



Consortium for Applied
Research Ethics Quality

Origin

- Co-founded by Stanford University & University of California
- Need for **trust mechanisms** as single IRB (sIRB) requirements gain momentum; SMART IRB Reliance 1.0 emphasized quality assurance
- Not all UC campuses had undergone (or planned to) undergo a quality assessment
- Same for some of our CTSA partner institutions

Approach

- How do you know if your policies & procedures comply with regulations/guidance or are complete?
- Are you following your own policies & procedures?
- Also wanted to provide Quality Improvement feedback



*To build an effective,
straight-forward, collegial,
member-driven process that
certifies the operational
quality of human research
ethics committees*



Aims

- ✦ Support the *practical* application of the human research regulations
- ✦ Ensure policies & procedures are **consistent with regulatory requirements**
- ✦ Strengthen the institution's IRB **quality improvement efforts**
- ✦ Evolve the consortium through ongoing engagement among members

Process

Assessment
of IRB P&Ps

- **IRB Written Procedures Assessment**
Adapted from the OHRP/FDA IRB Written Procedures: Guidance for Institutions & IRBs

Ongoing
Engagement



IRB
Evaluation
Visit

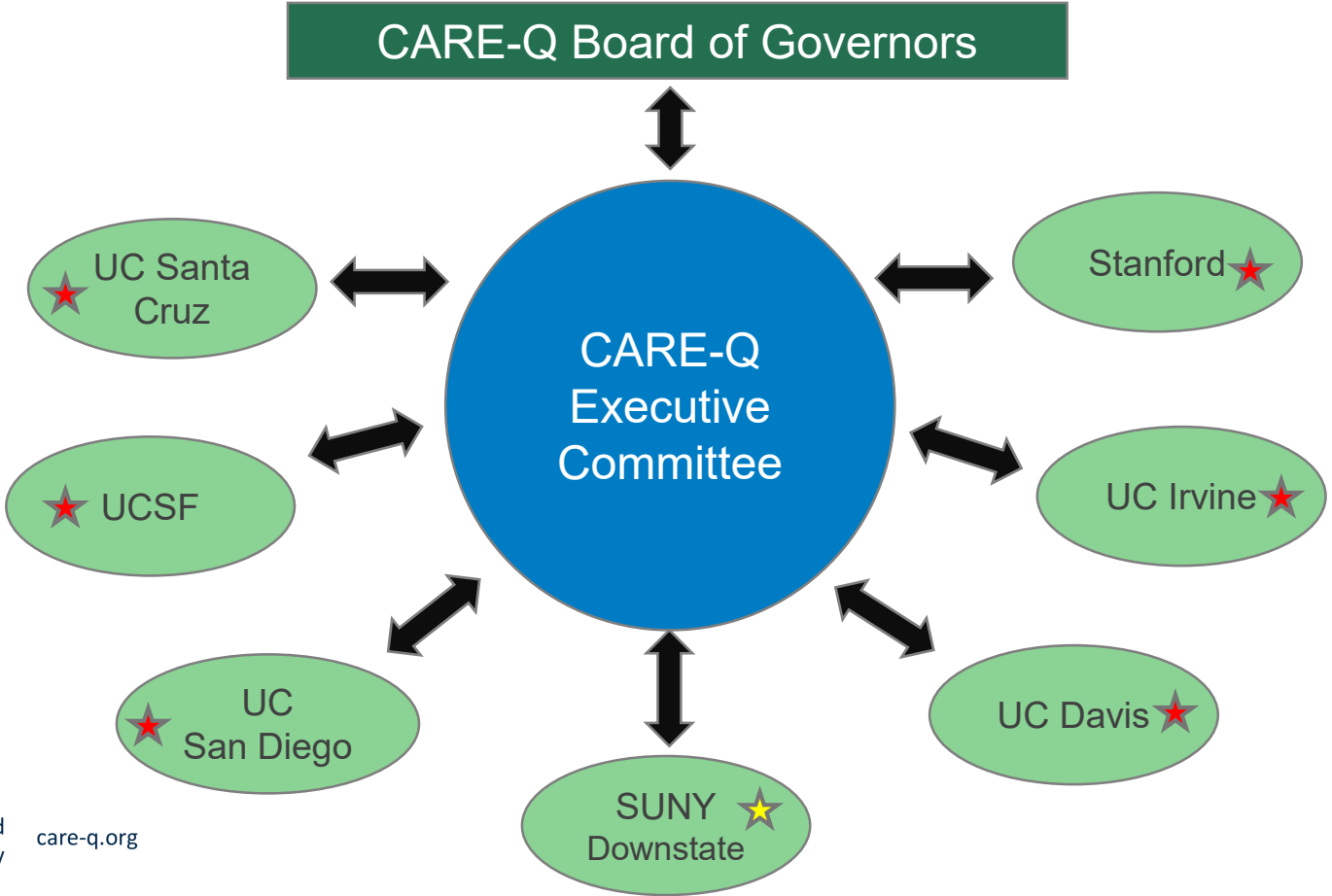
- **Assessment of IRB documentation**
- **IRB Observation**
- **Interviews**
- **Generate report to Board of Governors**

Board of
Governors
Certification



Governance

Support from UC Biomedical Research Acceleration, Integration & Development (UC BRAID) Consortium



★ CARE-Q Certified
★ Undergoing review in 2024

Certification

- **Five-year term**
 - ✓ Recertification
- **Requirement to Submit Annual Report**
 - ✓ IRB portfolio, IRB metrics
- **Ongoing CARE-Q Member Engagement | 3X/Year**
 - ✓ Foster efficiency, share best practices & address issues of common interest
- **Contribution of Reviewers**
 - ✓ Provide qualified senior staff to participate as Review Team Members
- **Dedicated In-Person IRB Evaluation Visit**
 - ✓ IRBs with 4+ registered IRBs require 1/3 of IRBs assessed within a membership term



★ Where are we now...

- Work w/ UC institutions and our local CTSA partners
- Ongoing Engagement
- Improving guidance and website

