Cambridge Health Alliance (CHA) is dedicated to supporting safe, compliant, high quality research.

To help our researchers achieve that goal the CHA Office of Research Administration offers services through our research QA/QI program. The program's concentration is on education and supporting researchers involved in the conduct of human subject research.

Continuous QA, QI, and monitoring of ongoing research by the study team and internal and external monitors enhance the CHA research enterprise and promote a culture of compliance and subject safety.

Services Available:

- Guide and assist Investigators on study start-up.
- Help Investigators prepare for an external inspection, *e.g.*, FDA, sponsor.
- Provide research education presentations.
- Help PIs develop and implement educational programs and tools to effectively train research team members in human research and related activities.
- Advise researchers on how to create and maintain QA/QI review of their research.
- Recommend education and process enhancements that will raise performance standards related to the conduct of human research.

Whom to Contact
(617) 806-8702

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CHA Cambridge Health Alliance

A teaching affiliate of HARVARD MEDICAL SCHOOL

Research Quality Assurance/ Quality Improvement Program

What is QA/QI?

QA/QI programs help to ensure researcher and institutional compliance with Federal and state regulations governing human research and institutional policies. Such programs assure subject safety, scientific integrity of a research study, and improve overall study performance.

What's involved in a QA/QI audit?

Periodically our QA/QI personnel perform random internal audits of human research conducted by CHA personnel. The following are typically as part of an audit:

- Study record review.
- Review of study procedures; ensure they are performed in accord with the IRB-approved protocol, Federal regulations, and CHA policies.
- Observation of the informed consent process.
- Review of on-site record keeping.

For links to the templates and other resources visit the QA/QI page on the IRB website:

http://www.challiance.org/Academics/InstitutionalReviewBoard.aspx

Additional Resources

HARVARD CATALYST
THE HARVARD CLINICAL AND TRANSLATIONAL SCIENCE CENTER

CHA is a participating institution of the Harvard Catalyst, a consortium founded in 2008 of Harvard hospitals and resources dedicated to advancing clinical research.

The Catalyst Regulatory Knowledge and Support Program provides numerous resources, including those related to QA/QI, education, and data protection. The Catalyst *Clinical Investigator Recommended Tools (CIRT)* is a list of web tools and resources clinical investigators can use to manage their research more efficiently and easily. As a Harvard Catalyst affiliate, CHA researchers are strongly encouraged to avail themselves of the many Harvard Catalyst research resources.

Tools to help Investigators

To assist our researchers, we have developed numerous guides and tools to help organize and monitor research, including:

Reference templates:

- Minimal Risk Study Start-up
- CHA Regulatory Binder
- PI Self-Assessment Checklist

Study management templates:

- IRB Submission Tracking Log
- Monitoring Log
- Research Education Training Tracking
- Research Team Task Delegation Log
- Serious Adverse Event/ Unanticipated Problem Log

Subject-related templates:

- Subject Screening
- Subject Enrollment Log
- Subject Payment

Drug/Device accountability templates

CHA researchers are strongly encouraged to use these templates or create their own to manage their studies.