Office of Clinical Research

- Fall 2009 – Huron/USF Health implement a clinical research management strategic planning initiative. Focus-
  - Developing a strong administrative infrastructure to better manage and administer clinical research, and
  - Designing and implementing a robust process for assuring compliance.
- Reviews performed across multiple USF Health departments and units that support clinical research:
  - Conducted surveys of clinicians and clinical research staff
  - Performed analyses of collected data;
  - Interviewed 55 leaders, faculty, administrators, and clinical research staff;
  - Hosted 3 open-invitation meetings with USF Health investigators;
  - Facilitated discussions with USF Health leadership

Recommendation:
Re-engineer the Office of Clinical Research (OCR) to serve as a centralized, multi-functional office to manage clinical research.
Implementation Approach

Priorities for Year 1

May 10
- Develop / implement communications plan
- Identify and hire staff for priority positions such as Clinical Research Ops.

June 10
- Impact of OCR Formation on existing staff
- Prepare / modify job descriptions as necessary

July 10
- Develop / modify study initiation processes - Build CA process into study initiation
- Develop policies and processes/operating procedures for in-study management

August 10
- Design and implement a front-end feasibility analysis to include: budget, recruitment, nursing, scientific review, priority, etc.

September 10
- Develop CT training and certification curriculum

October 10
- Develop FAST Transition plan (Identify system requirements / Pilot Solution / Execute transition)

November 10
- Launch & Run Pilots - Test, obtain feedback, collect metrics, update as necessary

December 10
- Formalize policies and procedures for the office and train new staff & institution on new procedures

January 11
- Year 1
OCR Functions

The OCR will function as the **enterprise-wide infrastructure for operational processes throughout the lifespan of clinical research.**

- The OCR will operate with a service orientation that addresses the needs of Principal Investigators and other key stakeholders, and builds the research portfolio at USF Health.

- The OCR will prioritize customer service and assist research teams in assuring that research at USF Health sites are:
  - Safe and effective
  - Integrated with clinical operations
  - Compliant with federal guidelines
  - Fiscally sound and transparent
  - Streamlined, sustainable and responsive to sponsors and patients
OCR Transition Office

Role of Transition Office:

- Responsible for coordinating and supporting the efforts of the workgroups and other stakeholders involved with the OCR Implementation Phase. The Transition Office will:
  - Prepare documents in support of workgroup activities
  - Help establish and manage agendas for the Transition Team and workgroups
  - Track and report progress toward the achievement of implementation goals
  - Report this project to the OCR Governance Group and support the Transition Team and workgroups

- The project office will act as dedicated project staff that will drive the transition process and allow the OCR staff to focus on the activities of the office
In order to best inform the organization, the OCR Advisory Groups will be comprised of three key constituencies: Clinical Chairs, Physicians / Investigators, and Administrators. The role of each group is described below:

1. **Clinical Chairs**: The Clinical Chairs will serve as a crucial Advisory Group during the early transition period.

2. **Physicians / Investigators**: A key group of PI ‘customers’ will be asked to provide feedback regarding OCR services and the progress made by the OCR transition project.

3. **Research Teams/Administrators**: A group of coordinators, research nurses, and research administrators will be asked to provide feedback regarding OCR services from the ‘user’ perspective and the progress made by the OCR transition project.
Each workgroup may be comprised of at least one ‘Study Team’ representative, i.e. Clinical Research Coordinator and/or Principal Investigator. **The Chair of each workgroup will also be a member of the Transition Team.**

**Goal:** designed to facilitate the decisions and process developments related to the critical areas of the Office of Clinical Research Implementation / Transition. **The OCR Transition Team will support the workgroups to establish proposed methodology which will be presented to the OCR Governance Group.**
OCR Workgroups

Information Technology Workgroup

Charge

The Information Technology Workgroup will be comprised of key members of IT and clinical/administrative departments.

The group is charged with developing processes and requirements for various aspects of information technology as it relates to the management of clinical research. Such areas of focus will include: the transition to FAST, selection and deployment of a Clinical Trial Management System (CTMS), creation and distribution of reports, system maintenance and storage, and HIPAA/data security.

- Kim Hauser (Chair)
- Jennifer Condon
- Tim Hamilton
- Mark McLaughlin
- Rebecca Puig
- Doreen Shockley
- Dan Van Der Meulen
- Diego Vazquez
OCR Workgroups

Study Initiation Workgroup Charge

The Study Initiation Workgroup will be comprised of key members of the OCR and Clinical / Administrative Departments.

The group is responsible for developing processes and requirements for the various aspects of study initiation including; budgeting, suitability & feasibility assessments, contracting, coverage analysis development, account set-up, and coordination with regulatory approval processes.

- Catherine Jahrsdorfer (Chair)
- Yvonne Bannon
- Lynn Cash
- Joanna Haller
- Tammy Myers
- Debbie Scott
- Michelle Singleton
- Dr. David Sheehan
- Robin Szekely
- Diego Vazquez
- Corinne Walters
- Anna Valencia
OCR Workgroups

In-Study Management Workgroup Charge

The In-Study Management Workgroup will be comprised of key members of the OCR and clinical / administrative departments.

The group is charged with the development of processes and requirements for in-study management, including scheduling and order entry for research patients, research billing, charge capture, research account monitoring, auditing, management of A/R and A/P, study close-out, residual/deficit fund management, reporting, and coordination of regulatory approval processes.

- Workgroup membership invitations pending
OCR Workgroups

**Communication & Training Workgroup Charge**

The Communication & Training Workgroup will be comprised of key members of the OCR and clinical / administrative departments.

The group is charged with developing an internal and external communication plan to distribute information about the OCR and resulting changes to the broader Research Community. The group will also be responsible for creating a clinical research training program and curricula to address the regulatory and education needs of the institution while managing / tracking the training efforts.

- Workgroup membership invitations pending
Workgroups-Final Product

Documentation/operating manual of pre-/post-award management process for clinical research
OCR Required/Optional Services

Some of these processes will be “required” functions of the office where the OCR is meeting a compliance requirement of the organization or is best able to develop a critical mass of expertise for that function. Other functions of the OCR are “optional” services offered by the office to facilitate clinical research.

Core/Required Services include:
- Developing and maintaining research charge master(s)
- Developing or approving budgets
- Negotiating contracts
- Clinical Trial Billing Compliance
- Developing, delivering and coordinating training programs, working with institutional subject area experts (TRAIN)
- Providing IT support for a CTMS
- Providing pre-/post-award accounting using FAST including account set-up, sponsor invoicing, A/R management, cash management, account closeout, and residual balance review and confirmation.

Optional Services would include:
- Grant writing
- Regulatory support (IND’s etc.)
- Assistance with IRB paperwork
- Assistance in protocol development (for investigator-initiated studies)
- Outpatient clinical research facilities
- A research coordinators pool
- Recruitment support
- Data management and biostatistics support
Timeline - DRAFT

May 2010
OCR Transition begins; work groups formed and begin

Sept 2010
Work group deliverables due

Nov 2010
Pilot study of OCR services begins

Feb 2011
Roll out of OCR services to selected departmental divisions begins

July 2011
OCR fully open to USF research community for all service offerings
Glossary

A/P    Accounts Payable
A/R    Accounts Receivable
CT     Clinical Trials
CTMS   Clinical Trials Management System
FAST   Financial Accounting System
GCP    Good Clinical Practice
HIPAA  Health Insurance Portability & Accountability Act
IND    Investigational New Drug
IRB    Institutional Review Board
OCR    Office of Clinical Research
PI     Principle Investigator
TRAIN  The Research Administration Improvement Network
USF    University of South Florida