Catalyst and Dana Farber Cancer Center Reliance Agreements

Policy

In accordance with **46.114** Children's Hospital may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort. This is typically done through the use of a reliance agreement where Children's relies on another institution or another institution seeks to rely on Children's. If Children's agrees to rely on another institution it will amend the assurance to reflect this agreement. Even when a reliance agreement is signed between institutions, it is acknowledged that each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this human subject protection policies . Children's has two master reliance agreements which are described below

Harvard Clinical and Translational Science Center (Catalyst)

Harvard Catalyst was founded in May 2008 with a five year, $117.5 million grant from the National Institutes of Health (Clinical and Translational Science Center, CTSC) and $75 million dollars from the Harvard University Science and Engineering Committee, Harvard Medical School, Harvard School of Public Health, Beth Israel Deaconess Medical Center, Brigham and Women's Hospital, Children's Hospital Boston, Dana-Farber Cancer Institute and Massachusetts General Hospital.

The Harvard Catalyst Regulatory Knowledge and Support Program and the institutional review boards (IRBs) of Beth Israel Deaconess Medical Center Brigham and Women's Hospital, Children's Hospital Boston, Dana-Farber Cancer Institute, Harvard Medical School, Harvard School of Public Health, Harvard University Faculty of Arts and Sciences, Joslin Diabetes Center and Massachusetts General Hospital have entered into a Common Reciprocal Reliance Agreement. This agreement creates a framework whereby investigators who wish to conduct a multi-center clinical study can request that the IRBs of the participating centers rely on the review of one center's IRB. Each participating IRB makes the decision on a protocol-by-protocol basis whether to rely on the review of another IRB (to cede the review) on a study or to conduct its own full review. In order to request ceded review, investigators must complete and submit a Cede Review Form. The Administrative Directors and Chairs of the involved institutions will determine fi they will accept the reliance agreement.

Dana Farber/ Harvard Cancer Center

Children's Hospital is one of the institutions participating in the Dana Farber Harvard Cancer center. As such all Cancer related research will be reviewed through the DFCI IRB. Children's Hospital also shares a scientific review committee for the department of hematology /oncology. This chart summarizes which protocols need to be submitted through the DF/HCC or CH scientific review and IRB review process.

How to determine which (CHB or DF/HCC) scientific review committee, IRB, and DSMC are appropriate for studies conducted in the Division of Pediatric Hematology/Oncology# (abbreviations defined below)

Type of trial	Scientific review	IRB	Data safety and monitoring responsibility
Pediatric oncology	DF/HCC PSRC	DF/HCC IRB-G	DF/HCC
Adult and Pediatric hematology-oncology	DF/HCC SRC or PSRC	DF/HCC IRB-G	DF/HCC
Transplant protocols: cancer	DF/HCC PSRC	DF/HCC IRB-G	DF/HCC
Transplant protocols: non-cancer	PSRC or Catalyst*	CHB IRB	CHB
Genetic therapies: cancer	DF/HCC PSRC	DF/HCC IRB-G	DF/HCC
Genetic therapies: non- cancer	PSRC or Catalyst*	CHB IRB	CHB
Greater than minimal risk non-malignant hematology – conducted at CHB only	DF/HCC PSRC or Catalyst	CHB IRB	CHB
Non-malignant hematology, multi-site within the DF/HCC institutions	DF/HCC SRC or PSRC	DFCI (non-cancer center)	DF/HCC
Minimal risk non-malignant hematology –conducted at CHB only	Pediatric faculty will forward directly to the Investigator identified by CHB as the reviewer for these protocols (A.Cantor).	CHB IRB	CHB
Any protocol (minimal risk and therapeutic) that is for patients (including oncology patients but not exclusive to oncology patients) that is looking at a non-oncology intervention or endpoint (eg new treatment for fungemia; psychological outcomes after ICU hospitalization)**	Scientific review in department conducting the research	CHB IRB	CHB
Any protocol (minimal risk and therapeutic) for oncology patients *exclusively* that is looking at a non-oncology intervention or endpoint	DF/HCC PSRC	DF/HCC IRB-G	DF/HCC

(eg new PET scan process for patients with tumors; surgical outcomes after limb sparing procedures for extremity osteo)			
Observational studies in pediatric oncology, including biology studies (when separate from clinical trials), biobanking protocols, chart reviews, genetic studies, surveys, outcomes or health services research.	DF/HCC PSRC	DF/HCC IRB-D	None
Psychosocial or behavioral intervention studies involving pediatric oncology patients only	DF/HCC PSRC	DF/HCC IRB-D	DF/HCC

*If cell manipulation at DFCI GMP facility, requires agreement of reliance by DFCI IRB on CHB IRB review (contact Dr. Jerome Ritz)

**Guideline; consultation with Susan Kornetsky (CHB) and Michele Russell-Einhorn (DFCI) is suggested prior to submission.

#DF/HCC=Dana Farber/ Harvard Cancer Center

CHB=Children's Hospital Boston

SRC= scientific review committee (adults)

PSRC=pediatric scientific review committee

*PSRC is same committee as DF/HCC PSRC, but does not include DFHCC follow-up (from investigator standpoint, submission is via usual process)

Document Attributes

Title	Detemining Whether a Protocol Requires Children's Hospital or Dana Farber Review		
Author	**Susan Kornetsky**	**Dates Reviewed/ Revised**	10/29/2009 03/19/2010
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