CONFIDENTIAL: Study Review Final Report

Principal Investigator:		Department/Division:	
Protocol Number(s):		Source of Funding:	
Protocol Title:			
Date of Review:		Type of Selection:	☐ Randomized Selection ☐ PI Requested Review
Prepared by:		Questions? Contact:	

■ It is the responsibility of the Principal Investigator:

1. To thoroughly review, assess and respond to the findings in this report
2. To share and disperse copies of the report with appropriate research staff
3. To address all *Required Corrective Actions* immediately upon receipt of report
4. To consider all *Recommended Actions* by choosing one of the following:

☑ Accept Action	Recommendation deemed useful and action implemented. Explain how.
☑ Postpone Action	Recommendation deemed useful, but will be implemented later in study or will be applied to future studies. Explain reason for postponement.
☑ Decline Action	Recommendation deemed impractical or unfeasible for this study as well as future studies. Please provide reason.
☑ Acknowledge	An observation may be noted in which no follow-up action is necessary. The PI should acknowledge the observation, or provide clarification.

■ When all required actions are addressed and recommended actions considered, the PI must:

1. Complete the attached Principal Investigator Response Form
2. Sign and return the complete PI Response Form within 1 month of receipt to:

EQuIP Office
333 Longwood Ave, 4th Floor

■ Once the EQuIP office determines all required and recommended actions have been satisfactorily addressed, the review will be formally closed.

Please note that this report is CONFIDENTIAL. The details specific to this report will not be shared with the IRB or other groups unless otherwise noted in this report. In such events, the study PI will be notified before any information is shared. A copy will be kept in a study specific file in the EQuIP Office and will be available only to the PI, and the EQuIP staff.

I. Study Review Timeline

Initial Meeting
Study & Subject Review
Final Meeting

II. Study Review Summary *overview of areas reviewed*

Areas Reviewed:	**Action(s) Required**	**Action(s) Recommended**
Regulatory Documentation	☐	☐
CCI Review and Documentation	☐	☐
Informed Consent Process & Documentation	☐	☐
Study Record Keeping & Documentation	☐	☐
Protocol Adherence & Deviation Reporting	☐	☐
Serious Adverse Event Reporting	☐	☐
Recruitment Method/Compensation	☐	☐
Research Staff, Training & Education	☐	☐

III. Notable Best Practices *overview of study strengths*

Part A. Required Corrective Actions

A1. Category/Area	
Observation	
Required Action	
Reason	

A2. Category/Area	
Observation	
Required Action	
Reason	

A3. Category/Area	
Observation	
Required Action	
Reason	

A4. Category/Area	
Observation	
Required Action	
Reason	

Part A. Required Corrective Actions

A5. Category/Area	
Observation	
Required Action	
Reason	

A6. Category/Area	
Observation	
Required Action	
Reason	

A7. Category/Area	
Observation	
Required Action	
Reason	

A8. Category/Area	
Observation	
Required Action	
Reason	

Part A. Required Corrective Actions

A9. Category/Area	
Observation	
Required Action	
Reason	

A10. Category/Area	
Observation	
Required Action	
Reason	

A11. Category/Area	
Observation	
Required Action	
Reason	

A12. Category/Area	
Observation	
Required Action	
Reason	

Part B. Recommended Actions

B1. Category/Area	
Observation	
Recommendation	
Reason	
B2. Category/Area	
Observation	
Recommendation	
Reason	
B3. Category/Area	
Observation	
Recommendation	
Reason	
B4. Category/Area	
Observation	
Recommendation	
Reason	
B5. Category/Area	
Observation	
Recommendation	
Reason	
B6. Category/Area	
Observation	
Recommendation	
Reason	

Best Practices

The following are some best practices that the EQuIP office encourages all research teams to implement. Please review the practices outlined below and the referenced guidance documents/policy. If these practices would benefit the research project and team, please implement as appropriate.

Staff Signature Log	The Staff Signature Log lists approved staff, with their original signatures, and the timeframe that the staff was on study. Reference EQuIP Tools & Templates: • Staff Signature Log Guidance • Staff Signature Log
Roles & Responsibilities Log	The Roles & Responsibilities Log outlines staff roles and responsibilities, including time on the study and which tasks have been delegated to the team member. Reference EQuIP Tools & Templates: • EQuIP Roles & Responsibilities Log Guidance • Roles and Responsibilities Log v.1 • Roles and Responsibilities Log v.2
Training Log	The Training Documentation Log serves to provide documentation that adequate training of the research staff has been conducted. Reference EQuIP Tools & Templates: • EQuIP Training Log Guidance • Training Log v.1 • Training Log v.2 • FDA Guidance: Protecting the Rights, Safety, and Welfare of Study Subjects - Supervisory Responsibilities of Investigators
Remuneration Log	The Remuneration Log and Receipts provide documentation of remuneration obtained by study staff and distributed to research subjects. Reference EQuIP Tools & Templates: • Remuneration Log • Remuneration Receipts • CCI Policy "Providing Remuneration to Research Subjects"
Informed Consent Form	Ensure all subjects receive a *copy of the signed* informed consent form. Ensure the subject/parent dates their own signature on the consent form. Do not date the signature of the subject/parent. The consent process, including any questions the families had and the date that consent was obtained, should be documented in the study documents. If a subject/parent signs the consent the same day study participation begins, there must be documentation to clarify that the consent was obtained *prior* to any study activity. Reference: • FDA Information Sheet: A Guide to Informed Consent • CCI Policy: Documentation of Informed Consent/Parental Permission/Assent

Just to Note

Scientific Review	The summaries of each Department/Division's scientific review process as well as a list their authorized signors can be found on the CCI website, under *Scientific Review*. * Please note: as of June 1, 2005, the CCI will return any new protocol application that do not include documentation of the scientific review, at minimum, the scientific reviewer notes and related correspondence must be included.
Continuing Review Reminder Notices & Amendment Summaries	Prior to each upcoming continuing review (protocol expiration), the CCI/IRB sends out 3 reminder notices, starting approximately 2.5 months before the protocol expiration date. Attached to each reminder notice, is an amendment summary for the protocol. Please ensure the information is correct, and submit back to the CCI/IRB with the application submission.
Outside Monitoring	Please note that for all research studies, any copies of outside monitoring reports, Data Safety Monitoring Reports, FDA Annual (or other) reports, and similar reports should be submitted to the IRB/CCI for their files.
Filing Study Documents	CH/CCI policy now requires investigators to specify in the protocol application and informed consent where each specific document will be filed and who will have access to these documents during and after the study. Guidance is provided on the CCI website in the "Storage of Research Data and Informed Consent Documents" policy.
Translation of Informed Consent Documents	The CCI has funds set aside to assist PIs with the translation of consent forms through interpreter services. To request that a consent form be translated, complete the form "Request for Translation of Research Informed Consent Documents" and submit to the CCI.
CCI Reviewer Worksheets Available	The CCI Reviewer Worksheets that the CCI members use to review new submissions, continuing reviews and amendments are available for the CHB research community to review and use to help prepare their submissions.
Registration of Clinical Trials	**Is your clinical trial registered with an ICMJE approved registry?** In September 2004, the International Committee of Medical Journal Editors (ICMJE) published a statement saying that they would only publish clinical trials that were registered on a publicly accessible registry. Currently, www.clinicaltrials.gov which is operated by the National Library of Medicine (NLM), is the only registry that meets the required elements of registration. Please see the CCI Website for more information
Laptop Encryption Policy	As of October 1, 2008, CHB employees and associated personnel that use a laptop for Children's related work or research are required to install encryption software. You may contact the ISD/Help desk or install the software yourself. Go to http://ehelp.tch.harvard.edu/Encryption.html and follow the instructions.