JHS Office of Research
1500 NW 12th Avenue; Suite # 803
Miami, Florida 33136-1094
Phone: (305) 585-7226
Fax: 305-585-6144

The Jackson Health System Office of Research **requires a complete submission of all required documents** for the study to be accepted and reviewed by the JHS Clinical Research Review Committee (CRRC):

I. Drug Studies

- Complete JHS Research Study Application & Study Calendar
- Study Protocol
- Electronic Modifiable Version of the Contract or Grant Award
- Form 1572
- FDA letter re: IND or IND Exemption
- IRB Application and Approval Letter (may submit Pre-IRB)
- Questionnaires and/ or Assessments
- JHS HIPAA or Waiver of Authorization
- Informed Consent Draft
- Administrative set-up fee

II. Device Studies

- Complete JHS Research Study Application & Study Calendar
- Study Protocol
- Electronic Modifiable Version of the Contract or Grant Award
- Sponsor Device Description
- FDA letter re: IDE or IDE Exemption
- Determination of Local Fiscal Intermediary (must be provided prior to final approval)
- IRB Application and Approval Letter (may submit Pre-IRB)
- Questionnaires and/ or Assessments
- JHS HIPAA or Waiver of Authorization
- Informed Consent Draft
- Administrative set up fee

III. Chart Review/ Repository Studies

- Complete JHS Research Study Application
- Study Protocol
- IRB Application and Approval Letter (may submit Pre-IRB)
- JHS HIPAA or Waiver of Authorization
- Informed Consent Draft
- Administrative set up fee

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JHS OFFICE OF RESEARCH APPLICATION FORM

PROTOCOL # ___________________

Please complete the following information accurately and to the best of your ability. If you need clarification on the forms, feel free to contact Clinicaltrialsoffice@jhsmiami.org.

Submissions will not be scheduled for review until deemed complete by JHS Office of Research Staff.

STUDY INFORMATION:

Study Full Title:	
Study title: *(Short Name -18 characters)*	
Principal Investigator (PI)	
PI Department / Division / Specialty	
PI Affiliation	
PI Address	
City, State, Zip	
PI Telephone	
PI Email	
PI Pager	
Study Coordinator (SC)	
SC Telephone	
SC Email	
Finance Contact	
Finance Contact Telephone	
Other Investigators (list Co-PI and all sub investigators here):	
Nurse Manager and Educator of Affected Floors **(REQUIRED)**	
Nurse Manager Telephone	

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Study Description: Please provide a detailed explanation of what will happen to subjects in the study	

Standard Treatment: Please describe what treatment subjects would receive if they were not participating in the study	

STUDY DETAILS:

Study Type / Study Design	☐ DRUG ☐ RANDOMIZED ☐ DEVICE ☐ PROGRAM EVALUATION ☐ BIOLOGIC ☐ GENETIC RESEARCH ☐ REGISTRY ☐ SURVEY ☐ PHYSIOLOGIC ☐ CREATING DATABASE ☐ THERAPEUTIC ☐ BLIND / ☐ DOUBLE BLIND ☐ DIAGNOSTIC ☐ PLACEBO CONTROLLED ☐ EPIDEMIOLOGIC ☐ MEDICAL RECORD REVIEW ☐ OTHER ________________
Drugs / Devices / Agents Being Investigated (List by name)	
Funding Source:	☐ Sponsored ☐ Grant Agency/Government/Foundation ☐ Investigator must have verified funding source ☐ Other ________________________________
Sponsor/Manufacturer	
Are these products FDA approved?	☐ YES ☐ NO ☐ N/A
Please provide the following IND / IDE / HDE information and check the corresponding box to indicate it is attached.	☐ Copy of FDA Letter (required) ☐ Investigator's Brochure/Product Labeling (required) ☐ Sponsor Reimbursement Package (if available)
Who will purchase the investigational drug/ device/ agent?	☐ Physician / Practice Group ☐ Jackson Health System (consigned/leased from sponsor) ☐ Sponsor will provide free of charge ☐ Other: _____ ☐ N/A

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What is the cost of the drug / device / agent? (REQUIRED)	
Where will the drug/device/agent be stored?	☐ Jackson Health System ☐ JHS Research Pharmacy ☐ Sponsor will provide on a case-by-case basis ☐ N/A Other: _____ ______________

HOSPITAL INFORMATION:

PI has Privileges to Perform Study	☐YES ☐NO
SC has Completed JHS Cerner class to utilize researcher Provider accounts. Offered by JHS Office of Research	☐YES ☐NO ☐N/A

Number of JHS Subjects to be enrolled or charts to be reviewed:	
Will you need to recruit in the Emergency Department:	☐ Yes ☐ No
Will you utilize a flyer to recruit at any JHS site? (If yes, please attach hereto.)	☐ Yes ☐ No
Which of the following research activities will occur at JHS?	☐ Recruitment (flyers, screening, etc.) ☐ Enrollment (consent) ☐ Treatment (surgical procedures, nursing care, monitoring, etc.) ☐ Blood Draw ☐ Labs ☐ Diagnostics ☐ Drug Dispensing ☐ Drug Administration ☐ Follow-Up ☐ Other ___________________________________
JHS Administrative set-up fee:	☐ $1400 (one-time) Sponsored ☐ $700 (one-time) Federal/Foundation ☐ $400 (one-time) Investigator Initiated ☐ $200 Administrative set-up fee for all chart reviews (this applies to **electronic review** of records

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COPIES	via Cerner)
	☐ $32.00 for every 40 **paper charts pulled**.
	☐ $0.12/page for **copies** requested of Med. Records (Submit Request to Marjorie Paterson).
Satellite Admin Support fee	☐ $100.00
In-patient Nursing fee:	☐ (subject to nurse manager's approval)
Out-patient Nursing fee:	☐ (subject to nurse manager's approval)
Research clinic visit	☐ $55.00 (each)
General Pathology Fee	☐ $500.00
Tissue Process/ Embed	☐ $10.00 (each)
Unstained Slide	☐ $3.00 (each)
H&E	☐ $5.00 (each)
Special Stain	☐ $24.00 (each)
Pull Block Only (each)	☐ $5.00 (each)
Pull/ Re-file Slide (each)	☐ $2.00 (each)
Multiple Blocks/Time	☐ $40/hr. (how many are multiple blocks?
Multiple Slides/Time	☐ $40/hr. (how many are multiple slides?
Prep Cell Block (each)	☐ $10.00 (each)
PAP Stain (each)	☐ $5.00 (each)
PCR-Cut Only (each)	☐ $5.00 (each)
Picture of slides	☐ $20.00 (3 digital photos per case)
Boxes	☐ $40.00 (each)
Venipuncture (each)	☐ $12.00 (small)
Slide Boxes	☐ $18.00 (large)
PACS Radiology Imaging fee:	☐ $20.00 (per patient exam/image)

Location(s) where research will occur (select all that apply):

- ☐ Ambulatory Care Center (ACC)
- ☐ CHI Doris Ison Health Center
- ☐ CHI Martin Luther King Jr (Clinica Campesina)
- ☐ Communicable Disease Control / infectious Control
- ☐ Community Health of South Dade
- ☐ Corrections Health services
- ☐ Critical Care Hospital Center
- ☐ Dr. Rafael A Penalver clinic
- ☐ Jefferson Reaves Sr. , Health Center
- ☐ Medical - Surgical Hospital Center (Transplant, Main OR, Perioperative)
- ☐ Behavioral Hospital Center
- ☐ Miami Hope Center
- ☐ North Dade Health Center
- ☐ Ortho-Rehab-Neuro Hospital
- ☐ Perioperative Services (Perianesthesia, Anesthesiology, Recovery, Main OR, AMSU, PARU, etc)
- ☐ Prevention, Education Treatment Center (PET)

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☐ Downtown Medical Center ☐ Emergency Care Clinic ☐ Holtz Children's Hospital Center ☐ Jackson Perdue Medical Center ☐ Jackson North Community Mental Health Center (Locktown). ☐ Jackson N. Med. Center ☐ Jackson Pediatric Center (PPEC) ☐ Jackson South Comm. Hosp. ☐ JHS Biscayne Imaging Center	☐ Radiology ☐ Rehab Hospital Center ☐ Rosie Lee Wesley Health Center ☐ South Dade Homeless Assistance Center ☐ Highland Outpatient Clinic Center

Is there adequate staffing to conduct the study?	☐YES ☐NO
Is bed-space available?	☐YES ☐NO ☐N/A

Describe your in-servicing/ training plans for all affected areas: Copy of signed in-servicing log **MUST** be provided to JHS after conduct of in-service.	
Delegated Person to conduct In-Service (if not PI)	
Expected Inpatient Length of Stay (LOS)	
Are any of the following additional resources needed for the study: If yes, please attach detailed description of additional resources needed.	☐ Additional Nursing Time (beyond standard-of-care) ☐ Office of Research Billing personnel time (collecting billing information) ☐ Database query from Office of Research Staff ☐ Additional Tech Time (ECG, PCT, Ortho, SPD, Respiratory, EEG, etc.) ☐ Special Equipment (computers, monitors, software, etc.) ☐ Modifications to Existing Space (if known) ☐ Supplies (kits, disposables, other, etc.) ☐ N/A
Does the routine care of these patients require JHS Pathology?	☐YES ☐NO

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Please indicate where the labs / specimen services will be performed: IF LABS sent out what labs & Where? ☐ N/A (no lab services required)	Storage ☐ JHS ☐ Central ☐ Other ____________ Processing ☐ JHS ☐ Central ☐ Other ____________ Shipping ☐ JHS ☐ Central ☐ Other ____________
If storage of specimens is required, please indicate how long specimens will maximally be stored?	
If storage of specimens is required, please indicate how often specimens will be collected from storage?	
Will the JHS Research Pharmacy services be required to perform any tasks associated with this study?	☐YES ☐NO $1600 - $2500
Please indicate which of the following will be performed at JHS	☐ Dispensing and/or Preparation ☐ Inpatient ☐ Outpatient ☐ Oral Inpatient per dose $35 ☐ Oral Outpatient dispense per medication $35 ☐ Special Prep (gene therapy, tracers) $150 ☐ Narcotic Dispensing $50 ☐ Preparation of infusion, per dose $60 ☐ Preparation of injections (non-manipulation $35 ☐ Preparation of vaccines (complicated) $100 ☐ Both Outpatient and Inpatient ☐ Randomization ☐ **Blinded envelopes/sequential enrollment** ☐ **IVRS database or automated** ☐ Blinding ☐ Dosing/Dose Calculation ☐ Drug Storage/temp ____________ (e.g. freezer -20/-70, room temp) ☐ **Delivery** ☐ Retrieved by RN ☐ Hand delivered ☐ Other (decontamination, order development, etc.) ☐ Annual Maintenance Fee(after 1 year of storage)

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PAYMENTS MUST BE MADE BY CHECK PAYABLE TO JACKSON HEALTH SYSTEM and sent to: JHS Office of Research

Jackson Medical Towers
1500 NW 12th Ave, Suite 803
Miami, Florida 33136

ENROLLMENT CHECKLIST:

Enrollment in your study cannot begin until all of the processes below are complete:

☐ **Clinical Research Review Committee**: The study must be approved by the JHS Review Committee.

☐ **Sponsor Contract (if applicable)**: The JHS Site Agreement or other sponsor contract needs to be signed by sponsor, JHS, PI, and UM (if applicable).

☐ **Budget Approval**: The budget needs to be approved and signed by PI.

☐ **IRB Approval**: The study must be approved by IRB, WIRB, or other private IRB and the JHS Office of Research must receive a copy of the approval letter.

☐ **JHS Staff Approval:** Staff on affected floors must be in-serviced on the research study and a copy of the signed in-service register or log must be submitted to our office.

I understand that I cannot begin enrollment to the study until the above processes are completed, *and all consents are sent on all my studies actively occurring at JHS*. When my study is approved I will inform the JHS Office of Research of any patient enrollment within 24 hrs by faxing 305-585-6144 or 305-355-2417 (for large files) the ICF (which includes patient signature, MR#, Date of Consent-) and I will provide monthly patient enrollment status using **Appendix "A"** (attached to this application form).

____

(Principal Investigator –Please PRINT and SIGN) (Date)

Submissions must be made at least two weeks in advance of JHS CRRC Meeting.

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Appendix "A" – PATIENT ENROLLMENT AND RETROSPECTIVE CHART REVIEW MONTHLY REPORT

All patient consents, re-consents based on amendments, and withdrawals must be faxed MONTHLY to the JHS Office of Research (305) 585-6144.

Patient Enrollment Report for the month of: _________________ **Year:** ________________

Protocol # ______________________________ **Study Name:** _____________________________

I _________________________________, hereby certify under oath that the information provided below is correct and complete. (**Principal Investigator Complete Name –PRINT**-)

A. TOTAL # of Patients Enrolled in Study: _____
B. # of patients enrolled this month: _____
C. Total # of Patients re-consented based on amendments: _____
D. Total # of Patients withdrawn from study: _____

PI SIGNATURE: _________________________________ **DATE:** ___________________

Enrollees or Retrospective Charts Reviewed for Current Month

	Name and Last Name	MR # (JHS)	Date of Consent	Observations/ Changes
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				