IRB Reliance

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UC Reliance Services (UCRS) Goals

• Expand the use of UC Memorandum of Understanding for Multi-campus Research
• Expand its use for clinical research
• Achieve efficiencies, eliminate duplicative IRB reviews
For patients, it means increased and earlier access to potential treatments

UCRS: WHY WE DO IT
Benefits of UCRS

• For patients
  – Increased/faster access to potential treatments

• For researchers
  – Decreased effort
  – Decreased time to IRB approval
  – Increased efficiency
  – Single point of contact and increased customer service

• For IRBs
  – Eliminates redundant reviews
  – Reduces burden on IRB and staff
  – Allows IRBs to focus on safety, quality

• For sponsors
  – Increased accrual
  – Decreased time to study activation across sites
UCRS Central Coordination

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

Central support facilitates IRB reciprocity approvals for **industry sponsored/industry authored** clinical trials
Where We’re At

✓ 7 studies across 5 campuses
✓ Model processes
  – Acceleration and facilitation
  – Check-ins and enhanced support
  – Templates and standardized documents
✓ UC Clinical trials search tool: TrialQuest
UCRS Approval Times

22.4 Days

- Reliance Request to UCRS
- Reliance Application Submitted to IRB
- Reliance Approved

1-15 Days

n=5

UCBRAID
University of California Biomedical Research Acceleration, Integration & Development
Stakeholder Feedback

PIs and Research Coordinators
• “I want to thank you for your help and fast approval process of this study through UCRS.”
• “I am so glad this service is in place, it has made this study so much easier.”

IRBs
• “Requires additional work during ramp-up”
• “Submissions much cleaner, reducing delays”
Moving Forward

• UC IRB Directors oversight
• **Expand** capacity
  – Incorporate into local business processes
• Build **sustainability model** and revenue mechanism
• Implement **phased outreach** and education plan
NCATS IRB Reliance Initiative

National network of regional IRB consortia

- 7 consortia including UC BRAID
- UC lead representative: Cindy Gates (UC Davis)
- Exec Committee representative: Lars Berglund (UC Davis)
- CTSA leads: Dartmouth and Virginia Commonwealth
NCATS IRB Reliance Initiative

• Phase I (Sept 2014 – Aug 2015)
  – Create a national IRB Reliance Agreement
  – Conduct a technology assessment and recommend solution(s)
  – Identify a large scale multicenter clinical trial to demonstrate feasibility
  – Expansion of Agreement to other sites
UC TrialQuest

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Anirvan Chatterjee, Director of Data Strategy, CTSI
Eric Mah, UC BRAID Project Director
Rachael Sak, UC BRAID Director
Unmet Need

An efficient means to identify clinical studies across the UC System
Solution: UC TrialQuest

• Easy to use search tool for UC staff and faculty
• All “in-process” and IRB-approved clinical trials across BRAID campuses
• Early identification using pre-submission data
Use Cases

• UC IRB Reliance Coordinators
  – Identify potential reliances and mitigate redundant IRB reviews

• Researchers
  – Potential collaborators, secondary analyses
Use Cases

• **UC Contract Negotiators**
  – Share terms, budgets, contractual language
  – Mitigate sponsor manipulating or playing off two or more campuses
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Partnerships and Thanks

• UC IRB Directors and Reliance Coordinators
• UCOP – Jeff Hall, Dragana Nikolajevic, Patrick Rogers, Hillary Kalay
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• UC BRAID Contracting Working Group