Network for Clinical Research Professionals (NCRP)

Program Director: JoNell Potter, PhD, RN
UPDATES

- Study Plan Folders
  - Second batch of English, Spanish, Creole language folders ordered.
  - Folder distribution is ongoing, upon request.

**MY STUDY PLAN FOLDER**
(as of 9/28/16)

<table>
<thead>
<tr>
<th>Language</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>English</td>
<td>1,211</td>
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<tr>
<td>Spanish</td>
<td>702</td>
</tr>
<tr>
<td>Creole</td>
<td>48</td>
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</tbody>
</table>
Next NCRP: Wednesday, December 7, 2016

Yolanda P. Davis, CCRP, Clinical Trial Disclosure Manager, Office of Research Compliance and Quality Assurance (RCQA)

New rule recently passed by HHS, effective January 18, 2017, that affects which clinical trials are registered and have results reported on clinicaltrials.gov.
NCRP-RSCP: Engaging Our Community Partners

Invited Speakers: Leonardo J. Tamariz, MD, Miami VA
Rosely De Los Santos, JHS Clinical Trials Office

Program Director: JoNell Potter, PhD, RN
Introduction

Leonardo Tamariz, MD

- Miami VA IRB Chairperson
- UM Associate Professor of Medicine
Navigating the Research Environment at the Miami VA

Leonardo Tamariz, MD, MPH
Miami VA IRB Chairperson
University of Miami
Navigating the Research Environment at the Miami VA

Leonardo Tamariz, MD, MPH
Miami VA IRB Chairperson
University of Miami
Objectives

- Discuss research resources at the Miami VA.
- Discuss the different types of grants at the VA.
- Discuss the regulatory implications for approval of clinical studies at the Miami VA.
Veterans Health Administration (VHA)

- Largest U.S. integrated health care system
- 162 VA hospitals, 137 nursing homes, 43 domiciliaries, and > 850 clinics
- VA Information Resource Center (VIReC)
- Corporate Franchise Data Center
  - Local, VISN, and National data sets
Inpatient Data Flow

Data Flow from the VHA Medical Centers to the Austin Automation Center (AAC) to the Medical SAS Inpatient Datasets

- **VHA Medical Centers (local VISTA system)**
- **AAC**
- **Medical SAS Inpatient Datasets**
  - Acute Care: Main, Procedure, Bed Section, Surgery Datasets
  - Extended Care: Main, Procedure, Bed Section, Surgery Datasets
  - Observation Care: Main, Procedure, Bed Section Datasets
  - Non-VA Care: Main, Procedure, Bed Section, Surgery Datasets
Grants

- Biomedical (BLRD)
- Clinical (CSRD)
- Rehab (RR&D)
- Cooperative studies (CSP)
- Health services (HSRD)
Research funding (% increase per year)


VA (blue) and NIH (red)

- 2002: VA 4%, NIH 0%
- 2003: VA 16%, NIH 0%
- 2004: VA 12%, NIH 0%
- 2005: VA 8%, NIH 4%
- 2006: VA 4%, NIH 8%
- 2007: VA 12%, NIH 16%
- 2008: VA 8%, NIH 12%
- 2009: VA 4%, NIH 8%
- 2010: VA 16%, NIH 12%
IRB office

- Located in the second floor 2b100
- Administrator: Mitscher Gajardo
  <Mitscher.Gajardo@va.gov>
- Phone: 305-5757000 ext 4465
- IRB Chair: Leonardo Tamariz
  <ltamariz@med.miami.edu>
- Ext 4487
Research at the VA

- Who can be a PI at the VA
  - Anyone with a VA ID

- How can I be a research coordinator at the VA
  - Need a VA ID
  - Not a VA employee need a WOC ID
  - To get at VA ID talk to Ana Vals (Ana.Vals@va.gov)
To facilitate Research and Education activities conducted at the VA Health Care System.

The Veterans Affairs Medical Center of Miami, Florida established the South Florida Veterans Affairs Foundation for Research and Education, Inc. (SFVAFRE) in May of 1990. This non-profit foundation is dedicated to the continuous support of important research topics that facilitate VA research, education, and the enhancement of quality patient care. Clinical research is an integral and important focus of the Miami VA Medical Center. The research conducted by the SFVAFRE benefits the Department of Veterans Affairs patients and the general public.
Process

Pre-review

IRB chair and Administrator
Privacy officer
Information security
Scientific review

Review

IRB Chair
Full committee
R &D

Approval

85 Years of Discovery, Innovation, and Advancement
Regulatory differences between UM and the Miami VA

• We have a 2 step approval process
  o Institutional review board
  o Research and Development Committee
• Research compliance officer review of all studies
• Constantly audited by the government
• Credentialing platform
• Informed consent quality improvement project
• Paper submission
Rationale for the perception

- DOD regs
- FDA regs
- VA regs
SOUTH FLORIDA VA FOUNDATION FOR RESEARCH AND EDUCATION, INC.
Mission: To Facilitate Research and Education Activities Conducted at the MVAHS

FUNDING OPPORTUNITIES
- Acorda
- American Heart Association
- American Cancer Society
- American Asthma Fnd.
- Astellas
- Bristol-Myers Squibb
- Celgene
- Genentech
- GlaxoSmithKline
- Lilly & Lilly
- Merck
- Novartis
- OncoGenex
- Pfizer
- Regenesis Biomed, Inc.
- Roche
- Sanofi-Aventis
- Sucampo
- Takeda
- Watson Pharm.

GRANT PROCEDURES
- Grant due date:
- Scientific Review
- Budget Review

CAUTION SUBAWARDS?

To Do:
The List is long

MBASTER AGREEMENTS
- AstraZeneca
- Allegro Diagnostics
- Amgen
- Astellas
- Bristol-Myers Squibb
- Celgene
- Genentech
- GlaxoSmithKline
- Lilly & Lilly
- Merck
- Novartis
- OncoGenex
- Pfizer
- Regenesis Biomed, Inc.
- Roche
- Sanofi-Aventis
- Sucampo
- Takeda
- Watson Pharm.

CRADA PROCEDURES
- IRB - R&D
- CDA
- CRADA
- BUDGET
- Clinical Research Starts
- Reconciliations by:
  - IRB Administration Pharmaceutical Corp.
- Reviews by:
  - R&D CPA Firm
  - Board of Directors

www.sfvafr.org
www.research.va.gov
Introduction

Rosely de los Santos Perez, MD

- Director, JHS Office of Research

Manuel Fraga

- Director, JHS Office of Grants
Navigating Research at JHS

JHS Office of Research and Grants

Rosely De Los Santos, Director, Office of Research
Manuel Fraga, Director, Office of Grants
Why do we exist?

1. To ensure that the research conducted at JHS is operationally and financially feasible.
2. To safeguard JHS from potential liability resulting from the conduct of research.
3. To prevent potential double-billing of protocol related items/procedures/services.
4. To ensure proper billing and coding of protocol related items/procedures/services.

JHS Office of Research
Rosely De Los Santos
Meet the JHS Office of Research and Grants

Front end
• Clinical Trials Coordinator Auditor
• Clinical Trials Coverage Analyst
• Research Contracts Manager
• Director of Research
• Director of Grants
• Grant Writers

Back End
• Research Billing/Coding Analysts
• Compliance Auditor
• Clinical Research Coordinator
• Grant Coordinators
Early Engagement

Our office requests to be involved earlier in the research process at the pre-submission phase when a research proposal is being prepared.

1. Does the grant involve the recruitment of any patients currently followed at JHS?
2. Does the grant require assistance or involvement of any personnel who work for JHS at any level?
3. Will any portion of the care/activity, may it be routine or study related, involve or be carried out at JHS facilities?
4. Will any requirements of the grant directly or indirectly involve any JHS clinical/financial/registration system? (i.e. Cerner, Siemens, Medical Records, etc.)
Principle #1
Communication & Consensus on Mutual Interest

a. When any research endeavor involves JHS, the JHS Research Office and Grants Office should be notified during the planning phase before grant submission and initiation of the research project.

b. Mutual interest in the research question as a driver of new knowledge, improved services and development of new treatments will be the prerequisite to moving forward with the UM-JHS research collaboration.
**Principle #2:**

**Identification of Faculty/Staff Champions & Written Documentation**

a. JHS faculty and/or staff champions will be preemptively identified to partner with UM faculty in fostering the proposed UM-JHS research collaboration. These same identified professionals should also be listed on the IRB’s application.

b. Together, the UM and JHS collaborators will provide the JHS Research & Grants Office written support for the proposed research.
Principle #3: Collaborative Assessment of Resources & Agreement on Mutual Benefits

a. Mutual agreement to real-time ongoing exploration of potential synergisms and value added as a result of clinical and translational research programs to better serve our community will be the expectation before proceeding.

b. A preemptive list of resources needed to conduct the proposed research (facility, personnel, equipment, materials, clinical laboratory tests, imaging studies) will be provided to the JHS Research Office.

c. Mutual agreement needs to be documented by UM and JHS on designation of funding type for needed resources to conduct the proposed research.
Front end Process Flow

IRB Submission

IRB Review

IRB Approval issued

JHS Office of Research Submission

JHS CRRC Review

Correspondence with Study Team

Contract and Budget review & negotiation

Contract execution

JHS CRRC Approval issued

Front End Forms:
1. JHS Research Application form
2. JHS Study Calendar form

JHS Office of Research
Rosely De Los Santos
Back end Process Flow

- CRRC Approval and Creation of Research Provider Account
- In-service
- Protocol Related Visit
- Patient signs consent
- *ICF submitted within 24 hrs.
- Bill is released
- Bill scrub
- Bill hold created

Back End Forms:
1. Research Encounter Ticket
2. Monthly Enrollment Form
UM IRB Application Form

4. * Study will take place at:
   - [ ] Check all that apply
   - [ ] University of Miami
   - [x] Jackson Health Systems
   - [ ] Miami VA
   - [ ] JFK Hospital
   - [ ] Mt. Sinai Medical Center
   - [ ] Other

6. * Will any study-related activities be performed or possibly performed at a Jackson Health Systems (JHS) site?

   This includes recruitment of subjects, facilities use, retrospective analysis of charts/records, subject interventions, such as tests, measurements, drug administration, or surgery, consenting subjects, and tissue/specimen collection.

   [ ] Yes [ ] No

   If yes, approval from the JHS Clinical Research Review Committee (JHS CRRC) is required and the JHS CTO Application Form must be uploaded in the Supporting Documents section.

Supporting Documents

Attach supporting files, naming them as you want them to appear in the approval letter:

<table>
<thead>
<tr>
<th>Document</th>
<th>Category</th>
<th>Date Modified</th>
<th>Document History</th>
</tr>
</thead>
<tbody>
<tr>
<td>View Intubation Study Data Sheet v2.xlsx(0.01)</td>
<td>Data Collection Sheet</td>
<td>7/2/2015</td>
<td>History</td>
</tr>
<tr>
<td>View JHS APP.pdf(0.01)</td>
<td>JHS CTO Application Form</td>
<td>6/30/2015</td>
<td>History</td>
</tr>
</tbody>
</table>

Suggested attachments:

- Completed checklist of meeting Department of Energy requirements, if applicable
- Other study-related documents not attached on previous forms

JHS Office of Research
Rosely De Los Santos
JHS Research Application Form

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@jhsmed.org.

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

<table>
<thead>
<tr>
<th>STUDY INFORMATION:</th>
</tr>
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<tbody>
<tr>
<td>Study Full Title:</td>
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<tr>
<td>Study title:</td>
</tr>
<tr>
<td>(Short Name – 8 characters)</td>
</tr>
<tr>
<td>Principal Investigator (PI)</td>
</tr>
<tr>
<td>PI Department / Division / Specialty</td>
</tr>
<tr>
<td>PI Affiliation</td>
</tr>
<tr>
<td>PI Address</td>
</tr>
<tr>
<td>City, State, Zip</td>
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<tr>
<td>PI Telephone</td>
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<tr>
<td>PI Email</td>
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<tr>
<td>PI Pager</td>
</tr>
<tr>
<td>Study Coordinator (SC)</td>
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<tr>
<td>SC Telephone</td>
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<tr>
<td>SC Email</td>
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<tr>
<td>Finance Contact</td>
</tr>
<tr>
<td>Finance Contact Telephone</td>
</tr>
<tr>
<td>Other Investigators (List Co-PI and all sub investigators here):</td>
</tr>
</tbody>
</table>

JHS Office of Research
Rosely De Los Santos
# Study Calendar

<table>
<thead>
<tr>
<th>Study Title:</th>
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<tbody>
<tr>
<td>Sponsor:</td>
<td></td>
</tr>
<tr>
<td>EHF/SMC:</td>
<td></td>
</tr>
<tr>
<td>Describe Study Type (device or clinical research, drug, etc.)</td>
<td>If Device number</td>
</tr>
<tr>
<td>Department:</td>
<td></td>
</tr>
<tr>
<td>Study Coordinator:</td>
<td></td>
</tr>
<tr>
<td>Contact:</td>
<td></td>
</tr>
<tr>
<td>Date Completed:</td>
<td></td>
</tr>
<tr>
<td>Completed By:</td>
<td></td>
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</tbody>
</table>

**Legend:**

- Please indicate if each procedure is study related by inserting "Sponsor" (not billable to insurance).
- Please indicate if each procedure is standard of care by inserting Medicare (billable to insurance).
- If procedure is taking place at a JHS facility, please DSWU/CS and highlight.

<table>
<thead>
<tr>
<th>Patient Care Procedure</th>
<th>GFI Code</th>
<th>Research</th>
<th>Baseline</th>
<th>Visit 1</th>
<th>Visit 2</th>
<th>Visit 3</th>
<th>Visit 4</th>
<th>Visit 5</th>
<th>Visit 6</th>
<th>Visit 7</th>
<th>Visit 8</th>
<th>Visit 9</th>
<th>Visit 10</th>
<th>Note</th>
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<tbody>
<tr>
<td>Referred to JHS Research Office</td>
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</tr>
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</table>

**Principal Investigator's Attestation:**

These charges are delineated as those which are standard of care and billable to insurance, or study only and reimbursed paid for by the sponsor grant award if applicable.

JHS Office of Research

Rosely De Los Santos
PRE-CRRC Review

- Detailed review of documentation submitted
- Medicare Coverage Analysis begins:
  1. Is the study a qualifying clinical trial?
  2. Reconciliation of JHS Study Calendar with other regulatory documents
  3. Determination of routine versus non-routine items/services/procedures
  4. Identification of national and internal guidance to support routine care
- Correspondence and discussions with Study Team
- Receipt of contract and budget
CRRC Review

- Key Disciplines
- Studies are presented by coverage analyst
- Any operational and financial impact discussed
- Studies may be approved, deferred or rejected
POST CRRC Review

• CRRC member concerns are communicated to study team.
• Additional collaboration may be warranted from other JHS disciplines
• *Receipt of contract and budget
• Contract review
• Budget review and creation of JHS Budget
The JHS Clinical Research Review Committee (CRRC) reviewed the study referenced below on May 13, 2015. This humanitarian use device (HUD)/data collection study is now approved and may commence at Jackson Health System.

IRB Protocol Number: [blank]
Principal Investigator: [blank]
Department: [blank]
Study Title: [blank]
Funding: PI-Initiated
Type of Study: Registry/Device – HDE # H100004
ClinicalTrials.gov Identifier: Not Available

If this study is registered with ClinicalTrials.gov, kindly provide us with the National Clinical Trials (NCT) Identifier.

Kindly apprise the Director and/or Manager of the relevant unit on the conduct of the study prior to commencement at the facility.

This study must be conducted in accordance with the JHS approval. The Informed Consent must be sent to the JHS Office of Research by next business day after signature by the patient, per JHS POLICY. The Patient Enrollment Monthly Report must be submitted to the JHS Office of Research in a timely manner (see template attached).

Thank you for working with the JHS Office of Research.

JHS Office of Research
Rosely De Los Santos
Thank you!
Please contact us

JHS Office of Research & Grants
Jackson Medical Towers,
Suite 803
1500 N.W. 12th Avenue
Miami, FL 33136-1096
P: 305-585-7226 & 305-355-1216
F: 305-585-6144
http://www.jacksonhealth.org/clinical.asp
Thank you for your participation in today’s seminar!

Today’s presentations will be uploaded to the Miami CTSI website under the archived seminar section.

If you have any questions, about this or upcoming seminars, please contact:

Marisabel Davalos, 305-243-6978