IRB Reliance

Eric Mah, UC BRAID Regulatory Project Director
Nate Buscher, UC BRAID Program Manager
Courtney McFall, UC BRAID Program Analyst
Rachael Sak, UC BRAID Director

UC BRAID
University of California Biomedical Research Acceleration, Integration & Development

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

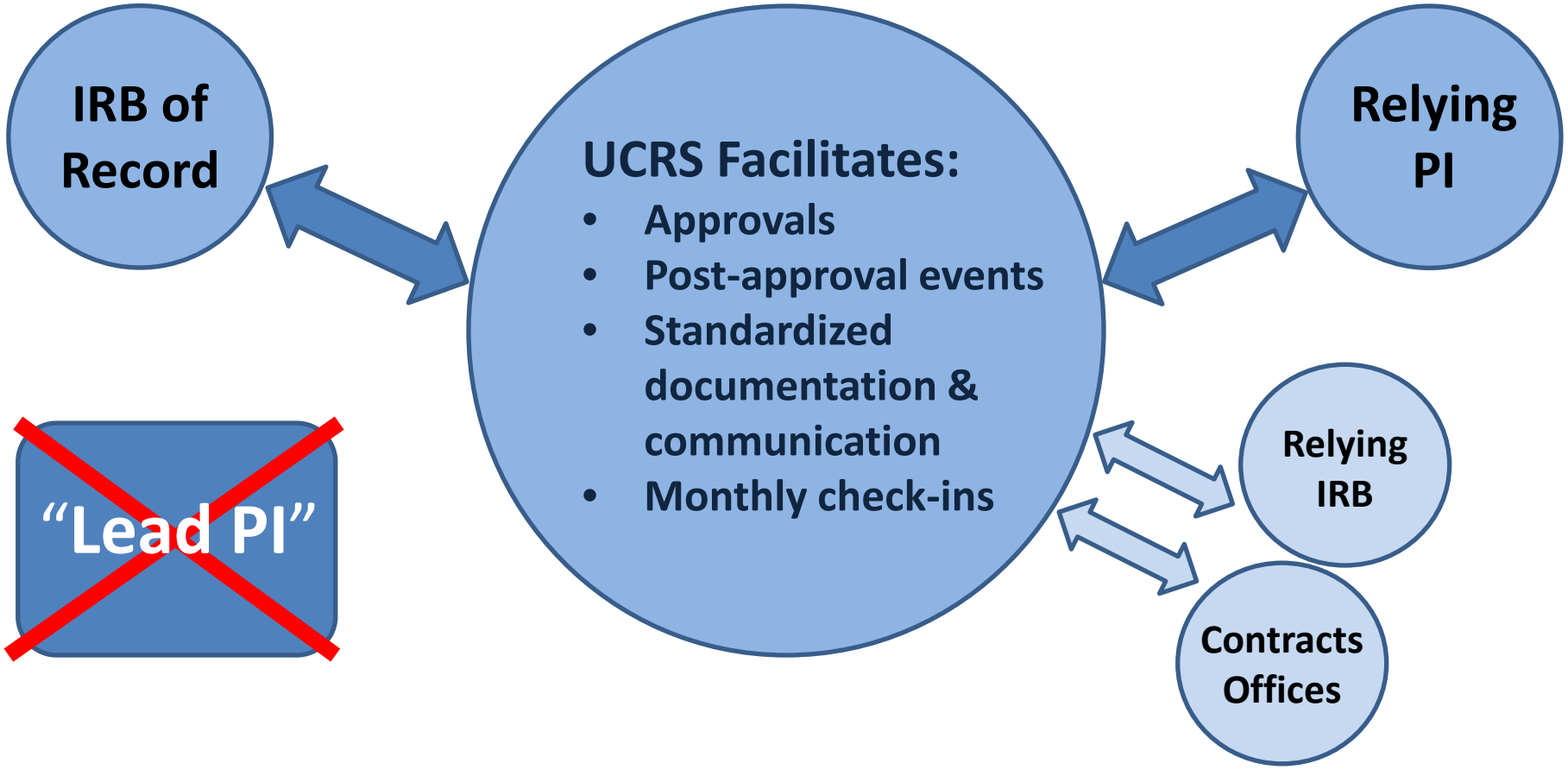
UCRS: WHY WE DO IT

UC BRAID
University of California Biomedical Research Acceleration, Integration & Development

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

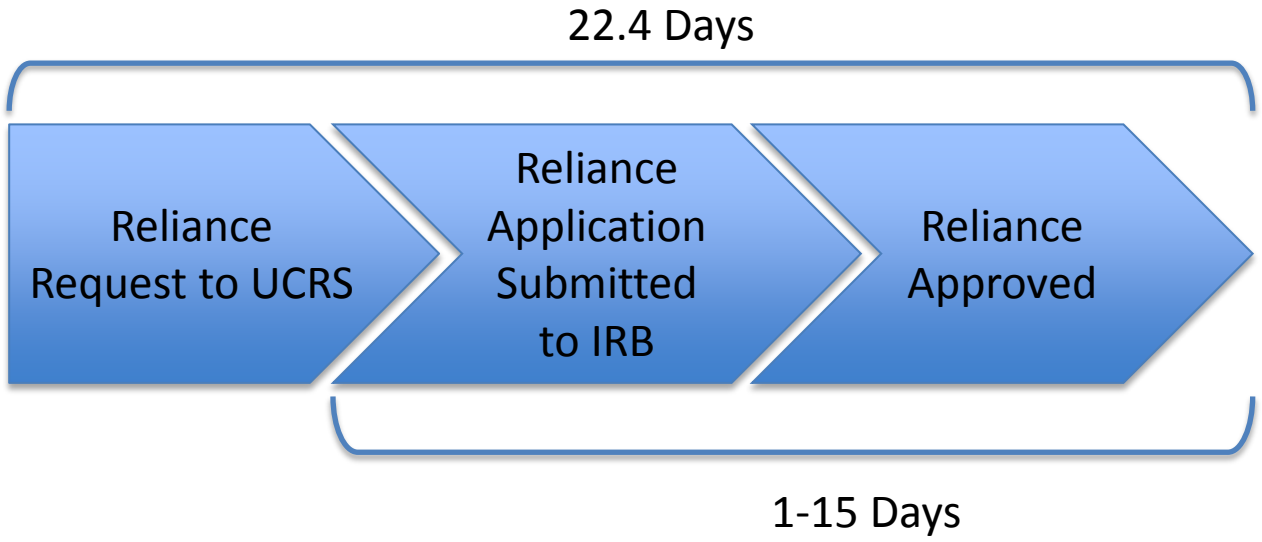


Central support facilitates IRB reciprocity approvals for **industry sponsored/industry authored** clinical trials

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



n=5

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 (UCDavis)
- 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

Nate Buscher, UC BRAID Program Manager
Anirvan Chatterjee, Director of Data Strategy, CTSI
Eric Mah, UC BRAID Project Director
Rachael Sak, UC BRAID Director

UC BRAID
University of California Biomedical Research Acceleration, Integration & Development

Unmet Need

An efficient means to identify clinical studies across the UC System

UC BRAID
University of California Biomedical Research Acceleration, Integration & Development

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

DEMO

UC TrialQuest

search 3,492 studies from 5 UC health campuses
by UC BRAID • CTSI at UCSF • UC Office of the President

UNIVERSITY OF CALIFORNIA

We need your feedback! Click to leave a comment.

Show 10 entries

Showing 1 to 10 of 373 entries (filtered from 3,492 total entries)

Search: multicenter

☑ active ☐ pending ☐ pre-submission ☐ inactive

☑ UCD ☑ UCI ☑ UCLA ☑ UCSD ☑ UCSF

Submission Date	Campus & ID	Status	Study Title	Sponsor	PI	ClinicalTrials.gov-ID
2014-09-15	UCLA #14-000618	active	caspofungin acetate (MK-0991): A Multicenter, Double-Blind, Randomized, Comparator-Controlled Study to Evaluate the Safety, Tolerability, and Efficacy of Caspofungin Versus Amphotericin B Deoxycholate in the Treatment of Invasive Candidiasis in Neonates and Infants Less Than 3 Months of Age	Merck and Company, Incorporated (Merck Sharp & Dohme)	Karin Nielsen	01945281
2014-09-10	UCD #656369-1	active	A Phase 3, Multicenter, Randomized, Open-Label Study to Compare the Efficacy and Safety of Sofosbuvir/GS-5816 Fixed Dose Combination for 12 Weeks With Sofosbuvir and Ribavirin for 12 Weeks in Subjects With Chronic Genotype 2 HCV Infection (Gilead 1139-ASTRAL-2)	Gilead Pharmaceuticals	Cohen, Stuart	
2014-09-10	UCD #635589-4	active	A Phase 3, Multicenter, Randomized, Open-Label Study to Compare the Efficacy and Safety of Sofosbuvir/GS-5816 Fixed Dose Combination for 12 Weeks with Sofosbuvir and Ribavirin for 24 Weeks in Subjects with Chronic Genotype 3 HCV Infection (Gilead 1140 ASTRAL-3)	Gilead Pharmaceuticals	Cohen, Stuart	
2014-09-09	UCD	active	HS110-201: A Phase 2, Multicenter, Randomized Study to Evaluate the Safety and	Heat Biologics	Lara,	

Partnerships and Thanks

- UC IRB Directors and Reliance Coordinators
- UCOP – Jeff Hall, Dragana Nikolajevic, Patrick Rogers, Hillary Kalay
- UCSF CTSI – Anirvan Chatterjee , Leslie Yuan: expertise and initial funding for UC TrialQuest
- UC BRAID Contracting Working Group