CARE-Q®
Consortium for Applied Research Ethics Quality

WEBINAR

Single IRB (sIRB): A Tale of Two UCs

November 4, 2024

Continuing Education Credit Available

Link to request certificate will be posted in the chat at the end of the presentations.

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Consortium for Applied Research Ethics Quality

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Contents

Today's Overview

- UC Davis: sIRB Process
- UC Irvine: sIRB Process & Continuous Improvement

UCDAVIS

Single IRB & Reliance

John Tupin, J.D.
Director, IRB Administration

What is a Single IRB (sIRB)?

- A designated IRB serves as a reviewing and managing IRB for multiple engaged sites.
- Allows your IRB to either be the designated IRB or rely on a designated IRB

WHY WOULD I DO THAT?!

- Required by the revised common rule and soon by the FDA
- May reduce administrative burden
- Increased efficiency… if everyone communicates well
- Consistent human subject protections… hope we share the same standards

How Did we Get Here?

- 21st Century Cures Act 2016 required FDA to Harmonize with DHHS Common Rule.
- 45 CFR 46.101 …this policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the policy applicable to such research.
- Revised Common Rule 2017 45 CFR 46.114 (b) Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States
- FDA The proposed rule, if finalized, would require any institution located in the U.S. participating in **FDA-regulated cooperative research** to rely on approval by a single institutional review board (IRB) for that portion of the research that is conducted in the U.S., with some exceptions.

When is sIRB Required?

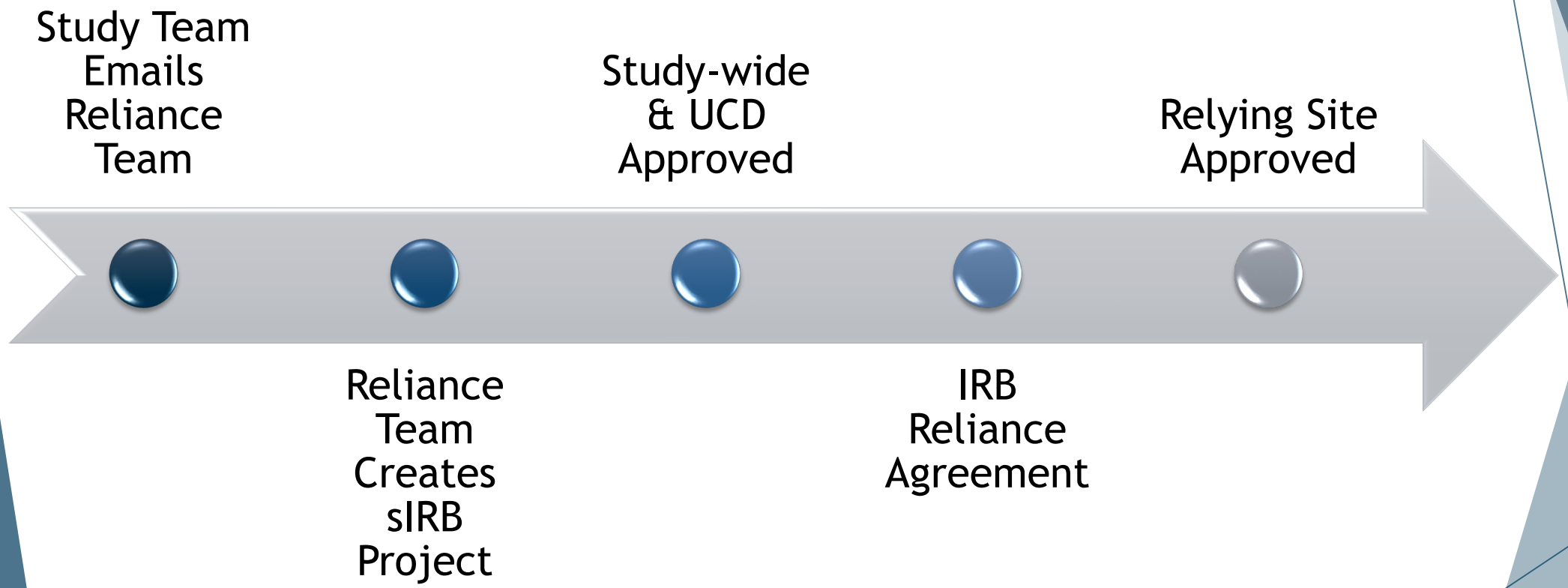
When funded by one of the 20* Federal agencies that have signed on to the Common Rule

Department of Homeland Security	Department of Education
Department of Agriculture	Department of Veterans Affairs
Department of Energy	Environmental Protection Agency
National Aeronautics and Space Administration	Department of Health and Human Services
Department of Commerce	National Science Foundation
Social Security Administration	Department of Transportation
Agency for International Development	Consumer Product Safety Commission
Department of Housing and Urban Development	Office of the Director of National Intelligence
Department of Labor	Central Intelligence Agency
Department of Defense	Department of Justice (*intends to join)

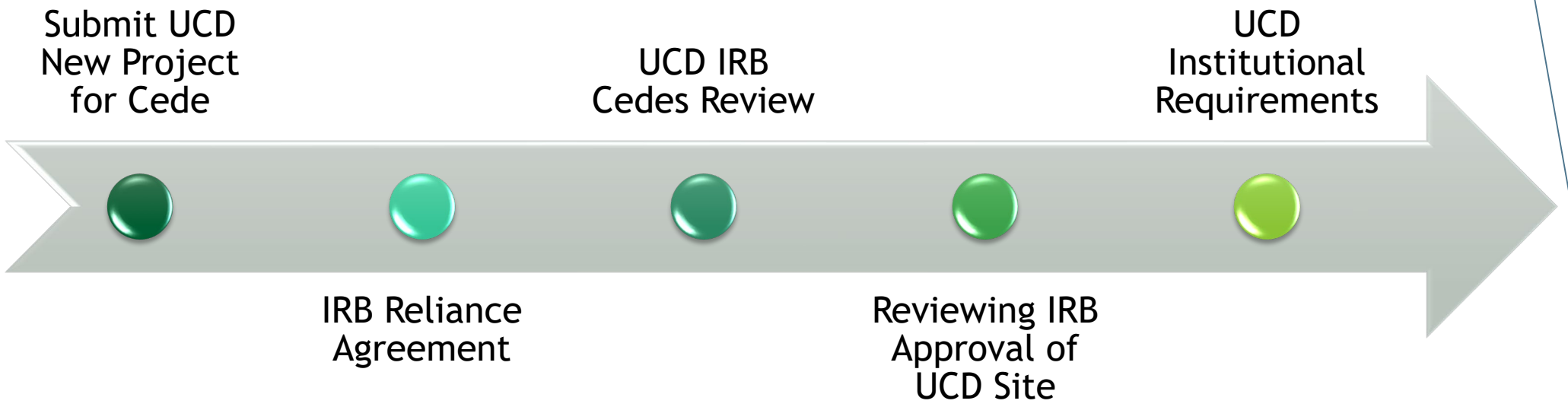
Who Should Be the Single IRB?

- Primary Awardee
- Human Subject Research
- IRB Expertise
- sIRB for All Sites

UCD as the Reviewing IRB



UCD as the Relying IRB



What are we signing up for?

- Reviewing IRB is responsible for reviewing for the criteria for approval, continuations, adverse events, post approval monitoring, modifications closure.

- Relying institution is responsible for ensuring research team reports to reviewing IRB, may receive all communications or official documents regarding study.

Local Context for UCD

- California Research Subject Bill of rights
- Moore clause – intellectual property statement
- Injury language
- Electronic signature
- California statutory requirements – privacy, OTHER?

UC Irvine

sIRB Review Process & Continuous Improvement

Rachna Basu, MS, CCRP, CIP
Assistant Director, Human Research Protections

Many Agreements & Processes

- Advarra
- Alpha Stem Cell Consortium (ASCC)
- CMU Reliance: CHOC / MemorialCare Health System (MHS) / UCI
- Fountain Valley Regional Hospital
- Individual Investigator Agreement
- Institutional Authorization Agreement
- IREx (IRB Reliance Exchange)
- Jaeb Center for Health Research Foundation, Inc (JCHR)
- Kaiser Permanente
- Long Beach Veterans Affairs (LBVA)
- National Cancer Institute Central IRB (NCI CIRB)
- National Institutes of Health (NIH) sIRB
- NEALs (Northeast ALS Consortium)
- NeuroNEXT
- SMART IRB Reliance
- StrokeNet
- UC BRAID (Biomedical, Research, Acceleration, Integration & Development)
- UC Reliance
- WIRB-Copernicus Group (WCG)

Streamlined Agreements: UCI as the Reviewing IRB

Implemented 2020

Long Beach Veterans Affairs (VA)

SMART IRB Reliance

- CMU Reliance: CHOC / MemorialCare Health System (MHS) / UCI
- National Institutes of Health (NIH) sIRB
- UC Reliance

Institutional Authorization Agreement

Individual Investigator Agreement

Streamlined Agreements: UCI as the Relying IRB

Implemented 2020

Jaeb Center for Health Research Foundation, Inc (JCHR)

Master Service Agreements

- WIRB-Copernicus Group (WCG)
- Advarra

National Cancer Institute Central IRB (NCI CIRB)

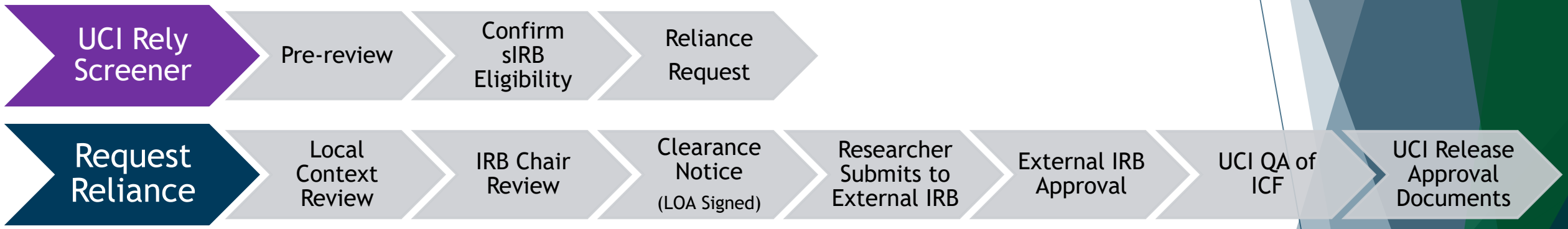
SMART IRB Reliance

- CMU Reliance
- Kaiser Permanente
- HHS/NIH
- NEALs
- NeuroNEXT
- StrokeNet
- UC Reliance
- UC BRAID

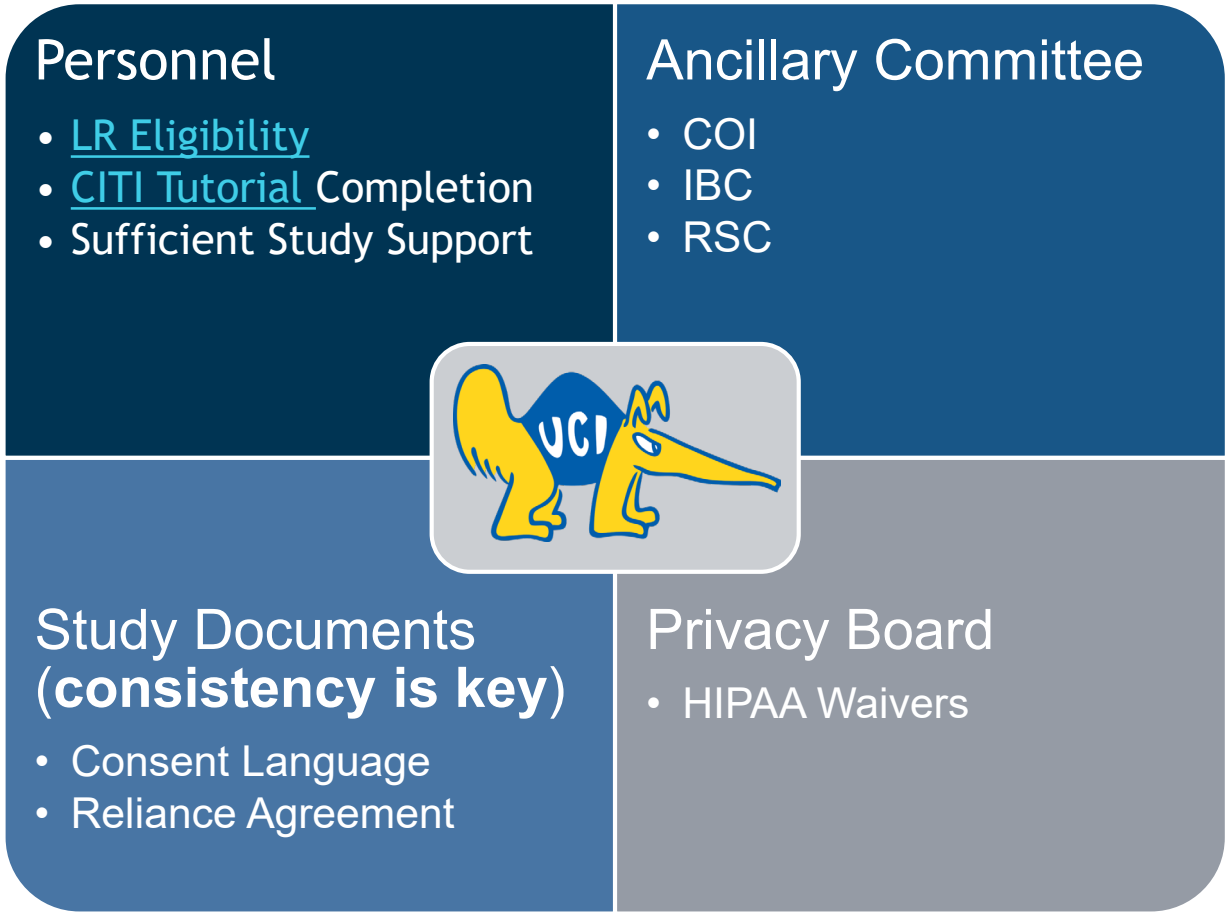
Institutional Authorization Agreement

Review Process: UCI as the Reviewing IRB

Review Process: UCI as the Relying IRB



Local Context: UCI as the Relying IRB



PI Responsibilities: Post UCI Rely

Amendments	Reportable Events	Renewals
• Personnel (UCI Heat Map) • HIPAA Waivers	• Determination Letter • Corrective actions	• Renewal Letter • Study Status • Subject Complaints • Reportable Events

Revised Process: UCI as the Relying IRB

- Remove subjectivity granting exceptions
- Align with FDA Proposed Rule
- Streamline review process

UC Campus sIRB Eligibility & Review Process

July 2024

Type of Research	Irvine[1]	Davis[2]	Los Angeles[2]	San Diego[2,3]	San Francisco[1,2]
Surgical Techniques	No	YES	YES	YES	No
Neonates	No	YES	YES	YES	No
Investigational Devices	YES[4]	YES	YES	YES	No
Gene Therapy, Transfer	No	YES	YES	YES	No
True Placebo	No[5]	YES	YES	YES	YES
Investigational Radiological Procedures, Agents	No	YES	YES	YES	No
Disclosable Financial Conflict of Interest	YES[4]	YES	YES	YES	YES
First in Human	No[5]	YES	YES	YES[3]	No
Phase 1	YES[4]	YES	YES	YES[3]	YES[4], academic IRB No[1,5]
Investigator Initiated Trial (IIT)	No[5]	YES	No	YES	YES[4]

[1] Chair review
[2] HRP staff review
[3] Medical Director or HRP Director review
[4] Case-by-case
[5] Exceptions granted

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Streamline: Align Eligibility w/ FDA Proposal

Fall 2024

Regulations or Policy	Exceptions
21 CFR 56.114 **FDA is proposing new regulatory text at § 56.114(b)(1) to require that any institution located in the United States participating in FDA-regulated cooperative research rely on approval by a single IRB for that portion of the research that is conducted in the United States.**	§ 56.114(b)(2)(i) **more than single IRB review is required by law**
	§ 56.114(b)(2)(ii) research involving a **highly specialized FDA-regulated medical product for which unique, localized expertise is required** ***Rare***
	§ 56.114(b)(2)(iii) research on **drugs that is exempt from the requirements for an IND application** under § 312.2(b)
	§ 56.114(b)(2)(iv) research on **medical devices that meets the abbreviated requirements** under § 812.2(b) **or requirements for exempted investigations** under § 812.2(c
	UCI POLICY: Investigator Initiated Trials (IITs) that do not meet the above exceptions

Streamline: Align with Other UCs

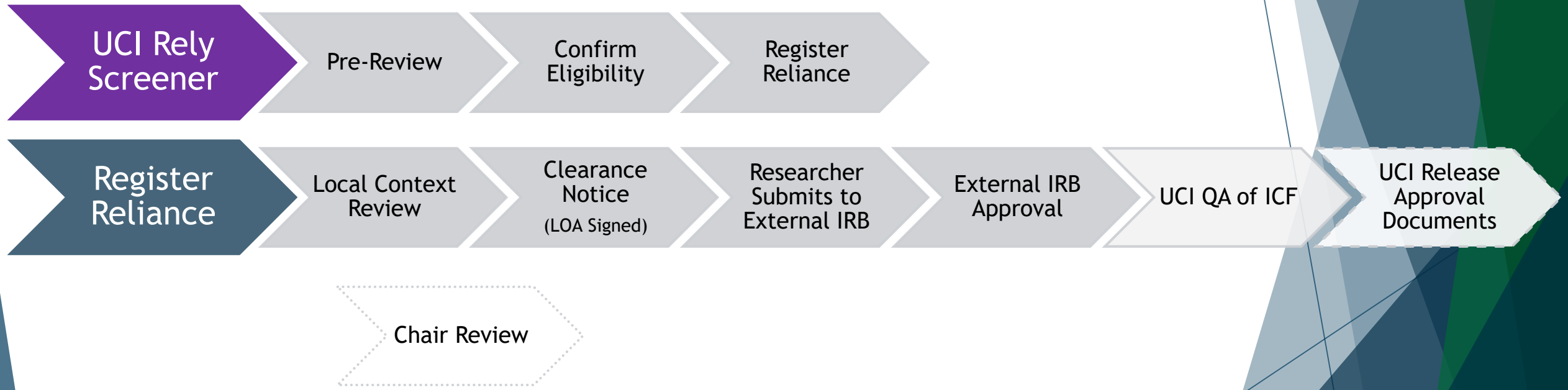
Fall 2024

Type of Research	Irvine[2,3]	Davis[2]	Los Angeles[2]	San Diego[2,3]
Surgical Techniques	YES	YES	YES	YES
Neonates	YES	YES	YES	YES
Investigational Devices	YES	YES	YES	YES
Gene Therapy, Transfer	YES	YES	YES	YES
True Placebo	YES	YES	YES	YES
Investigational Radiological Procedures, Agents	YES	YES	YES	YES
Disclosable Financial Conflict of Interest	YES[1]	YES	YES	YES
First in Human	YES	YES	YES	YES[3]
Phase 1	YES	YES	YES	YES[3]
Investigator Initiated Trial (IIT)	No	YES	No	YES

[1] Chair review
[2] HRP staff review
[3] Medical Director or HRP Director review
[4] Case-by-case
[5] Exceptions granted

Streamline: Review Process UCI as the Relying IRB

Fall 2024



Questions / Discussion

Continuing Education

To receive certificate, complete the questionnaire at the link posted in the Zoom chat:

https://ucsd.co1.qualtrics.com/jfe/form/SV_a5a7tyqW8oMKz5k

Questions? Email us at info@care-q.org