



IRB Office
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April 26, 2015

Mohsen Karimi
Connecticut Children's Medical Center
282 Washington Avenue
Hartford, CT

CCMC IRB#: 15-031

Study Title: Blood Conservation Cardiac Surgery in Pediatrics: A Retrospective Review of Blood Conservation and Non-Conservation Practices

Review/Type: Review of New Protocol

IRB Approval Date: April 22, 2015

IRB Approval Valid Thru: April 21, 2016

Progress Report Due Date: March 21, 2016

On April 22, 2015, an Institutional Review Board of the Connecticut Children's Medical Center approved the above-referenced human subjects' research.

As the Principal Investigator, you are responsible for complying with reporting requirements as described in the HRPP Standard Operating Procedures that are posted on the HRPP website. For example, you are responsible for reporting unanticipated problems involving risk to subjects or others.

You are also responsible for obtaining IRB review and approval in writing before changes are made to approved protocols or consent forms unless the change is necessary to eliminate an immediate hazard to the subject (in which case the IRB must then be notified at once).

Please note, when applicable, Principal Investigators are responsible for ensuring that IRB approval has been obtained and maintained at any collaborating sites involved in the research.

IRB Determination(s):

Main Study: 45 CFR 46.404

45 CFR 46.110 (5)

Overall Risk Level: Minimal Risk

HIPAA: The IRB has granted a waiver of Individual Authorization under 45 CFR 164.512(i)(2); in accordance with information provided in the HIPAA section of the IRB Application.

Consent: The IRB has granted a waiver of Informed Consent under 45 CFR 46.116(d); in accordance with the information provided in the Consent section of the IRB Application.

Assent: Not Applicable to this research.

Parental Signatures: Not Applicable to this research.

Current Approved CCMC Enrollment: 500

Approved Study Personnel:

Role	Name
Principal Investigator	Mohsen Karimi
Co-Investigator	Carrie Griffin Linthicum; Paul Kirshbom MD



Carrie Schmedding, BS, MS. CIP
IRB Manager, Human Research Protection Program

*All IRB correspondence addressed to the IRB Office should include your IRB protocol #.
Connecticut Children's DHHS Federal-Wide Assurance Number is: FWA00004706*