SOP: RECRUITMENT AND ADVERTISING MATERIALS IN USF HEALTH CLINIC WAITING AREAS

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Learning Objectives

- Recognize why this SOP has been developed and how it fits into the "bigger picture"
- Learn about this SOP and how to apply this process in daily practice
- Identify responsibilities of the study staff and the OCR in carrying out this SOP

SOP Development

- ICH defines Standard Operating Procedures (SOPs) as "detailed, written instructions to achieve uniformity of the performance of a specific function" (ICH GCP 1.55)

Why SOPs Are Important

- Assure process consistency
- Provide a set of guidelines by which the research should be governed for that site
- Assure that the research at the site is carried out according to all federal regulations, ICH GCP requirements, and institutional policies
- Supports the protection of human research participants

SOPs at USF

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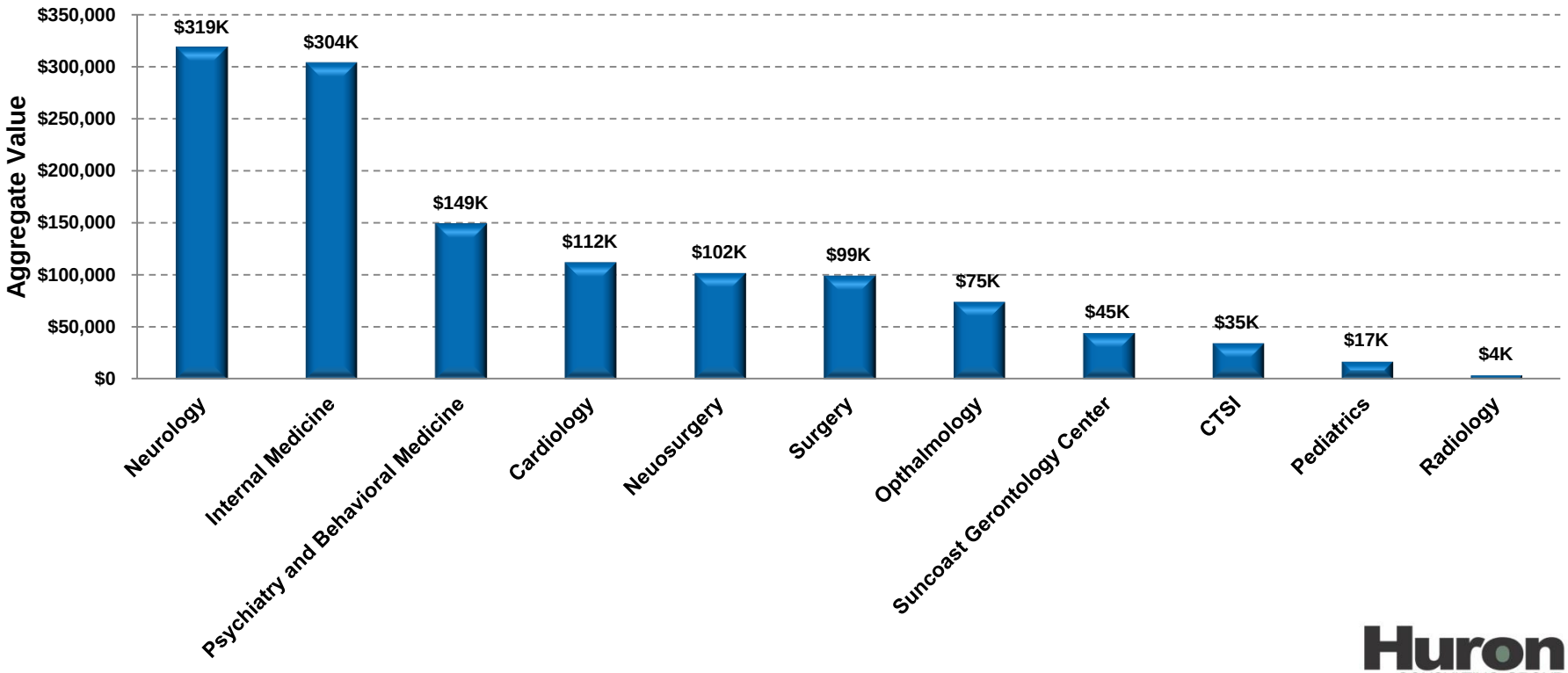
Closed Clinical Trial Data

Impact of One Additional Patient

- USF would earn $1.26 million if one additional patient was enrolled on each study closed during FY2009.
  - Indirect (at 27%): $340,000
  - Direct: $920,000

Revenue Potential by Department From One Additional Patient Per Study



Huron CONSULTING GROUP

A new opportunity to advertise and recruit for your studies…..

- Rotating brochure display carousels will be placed in several USF Health clinic patient waiting areas effective January 2012
  - ~3 ½ ft by 2 ft
- Carousels can be found at:
  - Morsani Center for Advanced Healthcare
  - South Tampa Center for Advanced Healthcare
  - Byrd Alzheimer's Institute
  - Children's Medical Services
- The Office of Clinical Research (OCR) will be responsible for the purchase, set up, and maintenance

View 1


Are You Interested in Clinical Trials?
Advancing the Science of Healthcare
Display provided by the USF Health Office of Clinical Research. To place materials here, please contact the Office of Clinical Research at OCR@health.usf.edu.

View 2


USF HEALTH
Now Enrolling at USF Health
Information on New Clinical Trials
Display provided by the USF Health Office of Clinical Research. To place materials here, please contact the Office of Clinical Research at OCR@health.usf.edu.

What can be placed on the carousels?

- Only **current, IRB approved** advertising materials will be permitted
- The IRB approval must include the method/location where the recruitment material will be used
- A generic statement in the IRB application such as "recruitment material will be placed in the USF Health clinic waiting areas" is acceptable for USF relied upon IRBs

How can I place approved materials on display?

- Interested study coordinators need to sign an attestation that they have read *USF HRPP Policy No. 708* and this SOP and agree to its terms
- A complete recruitment materials submission packet must be submitted including:
  - Recruitment Materials Cover Sheet
  - Attestation Statement
  - Hard copies of IRB approved recruitment material to be placed in the carousels
- The coordinator can meet with OCR staff to provide the complete recruitment materials submission packet

OR

- The coordinator may send a complete recruitment materials submission packet via campus mail to OCR at MDC28, attention Recruitment

RECRUITMENT AND ADVERTISING MATERIALS FOR HUMAN SUBJECTS IN USF HEALTH CLINIC WAITING AREAS

RECRUITMENT MATERIALS COVER SHEET

Date: _____

Submitter Contact Information (You may staple a current business card in the area below)

Name: _____

Email Address: _____

Telephone Number: _____

Study Information

PI Name: _____

Sponsor: _____

Protocol #: _____

IRB #: _____

IRB Approval Date: _____

Recruitment Material

Description of Recruitment Materials included in submission (Please list the name of the document(s) exactly as submitted and approved by IRB including date and version number as applicable. Typically this will be listed on the IRB approval letter)

_____
_____
_____
_____
_____

Submit the complete recruitment materials submission packet via campus mail to USF Health OCR MDC28, attention Recruitment.

Recruitment Materials Cover Sheet

Attestation Statement

USF HEALTH

RECRUITMENT AND ADVERTISING MATERIALS FOR HUMAN SUBJECTS IN USF HEALTH CLINIC WAITING AREAS

Attestation Statement

Please read this SOP and USF HRPP Policy No. 708 carefully to ensure that you understand them before signing this document.

By my signature below, I attest that I have reviewed and read the contents of this SOP and USF HRPP Policy No. 708 both of which outline my responsibilities as a member of the research team who wishes to display IRB approved printed clinical research materials in the brochure carousels located in the USF Health clinic waiting areas. I acknowledge, understand, accept and agree to comply with the information contained in the SOP provided to me.

I understand that the SOP referenced is available in hard copy form in the Morsani Clinical Research Center and in electronic form online at the Office of Clinical Research (OCR) website at http://health.usf.edu/research/ocr/index.htm for ongoing reference as needed. USF HRPP policies are found on the USF Office of Research & Innovation website at http://www3.research.usf.edu/dric/hrpp/policy-procedure.asp. If I have questions at any time regarding this SOP it is my responsibility to consult with my immediate supervisor and/or the OCR.

Employee Printed Name and Title: _____

Employee Signature: _____

Date: _____

For OCR Use Only:

Received by: _____ Date: _____

Who do I contact?

- Research staff interested in posting recruitment materials in the USF Health clinic waiting areas should contact:

- Marlo Crawford, Research Nurse, via email at mcrawfor@health.usf.edu or phone at 813-396-9179

OR

- Monique Green, Regulatory Coordinator, at tgreen2@health.usf.edu or 813-974-5489

Responsibilities of study staff

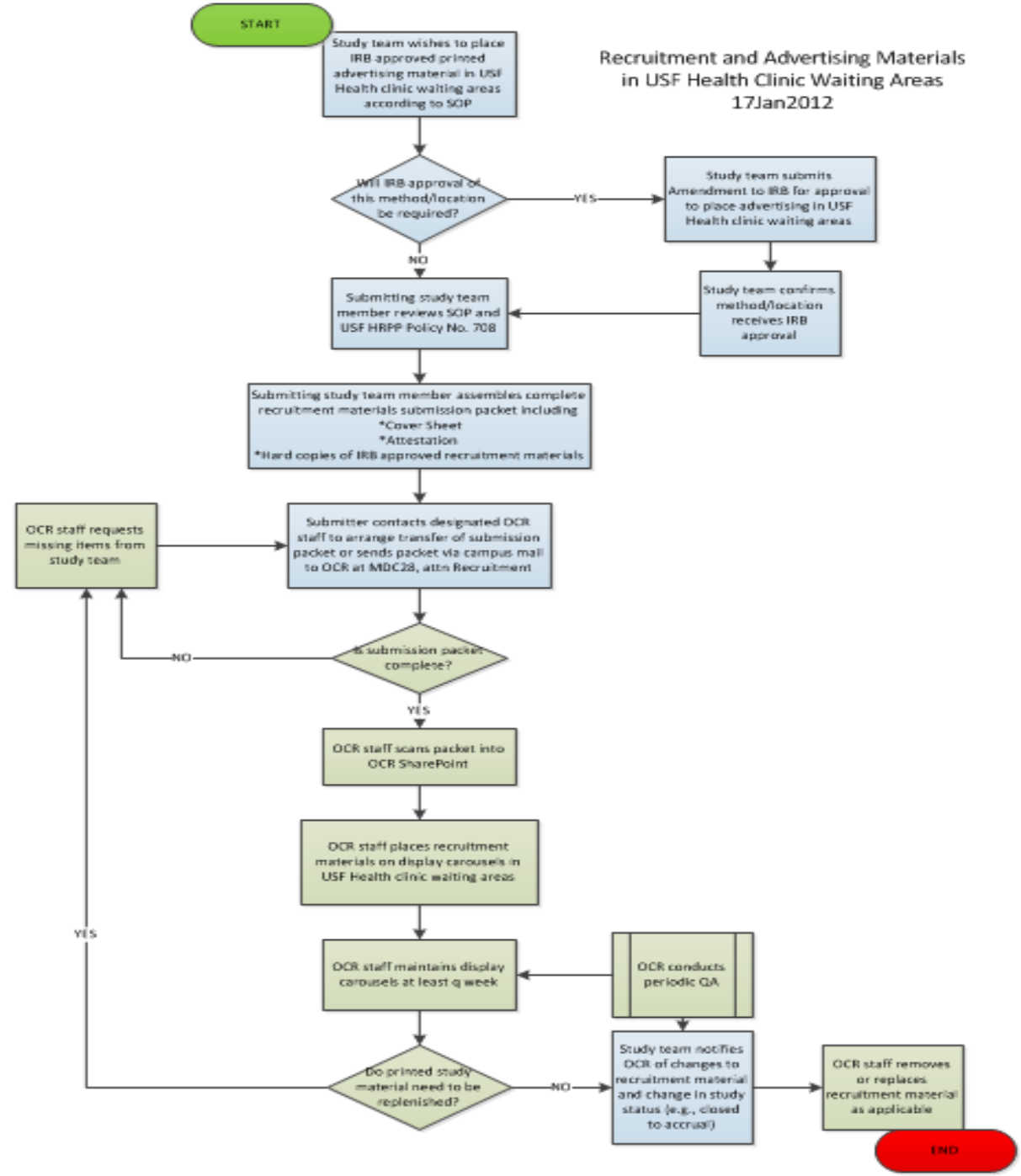
- Confirm current IRB approval of the method/location for recruitment materials
- Submit complete recruitment materials submission packet to OCR
- Provide OCR staff with additional hard copy recruitment materials when necessary
- Notify the IRB and OCR immediately of any changes in recruitment and advertising materials and/or change in study status (e.g., closed to accrual)

Responsibilities of OCR staff

- Scan a copy of the recruitment materials submission packet and store them in the OCR SharePoint
- Place and manage all recruitment materials on displays on a regular basis, at a minimum of once per week
- Notify the research coordinator via email or phone if recruitment materials need to be replenished

Responsibilities of OCR staff

- Compare the recruitment materials in the carousels to the SharePoint inventory list on a weekly basis
  - Any recruitment materials discovered on the carousels that is not on the inventory list will be removed
  - OCR staff will contact the person listed on the material that has been removed to initiate the process
- Conduct periodic quality assurance checks to confirm continuous IRB approval for the recruitment material



Process flow

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For more information….

- Please refer to:
  - OCR SOP on **Recruitment and Advertising Materials for Human Subjects in USF Health Clinic Waiting Areas**
  - Recruitment materials submission packet
    - » Both available on the OCR website at http://health.usf.edu/research/ocr/index.htm
  - HRPP Policy No. 708 – **Recruitment and Advertising in Human Subjects Research**
    - » Found at http://www3.research.usf.edu/dric/hrpp/irb_policies/Policy%20708%20Recruitment%20and%20Advertising%20in%20Human%20Subjects%20Research.pdf

Next Steps

- Gather submission packets
- Disseminate recruitment material to brochure carousels
- Pull SharePoint inventory list to use as a weekly "menu" of enrolling studies to be given to faculty and residents in clinic

Questions, Concerns, Comments?