UC Reliance Services (UCRS)
Proof of Concept

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Background

• Changing landscape to central review
• Increased attention to clinical research administration performance
  – Patients
  – NIH
  – Local institutions
  – Industry partners
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Goals

• enhance the “UC Memorandum of Understanding for Multi-campus Research”
• expand its use in clinical research
• eliminate duplicative IRB reviews, achieving efficiencies and improving study activation times
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Approach

• Provide central administrative support to facilitate IRB reciprocity approvals for industry sponsored/industry authored clinical trials
  – Reduce burden on PIs and research staffs
  – Reduce burden on local IRB offices
UCRS Timeline

- Campus visits & baseline assessment
  Dec. – Feb. 2013
- Proposed project at IRB Directors’ Meeting
  Feb. 2013
- First reliance initiated
  March 2013
- Reliance 2-5 initiated
  Apr. – Oct. 2013
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What we did

• Visited campuses for initial discovery of their reliance processes
• Assessed individual campus processes
• Developed standardized forms, processes
• Engaged campus partners
• Facilitated five studies across all 5 campuses
UCRS Central Coordination

- Approvals
- Post-approval events
- Standardized documentation & communication
- Monthly check-ins

IRB of Record

Relying PI

Relying IRB

Contracts Offices

"Lead PI"
## UCRS Project

### How long they took (n=4)

<table>
<thead>
<tr>
<th>Median days between learning of study and initial contact with PI</th>
<th>Median days between initial contact with PI and reliance approval</th>
<th>Median overall approval time</th>
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</thead>
<tbody>
<tr>
<td>17 days (SD: 6.99)</td>
<td>12.5 days (SD: 7.62)</td>
<td>29 days (SD: 13.96)</td>
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Opportunities

• Identifying studies
• PI independence
• Harmonized processes
  – Required documentation and steps
  – Definitions
  – Communication with campus departments and ancillary committees, including budget, billing, coverage analysis
The Optimistic Future

• Searchable database of approved studies across all five campuses
• Outreach to identify new studies
  – Investigators, cancer centers...
• Resourcing [approaches to sustainability]
• Continue to refine processes and harmonize where possible
• Community Partners
Thanks to our partners

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Contracting Working Group: Jennifer Ford, Erick Jenkins, Hillary Kalay, Helene Orescan, Irene Shin, Tam Tran

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