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
Vision

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

CARE-Q Board of Governors

CARE-Q Executive Committee

UC Santa Cruz
UCSF
UC San Diego
SUNY Downstate
UC Irvine
UC Davis
Stanford

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

CERTIFIED INSTITUTIONS

UCIrvine
University of California · Irvine
Stanford University
UC Santa Cruz
UCSF

UC Davis, UC San Diego, SUNY Downstate undergoing review in 2024