INFORMATION SHEET FOR UM INVESTIGATORS
JACKSON HEALTH SYSTEM (JHS) CLINICAL TRIAL'S OFFICE (CTO) AND
CLINICAL RESEARCH REVIEW COMMIMITTEE (CRRC) APPROVAL PROCESS

V3. October 6th, 2021
Developed by the Office of the Executive Dean for Research

Approval from the JHS-CRRC must be obtained for studies with any research activities (including recruitment of subjects, facilities use, or subject interventions such as tests, measurements, drug administration, surgery, or consenting subjects) occurring at a JHS facility, or for studies that involve accessing JHS patient information prior to the use of any JHS resources.

In order to avoid delays on approvals, complete the JHS CTO Application, required JHS forms (see section JHS CTO), and work with the JHS CTO and JHS IT (if applicable) while waiting for IRB approval.

If assistance is needed to complete the JHS application or any JHS forms, contact JHS CTO inbox: JHS-CTO-Submissions@jhsmiami.org

ADD JHS AS A SITE AT THE TIME OF A NEW SUBMISSION OR VIA A STUDY MODIFICATION	
HSRO (eProst)	eProst Application: In the section titled "Study will take place at," place a checkmark for Jackson Health System
HSRO (eProst)	eProst Application, In the section titled "Will any study-related activities be performed or possibly performed at the JHS site?" Select **yes and submit (applicable) study submission forms for review by JHS Clinical Trials Office**. • For studies in which clinical procedures or interventions are planned at JHS, incorporate the JHS footer or use the HRP502a3-Biomedical Studies UM-JHS combined form. A template of the ICF can befound in the HRSO website https://hsro.uresearch.miami.edu/researchers/forms-and-templates/templates/index.html. • For studies in which the only activity that occurs at JHS is recruitment of research participants (Recruitment only studies) there is no need to Incorporate the JHS footer or use the HRP502a3-Biomedical Studies UM-JHS combined form. A template of the UM ICF can be found in the HRSO website A JHS Authorization for Release of Confidential Medical Records is used if there is a need to obtain Medical Records from JHS.
JHS CTO	Submit (applicable) study submission forms to JHS Clinical Trials Office through UM IRB. Prepare: • CTO Application: https://jhsmiami.org/jhsofficeresearch/. • Upon request from JHS CTO: Study Calendar [a]: https://storage.googleapis.com/jackson-library/clinical-trials/StudyCalendar.xls • Workflow delineating JHS/UM duties and responsibilities of areas/departments (i.e if JHS nurse involvement specific research activities to be performed by the nurse or other personnel. •

	• Data collection sheet (JHS will request if not available in the IRB submission) • Case Report Form (if applicable) • Pathology Bypass letter (if applicable when tissue will be taken directly by the study team without involvement of pathology department). Contact at JHS is JHS CTO inbox: JHS-CTO-Submissions@jhsmiami.org
Data Exchange Form (DEF)	A DEF must be submitted for studies with any research activities (including recruitment of subjects, facilities use, or subject interventions such as tests, measurements, drug administration, surgery, or consenting subjects) occurring at a JHS facility, or for studies that involve accessing JHS patient information prior to the use of any JHS resources. Submit the following to the Executive Dean of Research Office at **medresearch@miami.edu**: • The PHT-UM Data exchange form (DEF) indicating the purpose usage of the data and signed by the principal investigator (UM faculty) [b] • The list of data variables or CRF's • A brief overview (about half a page and no more than 1 page) of the study aims, listing the activities that will be occurring at JHS
If CTRS involvement	CTRS will work with JHS and PIs to onboard clinical research staff to perform clinical research activities at JHS. For CTRS related questions: crcreservations@med.miami.edu
UM/ORA (if UM/JHS externally funded studies)	• For UM/JHS Externally funded studies (i.e. federal, industry), submit a copy of the CTO Application and Study Calendar to the UM Office of Research Administration (ORA). ora@med.miami.edu; (305) 284-4327 ORA will review the CTO Application and study Calendar and will work with JHS on preparing a work order. ORA engages JHS to develop formal Medicare coverage analysis (Billing plan, Study calendar)
UM/Business Services (if UM funded)	• For UM funded study (i.e. internal awards) or unfunded, ORA review is not necessary JHS submits Service Agreement to UM Business Services
JHS CTO	If access is needed to other relevant JHS web platforms (examples below), and toreceive JHS research communications contact: JHS-CTO-Research-Tickets JHS-CTO-Research-Tickets@jhsmiami.org 1. JHS email account and access to JHS portal 2. Cerner Access (Cerner application form) 3. Global protect vpn 4. Data Requests
JHS CTO (billing)	• All JHS setup fees (except for studies from residents and fellows) will be done via work order/service agreement. • For Device studies: Determination of Local Fiscal Intermediary – First Coast Service options (For Medicare approval) will be requested as per local Medicare Contractor guidelines.

JHS Approval	• JHS grants letter of approval when the following conditions have been met: 1. IRB approval 2. CRRC review and approval 3. Fully executed agreements (Work Orders, Service Agreements and Data Exchange Form) • JHS approval letter is uploaded to the IRB eProst system
JHS CTO Upon approval	• In-service and protocol trainings (upon completion of all the above steps and CCRC approval) • Study Team Training: Review of JHS Research Policies and Procedures, including but not limited to ICF submission process, Research Encounter Tickets (RET) etc.
JHS Research IT	A JHS approval letter is required to request data from IT. Contact JHS CTO after JHS approval: • For any Research IT needs: screening, EMR access, order sets) • Share Point folder (if needed) • Feasibility request to IT if applicable (i.e Sponsor's questionnaire's, data elements)

Research findings	PI initiated studies non externally funded, need to notify JHS of publications through JHS-PUB-Notifications jhs-pub-notifications@jhsmiami.org

a. JHS Study Calendar. The purpose of the study calendar is to outline study related versus routine clinical services within a study protocol. This document serves as the Medicare Coverage Analysis for JHS. Study calendar is required for:
   - Billable studies (interventions, procedures, and services)
   - Recruitment only studies (JHS is only used for recruitment purposes; include recruitment only and leave rest blank)

   Study Calendar is not required for chart reviews, non-billable activities (i.e. questionnaires)

   Contacts at JHS CTO
   JHS-CTO-Submissions@jhsmiami.org
   Dr. Katuska Barbery, JHS Director of Clinical Research: Katuska.Barbery@jhsmiami.org
   Dr. Priscila Sayuri Wagatsuma Lazaridis, JHS Sr. Financial Research and Grants Analyst: priscilachristianne@jhsmiami.org
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   Santana Caicedo, JHS Research Data Analyst: santana.caicedo@jhsmiami.org

b. Instructions to complete the DEF:

In the description section the instructions ask "the Recipient" to articulate the complete purpose and specifically intended usage of the Disclosing Party's Confidential Information and/or Data requested through the DEF. Below are a few examples of the language that can be used:

☆ Example if a UM only study: The Recipient and study team intend to submit manuscripts for publication and present findings associated with the research. Data will be deidentified and will not be shared with other investigators or institutions outside of UM.

- ☆ Example if a multisite study: The Recipient and study team intend to submit manuscripts for publication and present findings associated with the research. Deidentified (if data will have identifiers, LIST HERE WHICH ONES) will be shared with investigators on the study team, with institutions participating in the study (LIST WHICH INSTITUTIONS HERE), or with the study sponsor (LIST THE NAME OF THE SPONSOR HERE).
- ☆ If the intend to use the data is different than the above, please specify.