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

<table>
<thead>
<tr>
<th>Name</th>
<th>Title/Position</th>
<th>Institution</th>
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**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
“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