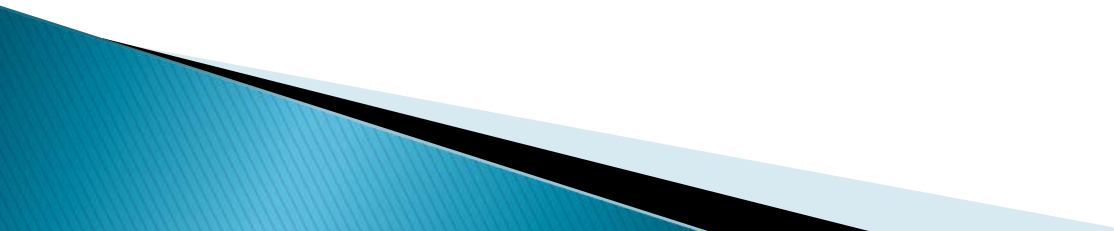


IRB and Contracting Metrics Subcommittees

UC-BRAID Retreat
23 September 2011

Agenda

- ▶ Mission and Team Members
 - ▶ Goals and Objectives
 - ▶ Accomplishments to date
 - ▶ Plans / Next Steps / Areas of Focus
 - ▶ Goals and Objectives for next year
- 

Mission & Goal

Mission: To harmonize the IRB approval and contract negotiation & execution process between centers across UC, thus ensuring a high level of service with nationally competitive start-up times for investigational studies.

Goal: Reduce study administrative start-up times to 40–50 days.

Team Members

David Asmuth	Associate Professor, Co-Director of CRC and CRRF Program	UCD	Metrics-IRB Metrics-Contracting
Erick Jenkins	Analyst, Health Systems Contracts	UCD	Metrics - Contracting
Mike Caliguri	Professor of Psychiatry and Director of HRPP	UCSD	Metrics - IRB
Tony Perez	Assistant Vice Chancellor, Health Sciences Affairs	UCSD	Metrics - Contracting
Bishoy Anastasi	Contracts Associate, Clinical Trial Contract Unit	UCLA	Metrics - Contracting
Sharon Friend	Director, Office of the Human Research Protection Program	UCLA	Metrics - IRB
Alison Orkin	Assistant Director, UCLA General Campus IRB	UCLA	Metrics - IRB
Bruce Morgan	Assistant Vice Chancellor for Research Administration ,Office of Research	UCI	Metrics - Contracting
Ruth Mulnard	Associate Professor, Associate Director, Program in Nursing Science, College of Health Sciences	UCI	Metrics - IRB
John Heldens	Director, UCSF Human Research Protection Program	UCSF	Metrics - IRB
Erik Lium	Assistant Vice Chancellor, UCSF Office of Innovation, Technology & Alliances	UCSF	Metrics-IRB, Metrics-Contracting
Thierry Musy-Verdel	Industry Contracts Officer, Industry Contracts Division, UCSF Office of Innovation, Technology & Alliances	UCSF	Metrics-IRB, Metrics-Contracting
Irene Shin	Associate Director, Industry Contracts Division, UCSF Office of Innovation, Technology & Alliances	UCSF	Metrics - Contracting
Susan Shih	Industry Contracts Officer, Industry Contracts Division, UCSF Office of Innovation, Technology & Alliances	UCSF	Metrics-IRB, Metrics-Contracting
Peter St. Wecker	Senior Program Manager, Clinical and Translational Science Institute	UCSF	Metrics-IRB, Metrics-Contracting
Michael Thomas	CHR Assessment Unit Manager	UCSF	Metrics-IRB

Goals and Objectives

Define

metrics to assess processes and outcomes

- Metrics should be cross-campus, measurable, and meaningful
- Improve performance and accountability

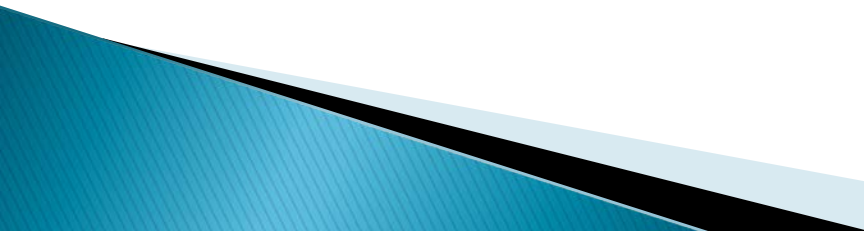
Develop

a simplified pilot system for tracking metrics across institutions

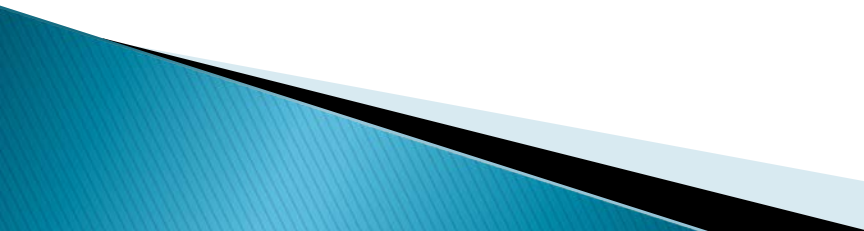
- Based on CTSA metrics collection project

Implement

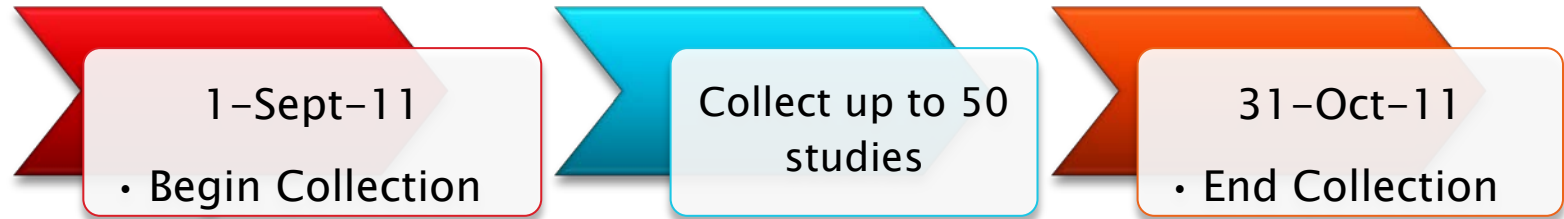
an initial study to track metrics

- Collect initial performance measures data
 - Monitor ongoing impact
- 

Contracting Metrics

- ▶ **Identifiers**
 - Institution, Sponsor Name, IRB Cross-Reference Number, NCT Registration Number
 - ▶ **Prior Terms**
 - UCOP Master?
 - Campus Master?
 - Existing Previous Terms?
 - ▶ **Study Design and CRO**
 - Phase of study (I, I/II, II, II/III, III, IV, early/device, other)
 - Multicenter?
 - CRO?
 - ▶ **Key Dates**
 - CDA Signature
 - Negotiation Start
 - First Comments Provided
 - Negotiations Finalized
 - Institution Execution
 - Sponsor Execution
- 

Contracting Metrics Data Collection



- “*Negotiation Start Date*” is considered the initial milestone for the contracting process.

IRB Metrics Data Collection

- ▶ Metrics based on those used for CTSA IRB study.
- ▶ Data collected on first 50 protocols approved 1–September–2010 through 30–November–2010 at each institution.

Data Collection Status

- ▶ Contracting: In Process
 - ▶ IRB: Data provided by 3 out of 5 campuses
- 

Goals and Objectives for Next Year

- ▶ Complete phase I data analyses
 - ▶ Design phase II study
 - ▶ Design operational map to predict optimal phasing of administrative processes
- 