



# CARE-Q

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Consortium for Applied  
Research Ethics Quality

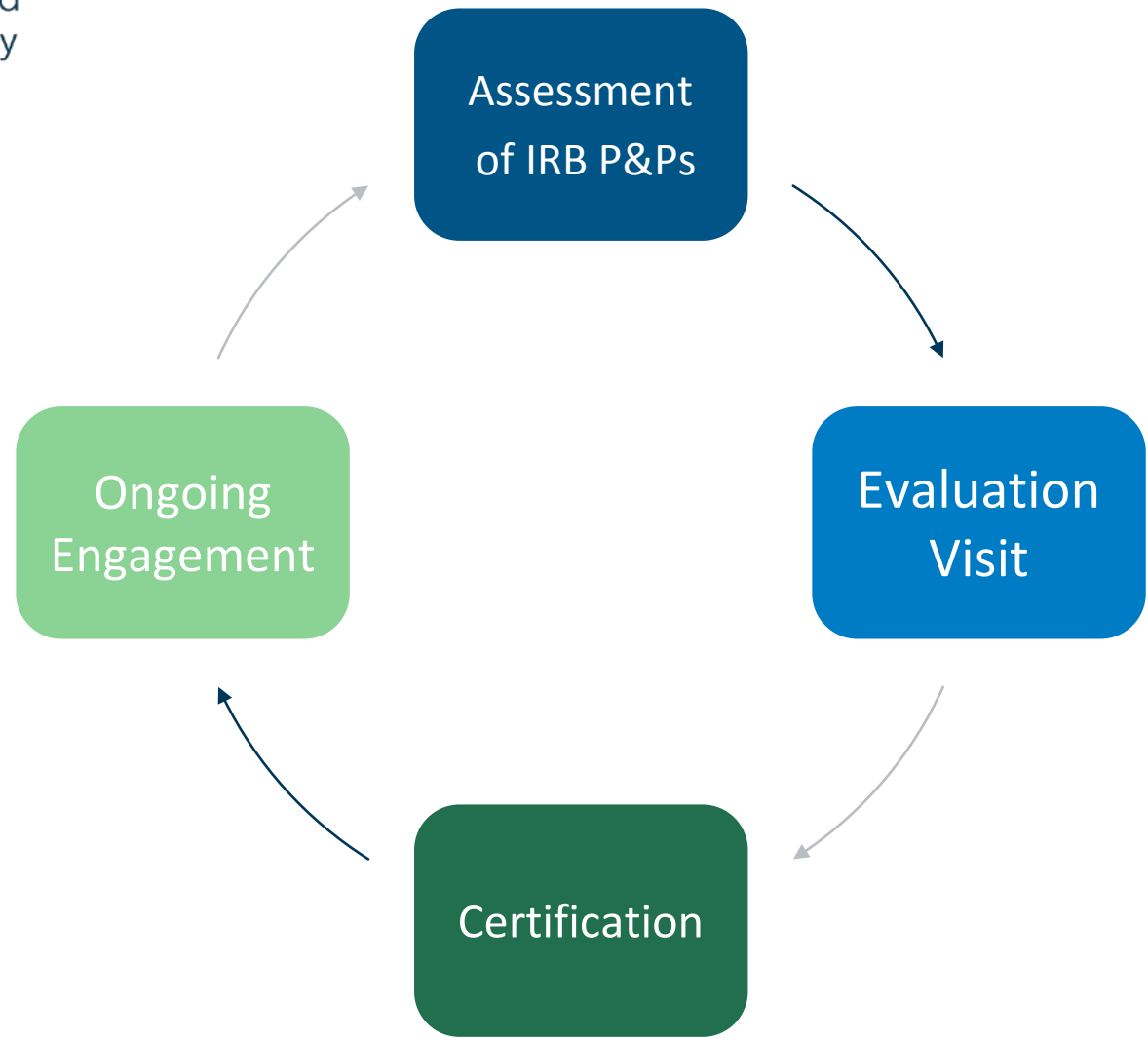
# What is CARE-Q™

- ✦ Grassroots effort initiated by UCs and Stanford to certify Institutional Review Boards (IRB)
- ✦ Addresses the following:
  - Does the IRB have P&Ps to address OHRP and FDA regulations/guidance?
  - Does the IRB follow their P&Ps when reviewing human subjects research/clinical investigations?
  - Is the IRB process effective and efficient?



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[care-q.org](http://care-q.org)

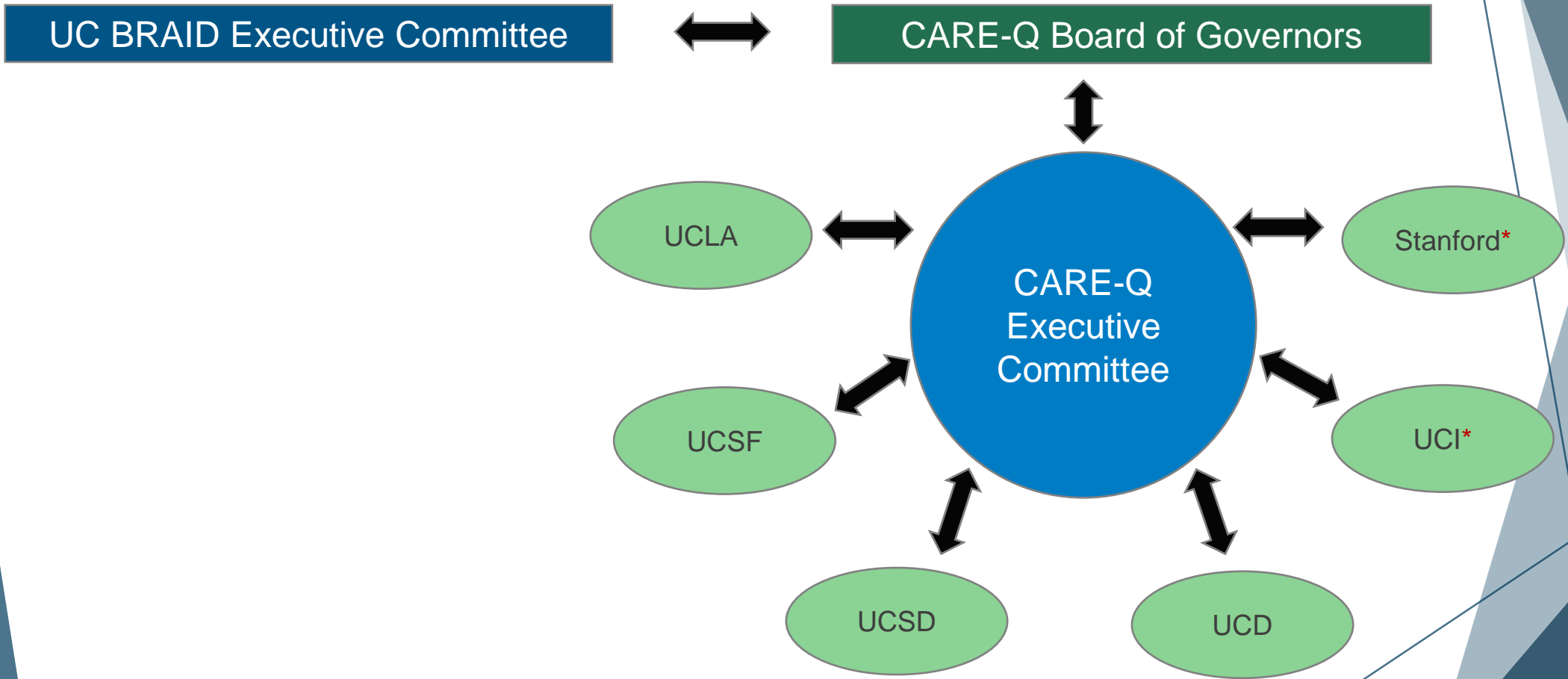


# Membership Includes...

- ✦ **Membership** - five-year term; recertification
- ✦ **Submission of Annual Report** – volume and metrics
- ✦ **IRB Evaluation Visit** – IRBs with 4+ registered IRBs require 1/3 of IRBs assessed within the membership period
- ✦ **Ongoing Engagement** - foster efficiency, share best practices, and address issues of common interest
- ✦ **Contribution of Reviewers** - Provide qualified senior staff to participate as Review Team Members



# CARE-Q Governance



\* CARE-Q Certified



# CARE-Q<sup>TM</sup> Board of Governors

- ✦ **Gary S. Firestein, MD**, Director of the Clinical and Translational Research Institute, Dean and Associate Vice Chancellor of Translational Medicine and a Professor of Medicine at UC San Diego School of Medicine
- ✦ **Elizabeth Boyd, PhD**, Vice President of Research Administration, Fred Hutchinson Cancer Research Center
- ✦ **Mark Cullen, MD**, Director, Center for Population Health Sciences, Senior Associate Dean for Research at the Stanford School of Medicine
- ✦ **Susan Rose, PhD**, Executive Director of the Office for the Protection of Research Subjects, University of Southern California
- ✦ **Ernie Prentiss, PhD**, former Executive Chair of Institutional Review Board and Institutional Official, University of Nebraska Medical Center



# CARE-Q<sup>TM</sup> Founding Members

- ✦ Karen Allen, UCI
- ✦ Lisa Denney, Stanford University
- ✦ Laurie Herraiz, UCSF,
- ✦ Kip Kantelo, UCSD,
- ✦ Eric Mah, UCSD
- ✦ Chris Ryan, formerly w/UCSF

# Current Status

- ✦ Certified Institutions:

- UC Irvine

- **Stanford University**

- ✦ Working with other UCs to prepare and apply for certification

- ✦ Developing...

- Guidance for IRBs

- Guidance for Review Team Members

- Website



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# Future Plans

- ✦ Present at Public Responsibility in Medicine and Research National (PRIM&R) Conference in November 2018
- ✦ Continue to work with UCs to apply for certification
- ✦ Expand to UC BRAID community partners
- ✦ Continue to refine program



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