to conduct the study.

Principal Investigator	Date	PI's Dept. Chair	Date
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Co-Investigator	Date	Collaborating Dept. Chair	Date
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Student	Date	Other	Date
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