New York City Health and Hospitals Corporation

Application Status ☐ **New** ☐ **Renewal**

Research Project/ Grant Authorization Application

HHC Control #	
Facility Control #	
IRB#	

General Information:

HHC Facility: _____ Department / Service _____

Principal Investigator Last Name _____ First Name _____

Co-Principal Investigator Last Name _____ First Name _____

Office Address: _____ Telephone/ Beeper _____

Complete Title of Protocol: _____

Email: _____ Fax: _____

NA (Does Not Apply) Box MUST be checked in every case where application section is not relevant to the protocol.

Funding Information: ☐ NA

Sponsor Name*: ☐ NA _____
(Attach Copy of Application / Award)

Funding Source:
☐ Affiliate
☐ Un-funded
☐ NIH
☐ Federal/State/City
☐ Other Non Profit
☐ Pharmaceutical Co.
☐ Other For Profit

Budget: ☐ NA

Total Grant Application/Award — Date From: _____ To: _____ Direct Costs Requested/Awarded: $_____

Current Budget Period: — Date From: _____ To: _____ Direct Costs Requested/Awarded: $_____

Is this an "umbrella" grant award? ☐ Yes ☐ No

Is this funded under an "umbrella" grant? ☐ Yes ☐ No HHC # _____

* If only drug device is supplied (no grant funds), indicate sponsor name. If no sponsor leave blank.

Facility Involvement: ☐ NA

(Put " X" for all boxes that apply).

- ☐ **Primary or Sole Site for Project**
- ☐ **One of Multiple Sites**
- ☐ **Patient Recruitment Only (Research off-site)**

Site List:

- ☐ _____
- ☐ _____
- ☐ _____

Project Type:

- ☐ **Drug Trial (Clinical Trial)**
- ☐ **Device Testing**
- ☐ **Other Clinical Study**
- ☐ **Patient Recruitment Only (Research off-site)**
- ☐ **Other:** _____
- ☐ **Specimens Analyzed**
- ☐ **Interview Questionnaire**
- ☐ **Medical Record Computer Run**
- ☐ **Medical Record Chart Review**
- ☐ **Social, Behavioral or Environmental**

Vulnerable Human Subject Involvement: ☐ NA

- ☐ **Diminished Mental Capacity**
- ☐ **Minors**
- ☐ **AIDS/HIV**
- ☐ **Pregnant Women**
- ☐ **Fetuses**
- ☐ **Prisoners**
- ☐ **Arbortuses**

Study Subjects

- ☐ **Patients**
- ☐ **Employees / Staff**

☐ **People of Color / Women Participation**

This project ☐ does ☐ does not restrict entry of women or minority populations. If does, attach statement of compelling justification.

☐ **Consent form in English and in other most commonly used language (s) at facility or statement explaining how investigator secures consent from non - English speaking patients is attached.**

HHC Facility Testing: ☐ NA

A. Interview / Questionnaire — Number Requested

- ☐ **Patient** _____
- ☐ **Staff** _____
- ☐ **Other** _____

B. Specimens

- ☐ **Blood Drawing**
- ☐ **Urine**
- ☐ **Anatomical / Pathol**
- ☐ **Abortuses**
- ☐ **Fetuses**
- ☐

C. Drug Testing

- # Inpatients _____
- # Outpatients _____

D. Device Testing

- # Inpatients _____
- # Outpatients _____

Ancillary Tests and Procedures: ☐ NA

List any test or procedures that will be performed (i.e., over and above standard clinical treatment regimen or reimbursed by grant).

	Test / Procedure	# Involved	Facility Administering / Analyzing	Cost
1.				
2.				
3.				
4.				

Research Facility Business Office, tel. # _____ Total Cost 0.00

Pharmaceutical / Device Information: ☐ NA

Name of Drug #1:	**Manufacturer Name and Address**	**Pharmacy Services Required**
If investigational, indicate: IND# _____ IND Sponsor _____ Is this drug on the facility formulary? ☐ Yes ☐ No		☐ Store ☐ Data Management ☐ Repack ☐ Dispense ☐ Dilute / Compound ☐ Label
Name of Drug #2:	**Manufacturer Name and Address**	**Pharmacy Services Required**
If investigational, indicate: IND# _____ IND Sponsor _____ Is this drug on the facility formulary? ☐ Yes ☐ No		☐ Store ☐ Data Management ☐ Repack ☐ Dispense ☐ Dilute / Compound ☐ Label
Name of Drug #3:	**Manufacturer Name and Address**	**Pharmacy Services Required**
If investigational, indicate: IND# _____ IND Sponsor _____ Is this drug on the facility formulary? ☐ Yes ☐ No		☐ Store ☐ Data Management ☐ Repack ☐ Dispense ☐ Dilute / Compound ☐ Label

Are any of these drugs being supplied by the sponsor free of charge? ☐ Yes ☐ No (if yes, complete below)

Drug Supplied	Cost Per Dosage	Estimated Facility Projected Savings	Actual Facility Savings Confirmed
1. _____	$ _____	$ _____	$ _____
2. _____	$ _____	$ _____	$ _____
3. _____	$ _____	$ _____	$ _____

TO BE COMPLETED BY FACILITY PHARMACY

Total Costs charged by facility pharmacy: $ _____

Total Costs to be waived by facility pharmacy: $ _____

Unfunded Personnel

PLEASE LIST ALL UNFUNDED PERSONNEL ENGAGED IN THIS PROJECT FOR RESEARCH AND INDICATE TIME COMMITMENT TO RESEARCH ACTIVITIES.

☐ NA

				Affiliate					
Personnel			HHC Staff % Effort in Project	% of Effort on Project	% of Effort Funded by Affiliate Contract	Annualized Number of Hours on This Protocol	Annualized Salary	Fringe Benefits	Total Costs Attributable to Protocol
Last Name	First Name	Title							
					Total				

TO BE COMPLETED BY FACILITY BUSINESS OFFICE

Personnel Costs to be recovered by facility: $ _____ Costs to be waived by facility: $ _____

Funded Personnel

PLEASE LIST ALL FUNDED PERSONNEL ENGAGED IN THIS PROJECT FOR RESEARCH AND INDICATE TIME COMMITMENT TO RESEARCH ACTIVITIES.

☐ NA

				Affiliate					
Personnel			HHO Staff % Effort in Project	% of Effort Funded on Project	% of Effort Funded by Affiliate Contract	Annualized Number of Hours on This Protocol	Annualized Salary	Fringe Benefits	Total
Last Name	First Name	Title							
					Total				

TO BE COMPLETED BY FACILITY BUSINESS OFFICE

Personnel Costs to be recovered by facility: $ _____ Costs to be waived by facility: $ _____

OTPS Utilization: ☐ NA

Please enter any of the following facility resources that you will be using:

(Put "X" for all that apply)	Specify Type	Quantity	Unit Cost	Facility Charge	Put "X" if covered by Affiliation or Grant
☐ Lab Supplies					☐
☐ Equipment					☐
☐ Office Supplies					☐
☐ Computer Support					☐
☐ Telecommunications					☐
☐ Transportation					☐
☐ Other					☐

To Complete this section, contact the Affiliation Office, tel.#: _____

Cost data, if needed, are obtained from the Facility Business Office, tel.#: _____

Total Cost: $ _____

TO BE COMPLETED BY THE BUSINESS OFFICE

Total cost to be recovered by facility: $ _____ Total cost to be waived by facility: $ _____

Space: ☐ NA

Please identify all space at facility in which research activity will take place.

	Location	Room #	Square Feet	Description	Square Feet Used for Research Only	Cost To Be Reimbursed to Facility*
☐						
☐						
☐						
☐						
☐						
☐						
☐						
☐						

* To be completed by Finance Dept.

TO BE COMPLETED BY FACILITY BUSINESS OFFICE

Total cost to be recovered by facility: $ 0.00 Total cost to be waived by facility: $ 0.00

Medical Records Required for Research: ☐ NA

☐ Inpatient ☐ Outpatient

☐ Chart Pull ☐ Computer Run

☐ Concurrent: # ☐ Retrospective: #

_____ _____

Total Cost: $ _____

NOTE: Chart retrieval fees are charged by the facility

THIS SECTION TO BE COMPLETED BY FACILITY BUSINESS OFFICE

Total costs to be recovered by facility: $ _____

Total costs to be waived by facility: $ _____

SUMMARY COSTS TO BE COMPLETED BY FACILITY BUSINESS OFFICE

	Costs Reimbursed To Facility	Costs Waived by Facility	Costs Saved by Facility
1 Medical Records	$ _____	_____	_____
2 Ancillary Tests / Procedures	$ _____	_____	_____
3 Pharmacy	$ _____	_____	_____
4 OTPS Utilization	$ _____	_____	_____
5 Space	$ _____	_____	_____
6 Personnel	$ _____	_____	_____
7 Fee	$ _____	_____	_____
8 Indirect	$ _____	_____	_____
Grand Total:	$ _____	_____	_____

Attestations and Sign Off:

1. Have you identified all research related utilization of hospital resources? ☐ Yes ☐ No
2. Have you identified sources of reimbursement for all expenses? ☐ Yes ☐ No
3. Have you identified all cost saving impacts on facility resources? ☐ Yes ☐ No
4. Are mechanisms in place to ensure the continuity of care for patients? ☐ Yes ☐ No
5. Have all individuals listed in the personnel section and any others who will participate in this research project at the facility received appropriate health clearance? ☐ Yes ☐ No
6. Have all persons listed in the personnel section and others who will participate in this research project at the facility demonstrated appropriate indemnification to the satisfaction of the facility? ☐ Yes ☐ No

Principal Investigator	Date	Director, Laboratory Services	Date
Director of Service	Date	Director, Radiology Services	Date
Chief Financial Officer	Date	Director, Pharmacy	Date
Affiliation Administrator	Date		
Medical Board President	Date		
Executive Director, HHC Facility	Date		
Facility Research Committee	Date		

☐ Put "X" if comments continue on next page.

IRB Approval: _____ (Number) _____ (Date) ☐ Check if Consent Waived

HHC Authorization: _____ (Chair, Central Office, HHC Research Review Committee) _____ (HHC Approval Date)

Attach:
- HIPAA Statement
- Current Consent Form
- Protocol and / or Summary
- Budget
- IRB Authorization Letter

Reset

Research Project / Grant Authorization Application
Comments