

# CONTRACTING

**Fall 2011 UC BRAID Retreat**

**Clay Johnston, MD, PhD**  
Director, UCSF CTSI  
Chair, UC BRAID  
Chair, UC BRAID Contracting

**Gary Firestein, MD**  
Director, UCSD CTRI  
Co-Chair, UC BRAID Contracting

# Participants

- **UC Davis**

- Rafael Gacel-Sinclair
- Ahmad Hakim-Elahi
- Erick Jenkins

- **UC Irvine**

- Jacob Levin
- Bruce Morgan
- Madeline Pahl

- **UCLA**

- Bishoy Anastasi
- Megan Brennan
- Mike Bunnapradist
- Helene Orescan
- Brian Roe

- **UCSD**

- Gary Firestein (CO-Chair)
- Tony Perez

- **UCSF**

- Clay Johnston (Chair)
- Melanie Funes
- Erik Lium
- Teri Melese
- Susan Shih
- Irene Shin

- **UCOP**

- Jeff Hall
- Hillary Kalay
- Dragana Nicolajevic

# UC Landscape

**UC BRAID-CONTRACTING**

# UC BRAID-Contracting within the UC Landscape

- **Why are we here?**
  - Forum that includes end-users
  - Strategic recommendations
  - Reinforce benefits of cooperation
  - Encourage new technologies/approaches
  - Focus on acceleration and innovation

# Year 1

## Goals and Objectives

# YR01 – Goals and Objectives

## **GOAL:** Accelerate Research Contracting at UC

1. Support efforts to increase Clinical Trial Master Agreements
2. Develop a Pilot Shared Database of Contract Terms
3. Support development of a Shared Clause Library
4. Plan a UC-wide Training Program for Contracting
5. Coordinate standardization of Material Transfer Agreements (MTAs)
6. Establish and Track Contracting Metrics

# **YR01 Work and YR02 Plans**

**Year 1: Accomplishments**

**Year 2: Goals**

# Master Clinical Trials Agreements (CTAs)

LEADS: Jeff Hall, Hillary Kalay, Dragana Nicolajevic (UCOP)

- **Problem:** Industry sponsors of clinical trials must negotiate each time they engage with a campus for a new trial
- **YR01 Goal:** Increase active CTAs (5 new)
- **Accomplishment:**
  - 5 New Master CTAs
  - 2 in negotiation



# Clinical Trials Agreements (CTAs)

LEADS: Jeff Hall, Hillary Kalay, Dragana Nicolajevic (UCOP)

- ***YR02 Goals:***
  - Continue increasing Master CTAs (5/yr)
  - Resolve issues, work through clauses, develop range of options for troublesome sponsor
    - Boehringer Ingelheim
    - Johnson & Johnson
    - Gilead
  - Increase Master Confidentiality Agreements

# UC-wide Contracts Database

LEAD: Erik Lium(UCSF)

- **Problem:** Most contracts are re-worked from scratch this is inefficient
- **YR01 Goal:** Develop Pilot Contracts Database
  - Easy to use centralized repository of contracts
  - Searchable to find companies, terms, types of studies
- **Accomplishment:** Pilot Database Created
- **YR02 Goals:**
  - Establish definitions
  - Evaluate implementation at each campus
  - Encourage deployment at each campus

# UC-wide Clause Library

LEAD: Bruce Morgan (UC Irvine)

- **Problem:** Contracting in its current state is a handicraft as opposed to being a scalable endeavor
- **YR01 Goal:** Support development of a Clause Library
- **Accomplishment:** Prototype Clause Library
  - Prototype expected in December 2011
- **YR02 Goals:**
  - Prototype testing
  - 2<sup>nd</sup> version created

# Clinical Trial Negotiators Training

LEAD: Hillary Kalay (UCOP)

- **Problem:** Staffing stability is key in contract negotiation
- **YR01 Goal:** Plan a Training Program
- **Accomplishment:** Online Training Program
  - Interactive modules
  - Content includes:
    - Clinical Trials
      - Definition/types
      - components
      - distinction between phases
    - Regulating Bodies
    - Drugs and Devices
    - Contracting
      - UC principles
      - negotiating a CTA
- **YR02 Goal:** Online Training Program
  - Wide adoption of training program

# Standardizing MTAs

LEAD: Gary Firestein (UCSD)

- **Problem:** MTAs can be problematic, lacking consistency from campus to campus
- **YR01 Goals:**
  - Establish a single MTA office at each campus
  - Define broader use of UBMTA
  - Develop MTA Standards systematizing across campuses
- **Accomplishment:** UC-wide agreement to use the UBMTA template as the default
- **YR02 Goals:** Mission Accomplished – Effort Retired

# Developing Metrics

LEAD: Erik Lium (UC Davis)

- **Problem:** Need data on contributors to delays in contract negotiations in order to improve business processes
- **YR01 Goals:** Create Metrics Working Group
  - Develop UC-wide process and organizational metrics
  - Use CTSA metrics as a model
- **Accomplishment:** UC BRAID Metrics Working Group
- **YR02 Goal:**
  - Set goal for Contracting component of Metrics

**Year 2**

**New Efforts**

# Faculty Research Consulting

LEAD: Clay Johnston (UCSF)

- **Problem:** Consulting for industry can lead to:
  - FACULTY: conflict of interest and compliance issues
  - UNIVERSITY: limits on future participation in clinical trials
  - INDUSTRY: complicated process
- **YR02 Goals:** Faculty Research Consulting Program
- Create a Template and SOPs for implementation
  - protect faculty from unknowingly conflicting themselves
  - maximize University's opportunity to participate in industry-sponsored clinical trials
  - provide resources to the University research community and companies in support of consulting engagements



**Thank You**

**Questions?**