



FREQUENTLY ASKED QUESTIONS (FAQs)

What is CARE-Q?

- A quality assurance initiative for IRB programs developed by University of California and Stanford University
 - Process is low-cost, peer-driven, collegial, and pragmatic
 - Developed to satisfy SMART IRB quality assessment requirements
 - Focused specifically on IRB regulations; no shadow or made-up requirements

Why should an institution seek CARE-Q certification?

- Ensure that IRB’s written procedures follow current regulatory requirements
- Ensure that IRBs follow their written procedures via IRB meeting observation
- Identify potential for greater efficiency in IRB office workflow
- Document compliance with regulatory requirements
- Document quality assessment for reliance purposes
- Receive a report on best practices recommendations
- Become integrated into a collegial peer network with continuing education and support
- Support regular engagement to learn how other institutions address common issues

Who can apply for certification?

- Any IRB office is eligible to apply

What are the costs of certification?

ACADEMIC/UNIVERSITY IRBs		
Program Size	Application Fee	Annual Fee
Large*	\$5,000	\$5,000
Small or Medium	\$2,500	\$2,500

NON-ACADEMIC IRBs		
Program Structure	Application Fee	Annual Fee
1-3 IRBs	\$2,500	\$2,500
4 IRBs	\$5,000	\$5,000
Each additional IRB	\$1,500	\$1,500

Each CARE-Q certified institution will make qualified senior staff available to conduct at least two reviews of other applicant institutions as in-kind effort. On-going engagement and participation in Consortium activities is required in accordance with membership agreement. The first annual fee is one year following certification.

*A large program is defined as an NIH Clinical & Translational Science Award Hub or NCI Designated Cancer Center

How does an IRB office apply for CARE-Q Certification?

- Contact the CARE-Q team at info@care-q.org to discuss application
- Review CARE-Q membership terms and application for certification
- Submit signed membership agreement and application
- Complete written procedures self-assessment (WPSA)
- Submit WPSA with supporting documents

What is involved in the review process?

- CARE-Q selects a team of 2-3 reviewers from CARE-Q community and member institutions
- CARE-Q reviewers assess application, WPSA, and documentation
 - May provide feedback and queries
- CARE-Q team initiates and conducts assessment visit
 - IRB meeting observation(s) and minutes review
 - Interviews with staff, IRB members, faculty, and other stakeholders
 - Review selected IRB applications
- CARE-Q team prepares report summarizing strengths, makes suggestions for improvement and if appropriate, provides recommendation to Board of Governors for certification
- CARE-Q Board of Governors reviews report and issues certification, if appropriate

How long does it take to get certified?

- The time it takes depends on a number of factors including the maturity of the IRB program and the sophistication and breadth of written procedures; typically this takes 6-12 months from the submission of the completed application.

What happens after certification?

- IRB office is expected to participate in regular CARE-Q meetings and engagement workshops
- IRB office is expected to provide qualified staff for CARE-Q assessments as learning and sharing opportunities
- IRB office submits brief annual report to maintain certification
- IRB office recertifies every 5 years which includes another program visit

Contact CARE-Q:

Email: info@care-q.org

Web: care-q.org