USF Health, Office of Clinical Research Processes and Procedures

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USF HEALTH

Outline

- USF Health OCR Core Functions
- Review the Process and Where to Get Information
- USF Clinical Research Center

- **Where is USF Health, Office of Clinical Research?**

Criterion for an OCR Success

- **Strong Research Administration**
  - Contracting and budgeting experienced staff
  - Sufficient office space
  - Rapid process- turn around time

- **Training Programs**
  - Training at all levels- Investigator to Coordinators to Departmental Administrators

- **Support Services**
  - Research pharmacy, dedicated research space, centralized coordinator and regulatory support

Core Competency Domains

- Scientific Concept and Study Design
- Drug Development and Regulation
- Ethical and Safety Concerns
- Fundamentals of Site Management
- Data Management and Informatics
- Fundamentals of Clinical Monitoring
- Communication and Team Work
- Good Clinical Practices

Moving From Compliance to Competency: A Harmonized Core Competency Framework for the Clinical Research Professional
By Stephen A. Sonstein, et al- Joint Task Force on Clinical Trial Conduct

Pre-Award Contracting Metrics

OCR Metrics FY 2014

Contracting Volume

	FY 13	FY14	
New Contracts Received	112	131	**FY 13 to FY14 14.5% increase in contracts received; 37% increase in amendments; 26% increase in disclosure agreements 37% decrease in contracts terminated.**
New Contracts Executed	118	105	
Contracts Terminated	17	14	
Amendments Received	133	90	
Disclosure Agreements	125	132	

Studies	FY 2013		FY 2014		
	n	%	n	%	
USF Open Studies (IRB Approved and Not IRB Closed)					**41% increase in open studies from FY2013 to FY 2014**
Total Open in FAST	**165**	-	**232**		
TGH Component	**34**	**21**	**51**	**22**	
Facility Only—No Use of Coordinators, Services, Etc.	8	-	10	-	
Coordinated by TGH	26	-	41	-	

OCR Key Features

- Centralized contracting/budgeting and post-award functions
- Some optional operational services offered as “fee for service”
- Departments and divisions pay expenses on studies
- Departments hire their own study coordinators who operate independently from OCR oversight and control
- Essential study documentation from paper file system to electronic database (Sharepoint) with remote access for study teams
- Partners with a major CRO (Quintiles)
- An intake tracking system for reporting clinical trial metrics

OCR
Business Operations Team (Pre award)

- Rita Tamcsu, Project Liaison
- Margot Reynolds, Administrative Specialist
- Cheryl Lesko, Contract Administrator
- Susan Potter, Senior Project Liaison

Business Operations Primary Functions

- CDA Facilitation
- Budget and Contract Negotiation
- Review ICF for Compensation/Subject Injury Before Sponsor Review
- Provide Internal Form Budget Figures
- Issue Approval to Enroll
- Establish Study in ClinCard and Issue ClinCards to Study Team
- Establish Project Accounts in FAST
- Process Contract Amendments

Initial Study Documents Needed for Negotiations and IRB Letter to Proceed

- Protocol
- Sponsor's Draft ICF
- Contract
- Budget
- Online New Study Questionnaire
  - Located on OCR Website under "Resources"

USF HEALTH

Morsani College of Medicine › Office of Research

Office of Clinical Research

Home | Patients | Resources | Research Centers | Education & Training | ClinicalTrials | Helpful Links

Industry-Sponsored Clinical Trials

USF Health | USF | Search

News | Education | Research | Patient Care

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Office of Clinical Research

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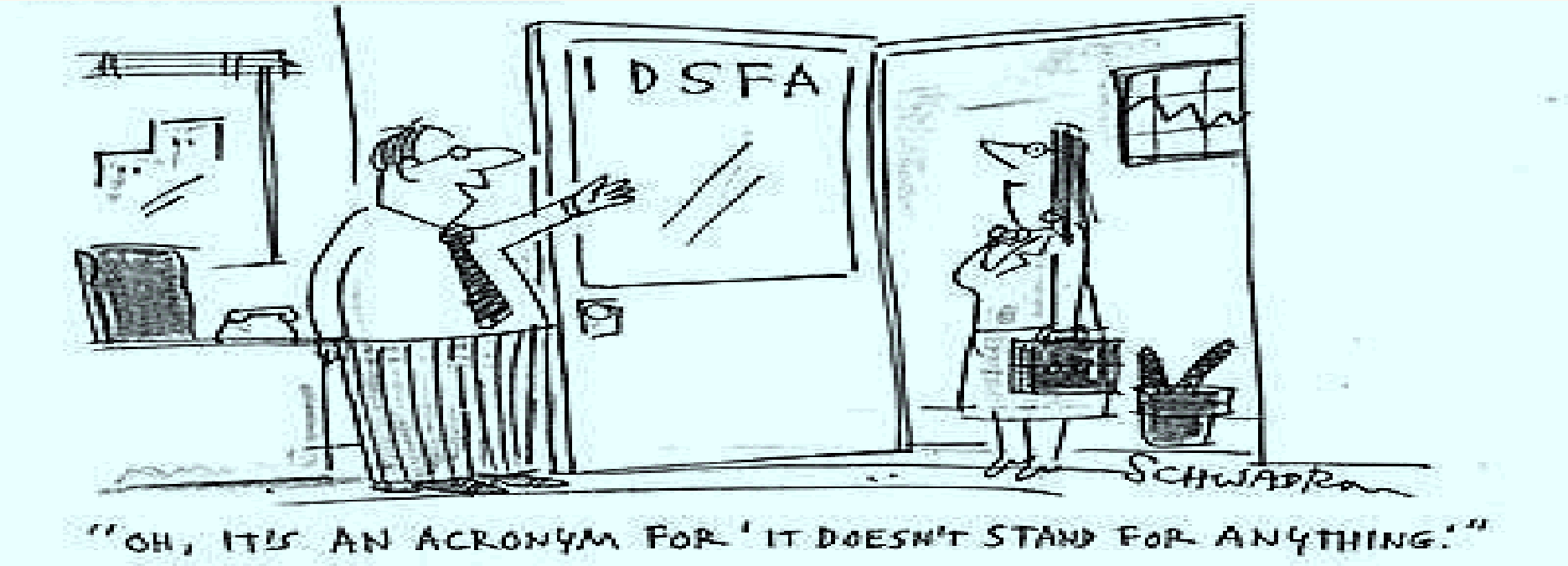
he mission of the Office of Clinical Research (OCR) is to provide faculty with resources, information and xpertise in clinical research to advance knowledge related to human disease and healthcare.

ClinCard System Overview

- Open to enrollment study - entered into ClinCard
- E-mail notification to the study coordinators
- Using Clincard required consent language in ICF
- OCRWebsite →Resources → Forms →IRB Forms → Required Consent Excerpts
- Did you know…
  - You can deliver automated appointment reminders and financial alerts via email and/or text message to patients that use ClinCard!

What is OT that is too much used in Clinical Research??



- "Ask the CTA to pull out the TMF", "Tell the IC that it is impossible for me to check NSQ and all these CRFs today"
- SAE - Some Antagonistic Episodes
- IVRS - IntraVenous Recording Software
- GBR- Guided Bone Regeneration
- TMF - Three Messy Folders
- IP – Intellectual Property
- SDV- Standard Deviation Variation

OCR Post Award Process Flow

Team:

- Caroline Holt, Manager Fiscal & Business Administration
- Kim Bare, Fiscal and Business Analyst
- Zeenat Monteiro, Fiscal and Business Analyst
- Baerbel Dagon, Fiscal/Business Specialist
- Margot Reynolds, Administrative Specialist

Invoicing/New Project Notification/Payment Posting

- Invoice sponsors/CROs for all invoiceable study specific items
- Email New Project Notification to:
  - PI
  - Coordinator
  - Department
- Post payments to projects

Expenses

- ClinCard:
  - Monthly and load fees
  - Subject reimbursements
- Fees for OCR services:
  - OCR's portion of study startup fee
  - Morsani Nursing Services
  - Study Coordination
  - Research Support Services
  - IRB Submissions
  - Morsani Space Costs
  - Overhead

Monthly Reporting and Budget Adjustments

- Financial Report
- Budget Adjustments

Closeouts

- Account Reconciliation
- Closeout Summary to sites/departments

Study Team Responsibilities

- Ensure that study specific items are included in the contract budget prior to submitting to ocrfm@health.usf.edu for invoicing
  - Examples:
    - IRB fees
    - Pharmacy fees
    - Unscheduled Visit details/completed CRFs
  - CTMS:
    - Real Time
    - Patient Status Updates
    - Screen Fails

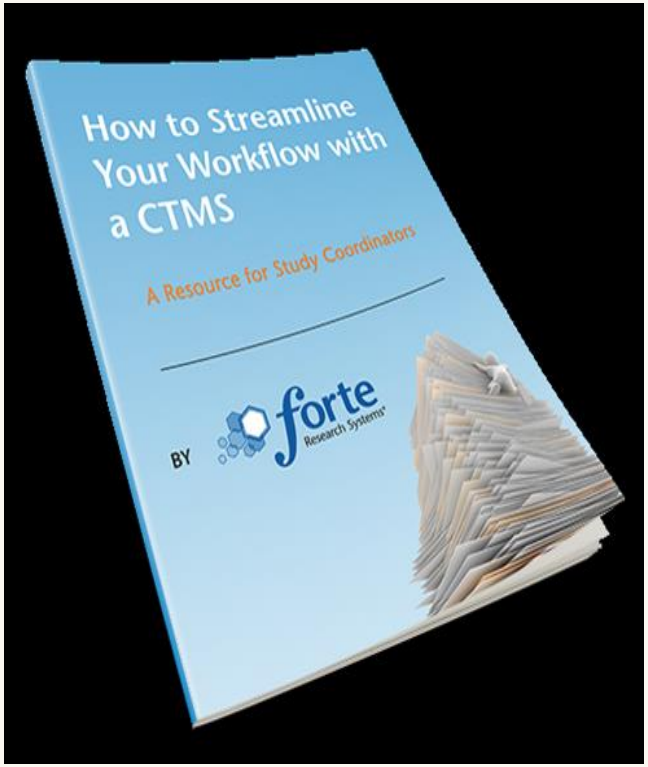
Study Team Responsibilities

- Closeouts:
  - Notify department administrator and ocrfm@health.usf.edu when study is about to close
  - CRF updates
  - Submit all final requests for invoicing to ocrfm@health.usf.edu

Clinical Trial Management System

- Web-enabled clinical trial management system for research professionals, coordinators, and physicians to closely monitor all phases of their clinical trials

- Single, centralized database in which, any number of patients and clinical trials can be tracked.



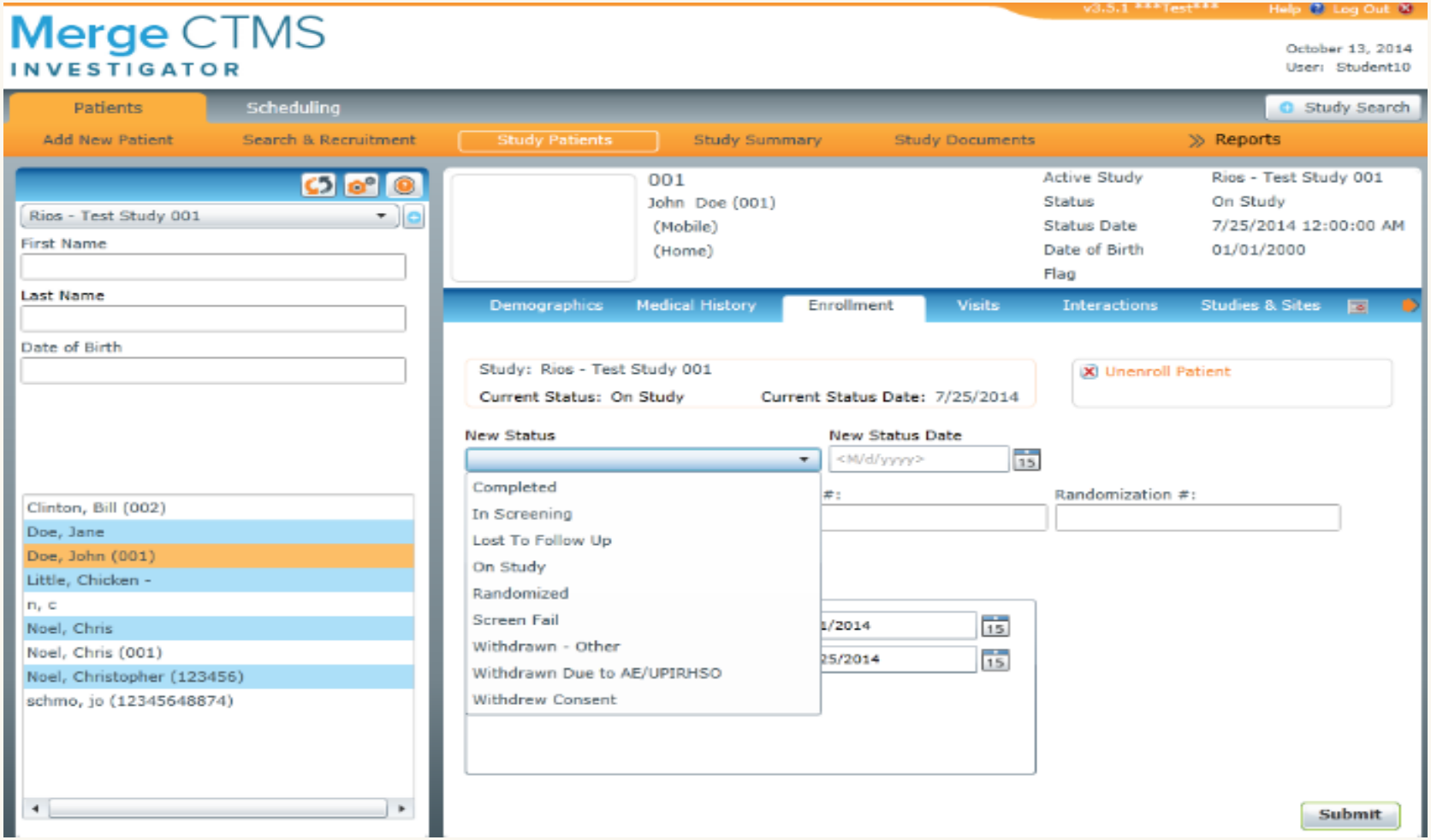
Studies in CTMS

Currently Enrolling Studies: 92
Active Studies: 16
Studies With SSLs Distributed: 16
Closed/Inactive: 34

TOTAL STUDIES IN CTMS: 158

Users: Current active users: 86

CTMS


Merge CTMS
INVESTIGATOR
Help
Log Out
October 13, 2014
User: Student10
Patients
Scheduling
Study Search
Add New Patient
Search & Recruitment
Study Patients
Study Summary
Study Documents
Reports
Rios - Test Study 001
First Name
Last Name
Date of Birth
Clinton, Bill (002)
Doe, Jane
Doe, John (001)
Little, Chicken -
n, c
Noel, Chris
Noel, Chris (001)
Noel, Christopher (123456)
schmo, jo (12345648874)
001
John Doe (001)
(Mobile)
(Home)
Active Study
Rios - Test Study 001
Status
On Study
Status Date
7/25/2014 12:00:00 AM
Date of Birth
01/01/2000
Flag
Demographics
Medical History
Enrollment
Visits
Interactions
Studies & Sites
Study: Rios - Test Study 001
Current Status: On Study
Current Status Date: 7/25/2014
Unenroll Patient
New Status
New Status Date
<M/d/yyyy>
Completed
In Screening
Lost To Follow Up
On Study
Randomized
Screen Fail
Withdrawn - Other
Withdrawn Due to AE/UPIRHSO
Withdrew Consent
#:
Randomization #:
Submit

CTMS

- Updating the patients status is of utmost importance in order to query accurate metrics.

- If a patients information/medical history changes or needs to be corrected, please follow these steps:
  - Select the patient demographics tab
  - Update/Correct
  - Click Submit!

- In order to keep the best records, it is important for the study team to contact the Office of Clinical Research OCR@health.usf.edu to update the Study Status when it becomes closed to enrollment, study becomes inactive due to non-enrollment, or is closed already.

CTMS

- If an invoiced item needs to be accrued under study specific items, please contact OCRFM@health.usf.edu Failure to do so, could result in delayed payment or even non-payment from the sponsor!

- Please contact OCR CTMS Database Administrator Christopher Noel @ 813-974-7163 or cnoel1@health.usf.edu to request training!

TGH Employee's – please provide the following details to request a USF Health Account:

- First Name
- Last Name
- Date of Birth
- TGH email

Clinical Operations Services

- Provide Research Nurse, Study Coordinator and Regulatory Coordinator support to PIs on a fee for service basis
- Manage the Clinical Research Center (CRC) in Morsani Center for Advanced Healthcare
- Maintain the regulatory documents for the OCR
  - Facilitate the commercial IRB process
- Implement and operate the CTMS
- Collect and analyze data for invoicing and reporting

Research Nurse, Study Coordinator and Regulatory Coordinator Support

- Fee Schedule maintained on OCR website
- Service Request Form also on OCR website
- Mainly limiting nursing and coordination to activity in the CRC

- Currently working with
  - Dermatology (C, R & N)
  - IM/Rheumatology (N & R)
  - Ophthalmology (N)
  - Cardiology (R)
- New Departments
  - Communication Sciences and Disorders/Otolaryngology (N)
  - Neurosurgery (N)

C = Study Coordination
R = Regulatory Coordination
N = Nursing Services

Management of the Clinical Research Center (CRC)

- Nurse Manager on site for day to day operational support
- Provide assistance to study teams
  - Receive IP or supplies
  - Notify of study patient arrival in CRC
  - Phlebotomy and IV insertion prn
- Purchase/maintenance of equipment, shared supplies
- Fee schedule is available on OCR website
- Will be moving to a new location – stay tuned

Maintenance of the Regulatory Documents for the OCR

- Receive approval letters from WIRB, Quorum and Schulman IRBs
  - Do *not* get notified by USF IRB, DOH IRB or ACH IRB – we need your help to get these documents
- Upload Initial, Continuing Reviews and Closure letters to SharePoint file + consents
- Update Intake Tracking
- Update FAST with IRB certification dates

Facilitation of Commercial IRB Process

- NSQ reviewed by Assistant Director
  - Which IRB is reviewing study?
  - Outside activity and/or financial COI with the sponsor?
  - Does protocol qualify for commercial IRB submission?
  - Request for ATP letter is sent to USF IRB via email
- USF IRB
  - Confirms protocol qualifies for commercial IRB submission
  - Verifies current Human Subjects Protections training for all study team members (GCP training ***does not*** qualify!)
- Institutional Contacts facilitate with IRB, site and sponsor/CRO issues prn

Help Wanted in the OCR

- Nurse/Researcher position
  - Major duties
    - Research nursing services including study coordination, study drug infusions, phlebotomy
    - Nurse Manager of the Clinical Research Center
- Regulatory Coordinator position
  - Major duties
    - IRB submissions, regulatory doc preparation and maintenance
    - Maintaining current IRB approval letters in OCR SharePoint file, updating Intake Tracking, updating FAST with IRB certification dates

How you can help us serve you better?

- Start your new study activity in the proper sequence
  - Financial COI or Outside Activity?
    - Submit ROAD or COI disclosure 1st
  - NSQ and submission of 4 essential docs is next
    - Spell names of study team members correctly
    - Notify us if a name has changed since last HSP training
  - Start your reg docs and IRB application
    - If study at TGH, submit TGH Feasibility Packet
  - Attach the ATP letter to the IRB application

How you can help us serve you better?

- Notify OCR
  - When study is closed to accrual
  - Of site personnel changes
  - Of changes to participant stipends
- Respond timely to inquiries through our Quintiles Site Partnership
- Forward invoices for study expenses to OCRFM for reimbursement from sponsor per CTA

Clinical Operations Team

- Catherine Jahrsdorfer, RN, BSN, Assistant Director
- Marlo Crawford, RN, BSN, Research Nurse, CRC Manager
- Beth Stevens, Clinical Research Coordinator
- Patti Lowe, LPN, CCRC, Research Nurse Coordinator
- Sara Thomas, nee Mochak, Research Support Specialist
- Chris Noel, CTMS Database Administrator
- TBH, Regulatory Coordinator

Center Watch

- Source of clinical trials information for both clinical research professionals and patients
- Clinical Trial Listing Service to provide patients unbiased information on clinical trials, with a clinical trial database currently enrolling trials
- Information on drugs and new medical therapies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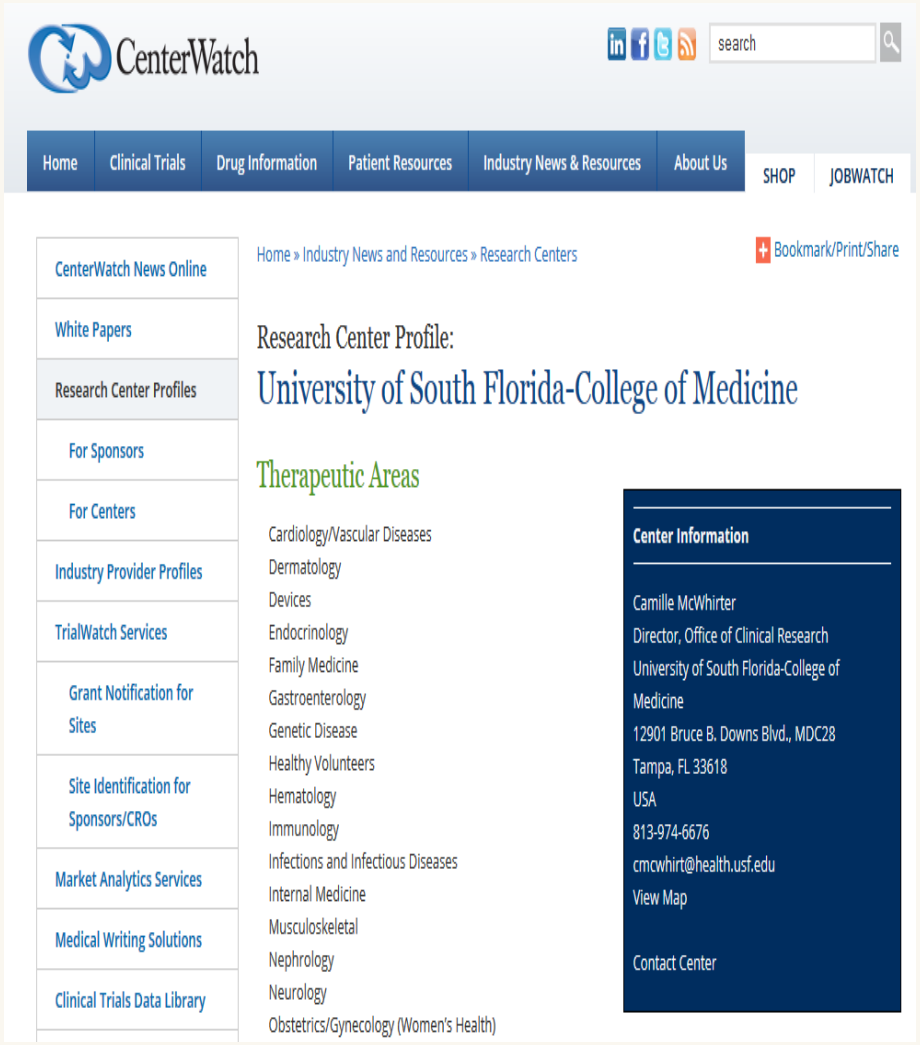
Industry News & Resources
About Us
SHOP
JOBWATC
Deciding to Participate in Clinical Research
Information about the clinical research process and whether participation is right for you.
FIND OUT MORE
Who We Are
Learn About Clinical Research
News and Analysis
ARE YOU AN
Industry Professional?
CenterWatch provides news, analysis, insights, training materials and a variety of services.
» Get Industry News and Market Data
» Search for CROs, Sites, and Vendors
CenterWatch NEWS ONLINE
DAILY CLINICAL RESEARCH NEWS
BBK acquires MEDL Mobile, company instrumental in developing its leading mobile app
Read it now »
Get Started
FIND CLINICAL TRIALS
SEARCH BY:
Medical Condition
Geographic Location
FIND RESEARCH CENTERS
SEARCH BY:
Medical Specialty
Geographic Location
FIND DRUG INFORMATION
SEARCH BY:
FDA Drug Approvals
New Drugs in Research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Site Identification for Sponsors/CROs
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Cardiology/Vascular Diseases
Dermatology
Devices
Endocrinology
Family Medicine
Gastroenterology
Genetic Disease
Healthy Volunteers
Hematology
Immunology
Infections and Infectious Diseases
Internal Medicine
Musculoskeletal
Nephrology
Neurology
Obstetrics/Gynecology (Women's Health)
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View Map
Contact Center

What if ?
Can we?
Should I?
Do you?

And Thank You all for your attention