Introducing the UCSF Office of Clinical Research

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Office of Clinical Research as Best Practice

- UCSF's 2014 Strategic Plan identified the need to create a Clinical Research Office to serve as the organizing entity and recognizable institutional home for clinical research at UCSF

- Academic Medical Center peers have also built out their Offices of Clinical Research in recent years, recognizing this as a best practice

  - UCLA, UCSD, Yale, Emory, Duke, U. Penn

- There are over 4500 active clinical trials at UCSF, confirming that we have the largest research portfolio in the nation

- Clinical research (defined as research involving patients and/or patient derived materials) represents approximately 50% of UCSF's overall research activities and grants.

- In October of 2017, the Chancellor's Executive Team extended its support to the Office in its planned three-year strategic plan

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The Office of Clinical Research Supports Strategic Plan Objectives

- Developing a supportive, transparent, and efficient infrastructure for clinical research billing

- Establishing a consistent process for study start up

- Providing a consistent and transparent financial strategy for performing coverage analysis

- Instituting clear pricing for study budget development

- Providing expertise and training to perform charge separation

- Infusing the value of clinical research into our organizational culture

- Supporting UCSF's CTSI as a core component of UCSF clinical administration and infrastructure

  - Streamlining under NIH's NCATS funding normalization (~50% reduction)

  - CTSI becomes part of OCR enabling collaboration, efficiency

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OCR Reports to UCSF Health and Campus

- This dual reporting represents a partnership between the two entities

- This partnership represents an alignment in goals, strategy, and operations in the support and conduct of clinical research across UCSF

- The process to start up and conduct a clinical trial is a complex one, one that spans – and has equal importance to – both UCSF's campus operations and Health Systems/Medical Center operations

- Every year, UCSF Health Systems provides clinical care for thousands of patients who are also enrolled as subjects in clinical trials

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Progress to Date

- The Office of Clinical Research has made great strides in the last year toward its goals. Today:

  - Coverage Analysis at UCSF is centralized, consistent, and ensures UCSF is compliant with the ever-changing regulatory environment

  - Compliance Experts and Billing Segregators ensure accuracy in the clinical research billing process, contributing to participant satisfaction and the financial health of the institution, and freeing up Clinical Research Coordinators' time for other study management related tasks

  - Progress is being made on increasing the transparency and interconnection of clinical research systems, including OnCore and APeX

  - UCSF has increased its audit-preparedness for its clinical research portfolio

  - CTSI has been administratively moved under OCR, enabling coordination of the activities of the CTSI more efficiently and effectively, including recognizing cost savings, increased efficiency, and FTE consolidation

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What is Track More with OnCore?

- Campus-wide initiative to use OnCore for Subject Enrollment and Subject Visit Tracking beginning Monday May 7, 2018

- OnCore (Online Collaborative Research Environment) is UCSF's Enterprise Clinical Trials Management System

- OnCore provides a secure, standardized, and reportable database for clinical trials management data

- Increased usage of OnCore supports:

  - Better data by moving all UCSF Clinical Research Study Subject Enrollment Data to a central location (OnCore)

  - A more compliant clinical research billing process by ensuring that all clinical research conducted at UCSF is compliant and billed appropriately

- This is a critical step to protect UCSF and UCSF faculty and to streamline processes

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Impacts and Importance

- Who is impacted by Track More with OnCore?

  - Faculty/Principal Investigators & Staff who run and support UCSF Clinical Research

  - Specifically, studies that involve research charges in APeX need to have their patients entered into and managed in OnCore

  - You, your CRCs and Study teams are critical to project success

- Why do we need OnCore?

  - UCSF has ~4500 active research protocols at any given time! OnCore is a single source of record for our extensive research portfolio to ensure key study information is in one compliant location.

    …world-class care and research requires world-class data management

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