Clinical Trial Contracting at UC
Achievements and Goals

UC BRAID Retreat
October 15, 2013
Hillary Noll Kalay

Agenda

• Achievements
  ▫ Master Agreements
  ▫ Increased training and resources
  ▫ Clarified policies and processes
Agenda

- Achievements $\rightarrow$ Goals
  - More Master Agreements
  - More training and resources
  - Additional Clarified policies and processes

Agreements: Achievements

- Abbott Vascular
- AbbVie
- Allergan
- Alvine
- Astellas
- Bayer
- Cook
- Gilead
- GSK
- Lilly
- Merck
- Pharmacyclics
Agreements: Goals

- Boehringer Ingelheim
- Biogen Idec
- EMD Serono
- Gore
- Janssen
- Otsuka
- Seattle Genetics

- Investor-initiated master agreements

- And more...

Training and Resources

- Achievements
  - Sharepoint site now a vital resource for negotiators
  - One-day in-person intensive training session
  - Annual in-person meeting
    - Intellectual property, health records, PPSA
  - Model device and PI-initiated CTAs
Training and Resources

• Achievements
  ▫ Sharepoint site now a vital resource for negotiators
  ▫ One-day in-person intensive training session
  ▫ Annual in-person meeting
    • Intellectual property, health records, PPSA
  ▫ Model device and PI-initiated CTAs

• Goals
  ▫ Additional and new training sessions
  ▫ Rationale library

Clarified Policies and Processes

• Achievements
  ▫ Exceptions to IP policies for Clinical Trials
  ▫ New guidance
    • Subject injury policy
    • Intellectual property
    • PPSA
Clarified Policies and Processes

• Achievements
  ▫ Exceptions to IP policies for Clinical Trials
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• Goals
  ▫ Research restrictions
  ▫ Data management
  ▫ FCPA

Questions?

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