EQuIP: Program & Services

Education and Quality Improvement Program @ Children's Hospital Boston

EQuIP's Mission

EQuIP's mission is to improve policies and practices in clinical research at Children's Hospital, Boston with the aim to continually maximize the protection of human subjects, and to promote good clinical practices regarding research conduct and documentation.

EQuIP aims and goals are created to educate and support the research community to safely conduct compliant clinical research.

Please feel free to contact us with questions or comments.

EQuIP Staff and Contact Info

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www.childrenshospital.org/research/equip

EQuIP Services

- **Study Reviews** (required or optional)

  A one-time, confidential, full or partial review of on-going studies to ensure compliance with applicable regulations and policies, and to evaluate study conduct, organization, record-keeping and documentation. The EQuIP office aims to help research teams implement tools and strategies to improve identified 'problem' areas.

  Reviews are required when randomly selected or IRB-requested, but may be requested by PI/staff (e.g. ensure compliance, during staff changes, to prepare for outside audit).

- **Study Pre-Review and Set-up** (optional)

  Prior to initiating a study, upon request, the EQuIP office will review any study start-up materials (e.g. regulatory binder, case report forms) and will work with the PI/staff to identify the regulations and policies applicable to the study. When possible, the EQuIP office will provide educational materials, support and study tools.

- **New/Transfer Investigator Pre-Reviews** (required)

  New Investigators (conducting clinical research for the first time) and Transfer Investigators (conducting clinical research at CH for first time) must meet with the EQuIP office prior to IRB approval to review applicable resources, regulations and CH policies.

- **Sponsor-Investigator (IND/IDE Holders) Pre-Review** (required)

  Sponsor-Investigators (IND/IDE holders) are required to meet with EQuIP prior to IRB approval to review the additional responsibilities of a sponsor versus the responsibilities of an investigator.

- **Study Monitoring for Sponsor-Investigators** (optional)

  Upon request, on-going monitoring services as required by Federal regulations for Sponsor-Investigators IND/IDE studies is available for fee.

- **Talks/Presentations**

  Upon request, the EQuIP staff is available to present various topics about research compliance and good clinical practices.

- **Educational Initiatives and Materials**

  Educational initiatives and materials are continuously developed and disseminated to assist the research community. Guidelines and templates are available on the EQuIP website.

Study Tools & Templates

The EQuIP website offers many study tools and templates to download and customize for your study. Guidance documents are available for most templates.

- Subject Screening Log and Guidance
- Subject Enrollment Log and Guidance
- Recruitment Log and Guidance
- Staff Signature Log and Guidance
- Monitoring Log and Guidance
- CCI Tracking Log and Guidance
- Document Log and Guidance
- Subject Visit Checklist
- Training Log and Guidance
- Document Log and Guidance
- Consent Revision Log and Guidance
- Roles & Responsibility Logs and Guidance
- Training Documentation Logs and Guidance
- Remuneration Vouchers

Study Regulatory Binders

EQuIP has developed a pre-assembled, template Study Regulatory Binder which is available free to CHB research teams (one per protocol).

The Study Regulatory Binder contains customized, pre-labeled sections to help PIs and research staffs identify, maintain and organize all required and useful study documents and correspondence in one central location.

Contact the EQuIP Office to request a Study Regulatory Binder for your study.

Remember, each study is different, so each binder will be different. Tailor your study binder to fit the needs of your study.

EQuIP staff is available to provide one-on-one guidance for study binder set-up. If interested, contact the EQuIP Office to set-up a meeting.