Clinical Trial Contracting at UC
Achievements, Obstacles and Goals
UC BRAID Retreat
September 14, 2012
Hillary Noll Kalay

Agenda
- Achievements
  - Training
  - Communication across the system
  - Agreements
- Obstacles to Negotiation
  - UC policies vs. industry practices and policies
- Goals for 2012-2013
  - More master agreements
  - Improve relationships with certain companies
  - Improve communication across UC

Achievements: Training
- Developed comprehensive, 11-module training program for clinical trial negotiators across UC
- Covers:
  - Overview of phases of clinical trials, classes of devices
  - Laws and regulations
  - UC’s policies
  - Negotiation do’s and don’ts of clinical trial agreements

Achievements: Greater Communication and Collaboration
- Sharepoint site
  - Discussion board
  - Agreements in negotiation
  - Resources
- Working groups
  - Budgeting
  - Device Trials

- Abbott
- Allergan
- Bayer
- AstraZeneca
- Gilead
- Merck
- Novartis
- Pfizer
- Pharmacyclics*

Achievements: Greater Communication and Collaboration
Obstacles to Agreements

- Not negotiating directly with decision-makers
  - CROs: will often not honor terms of masters
- Negotiation of contract AND budget
- Study team completion of paperwork
- Demands of sponsors vs.:
  - Legal obligations (as a research site, public institution)
  - Principles and policies of the University
  - Realities of UC as a large, public institution

Obstacles to Agreements: Sponsor Demands vs. UC
Legal/Accreditation Requirements

<table>
<thead>
<tr>
<th>Sponsor Demands</th>
<th>UC’s Obligations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keep terms of the agreement, budget, etc. confidential</td>
<td>UC must disclose public records, unless exempt under law</td>
</tr>
<tr>
<td>Access to protected health information</td>
<td>Access must comply with federal and state law</td>
</tr>
<tr>
<td>IP extending beyond performance of the study</td>
<td>Bayh-Dole; UC’s obligations to other research funders</td>
</tr>
<tr>
<td>No notification of adverse events following study closure; no access to study records provided to Sponsor following study</td>
<td>Must have access to records post-study; accreditation requires notification of adverse events following study closure</td>
</tr>
</tbody>
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Obstacles to Agreements: Sponsor Demands vs. University Policies and Principles

- The goals of our policies:
  - To promote research
  - To make advances available to the public
  - To leave the subject in no worse position (physical or financial) for participating in the research

Obstacles to Agreements: Sponsor Demands vs. University Policies and Principles

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<thead>
<tr>
<th>Sponsor Demands</th>
<th>UC Policies and Principles</th>
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<tbody>
<tr>
<td>No payment for subject injury</td>
<td>Policies require reimbursement for injuries that directly result from studies</td>
</tr>
<tr>
<td>Ownership of raw data</td>
<td>UC must own raw data</td>
</tr>
<tr>
<td>Right to edit publications</td>
<td>UC and its researchers must have control over publication</td>
</tr>
<tr>
<td>Everything related to the study must be kept confidential</td>
<td>Confidentiality terms cannot interfere with publication rights; principle of open academic environment</td>
</tr>
<tr>
<td>No “related” research</td>
<td>Research of one investigator cannot affect the research of another</td>
</tr>
<tr>
<td>Will only register study as required by federal law</td>
<td>ICMJE registration guidelines</td>
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Goals

- More master agreements
  - Abbott device subsidiaries
  - Alvine
  - Biogen Idec
  - Boehringer Ingelheim
  - Celgene
  - Cook
  - Merck
  - Medtronic
  - Otsuka

Obstacles to Agreements: UC is a large public research institution

<table>
<thead>
<tr>
<th>Sponsor Demands</th>
<th>UC Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restricted use of biological samples</td>
<td>Lack of funds and mechanisms to restrict use</td>
</tr>
<tr>
<td>Present assignment of intellectual property</td>
<td>UC needs the paper trail, to record existence of invention and assign to proper party</td>
</tr>
<tr>
<td>No start up costs, no overhead for certain services</td>
<td>UC will incur a loss if these charges are not assessed</td>
</tr>
<tr>
<td>Withholding all payment until data queries are resolved to sponsor’s satisfaction</td>
<td>UC needs payment for expenses properly incurred and work performed</td>
</tr>
</tbody>
</table>
Goals

• More master agreements
• Improve relationships with key companies
  ▫ Example: Johnson & Johnson
    • Address each party’s concerns regarding:
      • Data and IP ownership
      • Research restrictions
      • Scope of confidential information
      • Subject injury and indemnification
  ▫ External RPAC website

• More master agreements
• Improve relationships with key companies
• Improve communication across UC
  ▫ Campus to Campus:
    • More advanced training
    • SharePoint, work groups
    • Single system-wide database?

Contract Repository

Thank You

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