



**Children's Mercy**

HOSPITALS & CLINICS

www.childrens-mercy.org

**Cardiovascular Surgery**

2401 Gillham Road

Kansas City, Missouri 64108

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Gary K. Lo  
Professor of  
Joseph Boe  
Section of C  
Phone (816)  
Fax: (816) 8  
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Dear CHSS Member:

Enclosed please find the IRB Application and IRB Approval for CHSS Studies for The Children's Mercy Hospital in Kansas City. As each of you know, with the implementation of the Health Insurance Portability Accountability Act of 1996 on April 14, 2003, IRB approval must be obtained for all patient related studies, including retrospective reviews. The packet you have received was formulated to be used as a template by any CHSS institution. The individual components of the packet will be explained.

Tab One is the actual IRB approval letter. It is customary for the IRB of one institution to acknowledge or even accept the IRB approval of another institution, especially if an institution is struggling with the approval process.

Tab Two is the IRB application packet specific to the Critical Left Ventricular Outflow Tract Obstruction study. You can use this in your own IRB application by simply listing your own institution anywhere The Children's Mercy Hospital is listed, and by identifying your own principal and sub-investigators. This application includes the CHSS Patient Enrollment and Patient Follow-up Forms.

Tab Three is the IRB application packet specific to the Pulmonary Conduit study. You can use this in your own IRB application by simply listing your own institution anywhere The Children's Mercy Hospital is listed, and by identifying your own principal and sub-investigators. This application includes the CHSS Patient Enrollment and Patient Follow-up Forms.

Tab Four is the IRB application packet specific to the Tricuspid Atresia study. You can use this in your own IRB application by simply listing your own institution anywhere The Children's Mercy Hospital is listed, and by identifying your own principal and sub-investigators. This application includes the CHSS Patient Intake and Patient Follow-up Forms.

Tab Five is the consent form, which is also institutionally specific. This consent form can also be used by you and your institution by simply changing the institutionally specific items (name of institution, investigators, etc.).

Tab Six is the Data Use Agreement which must be signed by your institution and CHSS Data Center. This only needs to be signed once, and does not need to be submitted for each individual patient. Please note though that in order to utilize a Data Use Agreement,



# Children's Mercy

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Office for Research Integrity

Pediatric Institutional Review Board

2401 Gillham Road, Suite HHC600

Kansas City, Missouri 64108

Phone: (816) 234-3879

February 3, 2006

Gary Lofland, MD  
Surgery  
Children's Mercy Hospital

RE: IRB# 03 03-033E: Congenital Heart Surgeons' Society (CHSS) Studies in Congenital Heart Disease (CHSS- Hosp for Sick Children, Toronto, Ontario, Canada)

Dear Dr. Lofland:

Thank you for providing us with the information necessary to review the progress of the above referenced study.

The continuing review and monitoring report for the project was given expedited review by the Children's Mercy Hospital Pediatric Institutional Review Board in compliance with 45 CFR 46.110.(F) (5). The protocol has been reapproved for continuation of another year. Approval will be valid through 2/2/2007.

Enclosed is a copy of the approved permission/assent form for your study. The stamp at the top of each page indicates the current approval dates. Use only the stamped form to make copies for subjects/parents to sign when they enroll in the study and keep this stamped original in your study file.

The committee assigned this study to Risk Category 1 (21 CFR 50.51 and 45 CFR 46.404) no more than minimal risk.

The continuing review and monitoring report will be shared with the full IRB committee at the meeting to be held on 2/23/2006. If there are questions, you will be contacted at that time.

The IRB will have the authority to suspend or terminate approval of research that is not being conducted in accordance with applicable policies and procedures.

If your project is terminated, a final report to the IRB is required within 90 days.

Sincerely,

Doug Swanson, MD, Vice-Chair  
The Children's Mercy Hospital  
Institutional Review Board

cc: Research and Grants Office  
Marcy Tarrants

April 21, 2003

Gary Lofland, MD  
Cardiovascular and Thoracic Surgery  
The Children's Mercy Hospital

IRB # 03 03-033E "Congenital Heart Surgeons Society Studies in Congenital Heart Disease"

Dear Dr. Lofland:


Thank you for submitting the revised documents for the above referenced study. The Children's Mercy Hospital Pediatric Institutional Review Board has approved the following:

- Protocol as named above.
- Permission/assent form dated April 21, 2003 with the IRB validation stamp on each page. (Use only copies of this stamped form when obtaining permission/assent.)

Approval is valid for one year and will expire on April 21, 2004. As Primary Investigator your responsibilities to the IRB include:

1. Report any changes or deviations in the protocol to the Review Board. Obtain approval prior to implementation of all protocol changes unless the change is imperative to subject safety.
2. Report any unexpected significant adverse events or problems related to your study promptly to the IRB Chairman for consideration so that action may be taken, if needed. Adverse events that are serious (SAEs), unexpected, and in any way related to the study, must be promptly reported to the IRB:
  - Serious is defined by the federal regulations as an event that is fatal or life-threatening, results in permanent disability, requires or prolongs hospitalization, or which results in a congenital anomaly/birth defect in the offspring of a study subject. (21 CFR 312.32)
  - If a serious adverse event occurs in a subject on study at CMH:
    - Notify the IRB chairperson, at 234-3879 within 24 hours. (Also notify sponsor.)
    - Submit a written report to the IRB within five (5) working days. The appropriate electronic form may be obtained on the CMH Pediatric Research website.
3. Submit a progress report to the committee in sufficient time for the Review Board to meet and take action regarding reapproval prior to April 21, 2004. If the study is completed prior to that date, a final report to the Review Board is required within 90 days of completion of the study.

Sincerely,



Gary Pettitt, MD, Chair  
Children's Mercy Hospital Pediatric  
Institutional Review Board

cc: Marcy Tarrants  
William Caskey, PhD

you must stipulate in the consent form signed by the parents what patient identifiers will be released to the CHSS Data Center (name, date of birth, address, phone numbers, medical record numbers, etc).

Please feel free to include the The Children's Mercy Hospital Application and Approval Packet with your own IRB application packet. IRBs like to see that other institutions have successfully navigated the approval process, and sometimes even explore the way in which approval has been accomplished. Dr. Gary Pettett (see Tab One) has graciously volunteered to serve as an information resource in the event your IRB has any questions.

We hope that this information proves to be helpful. Please feel free to call or e-mail if we can be of any additional assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Gary K. Lofland".

Gary K. Lofland, M.D.

**The Children's Mercy Hospital Pediatric  
Institutional Review Board**

**Instructions for Submission of a New Protocol**

Each submission should include:

- The original and 4 copies of “Request for Approval of Investigation Involving Human Subjects”
- 5 copies of the complete human subjects protocol. (Information in the submission form must correspond accurately with the protocol.)
- 5 copies of the grant application, if different from the protocol (in most instances the human subjects protocol will be contained within the grant proposal)
- 5 copies of the proposed permission/assent form in the recommended format
- 2 copies of the Investigators’ Drug Brochure or any applicable information sheets
- 5 copies of any proposed advertisements or other recruitment materials
- 2 copies of the Primary Investigator’s CV (if applicable, see below)

The committee will not review incomplete or inadequate submissions. Please provide double-sided copies whenever possible. Upon request, the IRB office will preview documents prior to final submission to assist with wording and form completion.

**Instructions for Completing the Request for  
Approval of Investigation Involving Human Subjects**

This form is intended to be used in its electronic form so that each section can be expanded or reduced to accommodate your submission. Please use font size 11 or greater to complete the form. Questions regarding the form should be directed to Kathy Johnson, RN, CCRC (816-234-3905) or Amy Leavell (816-234-3813). Most sections should be self-explanatory and require succinct responses. Because the IRB uses a “Primary reviewer system, only 3 members of the committee will receive the full protocol and all other reviewers will receive the submission form and permission assent form only. Therefore, it is important that the submission form contain all the important information. The following details may be helpful.

- Section C - The primary investigator must be a UMKC faculty member and/or staff member at Children’s Mercy Hospital or at an affiliated institution of either. A current curriculum vita is one that is dated within the past two years. Do not send a CV with each submission, only if this is the first time you have submitted a project for review to this IRB.
- Section G - Most projects require full committee review. If you are requesting expedited review or an exemption, refer to 45 CFR 46.101 (b), and 45 CFR 46.109-111.
- Section S – Risks of routine care items may not need to be included in the permission/assent, unless required for other reasons.
- Section N - If samples are to be stored for future use, explain how the samples will be identified, the expected length of storage, what is the expected use, whether additional consent will be required for subsequent use.
- Section O - Provide information for all investigational drugs directly involved in meeting the objectives of your study. Medications used to treat potential adverse events or that are part of routine care do not need to be detailed in this section.
- Section T – As of January 1, 2001, investigators and all key personnel involved in the conduct of the study are required by hospital policy to have “Responsible Conduct of Research” education. Protocols that list investigators who do not have the required credits will not be reviewed. Contact the Office for Research Integrity (816-234-3879) for details.
- 5-minute presentation, followed by a 10-15 minute question and answer period, to the IRB when the submission is reviewed.

7/11/02

**The Children's Mercy Hospital Pediatric  
Institutional Review Board  
Protocol Submission Form**

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**A. Project Title:** Critical Left Ventricular Outflow Tract Obstruction (LVOTO) Study:  
Congenital Heart Surgeons' Society (CHSS) Studies in Congenital Heart Disease

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**B. Sponsor name/Protocol or Grant #:**  
The Congenital Heart Surgeons' Society (CHSS) Data Center  
Hospital for Sick Children, Toronto, Ontario, Canada

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**C. Primary Investigator:**  
**Address:**  
**Phone #:**  
**Email address:**

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**D. Sub-Investigator(s):**  
**Coordinator(s):**

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**E. Prior Scientific Review?** N  Y  By whom? CHSS research committee  
**Reviewed by other IRBs for this group of investigators?** N  Y  By whom?

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**F. Requested Review:** Full Committee  Expedited  Exempt

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**G. Study Objectives/Specific Aims:**

**Overall Goal:** To assemble a multi-institutional inception cohort of patients with critical LVOTO.

**Objective 1:** Identify risk factors that are predictive of late outcomes.

**Objective 2:** Determine the value of emerging management strategies.

**Objective 3:** Assess late outcomes by functional assessment, quality of life, developmental outcomes and identification of electrophysical complications.

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**H. Background:**

The Congenital Heart Surgeons' Society (CHSS) is a group of 70 pediatric heart surgeons who meet once a year to discuss problems of mutual interest in patient management. The history of the group goes back to the early days of cardiac surgery in the mid 1950s, when 16 surgeons met annually to relate their early pioneering experience in operating on children with congenital heart defects.

Congenital heart disease affects 8 of every 1000 newborn children. There are over 100 congenital defects that may deform the heart, and these defects may occur singly or in various permutations and combinations. Not every newborn child with congenital heart disease will require heart surgery, but about 50% do need surgery either in the newborn period, later in life or both. Improvement in the medical and surgical care during the past 40 years has changed the outlook for these children and 50% of patients with congenital heart disease are now adults.

In 1985, Dr. John Kirklin and Dr. Eugene Blackstone proposed that the centers pool their experience in managing infants with rare congenital anomalies of the heart. Because these lesions are rare, the experience in even the largest center was insufficient to provide generalized inferences. By combining the experience of many institutions, sufficient data could be accumulated in a relatively short time to allow meaningful analysis and to create new knowledge that could improve the care for children with congenital heart defects.

The initial data collection included information on babies in the first 2 weeks of life, born with complete transposition of the great arteries, and who were admitted to any one of the CHSS institutions. From 1985 to 1989, 985 newborns with transposition were entered into the newly established data center in Birmingham, Alabama. Subsequently, 7 other studies of neonates with specific congenital cardiac lesions have been initiated. The data center has entered over 4,000 babies from these series and maintains long term follow up information on the survivors. To date these studies have resulted in many presentations at national and international meetings and in 16 publications.

Data collection required the establishment of a Data Center, initially in Birmingham, Alabama. The personnel in the Data Center collated the information, collected reports from the various institutions, and entered all of the information into computerized data files. They also conducted an annual review to follow the progress of the babies entered in the study. The era of data collection for these patients was an important one because the surgical management of the neonates with transposition changed dramatically from an atrial or inflow redirection to an outflow or arterial operation. The former was not performed until age of 3 to 18 months, whereas the arterial switch operation was performed routinely in the first two weeks of life. The data analysis on these patients has resulted wealth of information in 7 publications to date.

The success of data collection in the transposition babies led to 6 subsequent studies of infant groups including pulmonary atresia intact septum, pulmonary stenosis, interrupted aortic arch, coarctation, critical aortic stenosis, and aortic atresia and most recently tricuspid atresia.

In 1997, the Data Center moved from Birmingham, Alabama to the Hospital for Sick Children in Toronto. The Data Center employs 3.5 full-time people and has two physicians/surgeon-consultants.

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### **I. Study Design:**

CHSS is a group of 70 pediatric heart surgeons enrolling patients at 45 participating institutions throughout North America and South America.

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### **J. Subject Selection Criteria:**

**Recruitment of Subjects:** All patients presenting to our Hospital that meet the listed inclusion and exclusion criterion will be eligible for the study. Patients will enter the system via their referral lines and will be funneled to the cardiology section. The primary investigator, or his designee in his absence will obtain informed permission. This will be done at the time the patient is identified as eligible for the study.

Informed permission will be obtained in writing from the parent(s) or legal guardian prior to participation of any minor child. The purpose and nature of the study along with the procedures, possible benefits, and potential risks are verbally explained to the parent and/or potential subject in age appropriate language. A copy of the permission document is provided to the parent for review and all questions are answered. At the point that the parent/subject appears to understand the information, written permission is obtained if the parent/subject agrees to participate. A copy of the signed and dated permission form is provided to the parent/subject, one copy is placed in the patient's medical record, and the original will be maintained in the subject's confidential study records.

**Expected Sample Size: Total study:** Past enrollments in this study indicate an average of 2 enrollees per month. Total sample size will be dependent upon length of time that the study is left open which is determined by the CHSS research committee.

**CMH only:** Based upon referral area and published incidence of the study population, we could expect to enroll approximately 24 patients per year.

**Inclusion Criteria:** (Full CHSS Protocol Attached)

- 1) Neonate ( $\leq 30$  days at admission to a CHSS institution) Date of admission AFTER December 31, 2004.
- 2) AV & VA concordance whose LVOTO precludes an adequate systemic cardiac output through the aortic valve. This may include Critical LVOTO due to either aortic valve stenosis OR anatomically normal but hypoplastic left heart.
- 3) Patients who meet criteria but died prior to surgery will be included.

**Exclusion Criteria:**

- 1) First intervention at non-CHSS institution.
- 2) AV or VA discordance.
- 3) Atrioventricular Septal Defect.

**K. Study Groups:** (include information regarding randomization procedures, treatment groups, etc)

N/A

**L. Observations/Measurements:** Following receipt of informed permission a patient enrollment form is completed for enrollment into the study (See attached Patient Enrollment form). Information gathered will be obtained from existing data and records, diagnostic testing and surgical interventions will not be altered in any way. At yearly intervals, specially trained personnel from the Children's Mercy Hospital or CHSS may call and/or mail a letter to the family and child, checking on the child's clinical progress and obtaining additional follow-up information and records (See attached Follow-up form).

**M. Confidentiality of Subjects and Data**

**1. What subject identifiers are used in:**

**a. study documents to funding agency**

Name  
Address  
Parent's Name  
Birth Date  
Social Security Numbers  
Telephone Numbers  
Medical Record Numbers

**b. study documents retained at CMH**

Name  
Address  
Parent's Name  
Birth Date  
Social Security Numbers  
Telephone Numbers  
Medical Record Numbers

**2. Where will data be stored and how will confidentiality be maintained?**

Data is collected by the Cardiovascular Surgery Research Coordinators from the patient's medical record. Data is maintained in the Cardiovascular Surgery department in locked file cabinets devoted to study records in a locked room. Each study participant is assigned a corresponding study number that is used for all analysis purposes. Information will be stored in a secure location, kept confidential, and specific variables will be entered into a secure, password protected computer file. These data files are restricted to the study investigators.

The Hospital utilizes a HIPAA data use agreement with the Congenital Heart Surgeon's Society to maintain the highest level of confidentiality for all participants. Data is mailed to the CHSS Data Center where it maintained in locked file cabinets in a locked room devoted to study records. Each study participant is assigned a corresponding study number that is used for all analysis purposes. Information will be stored in a secure location, kept confidential, and specific variables will be entered into a secure, password protected computer file and access to the data files are restricted to the CHSS Data Center employees. Data analysis, review, and published results are all performed in an unidentified manner.

**3. Who will have access to data?**

Data files are restricted to the study investigators and CHSS Data Center employees.

**4. Will tissue/blood samples be stored beyond the end of the study?**

Y  N  NA

a. If yes, explain, and specify what subject identifiers will be retained on the samples:

b. Is this clearly stated in the consent form?

**5. What will happen to data and samples if subject withdraws prior to completing study?**

Data previously collected will be maintained. No further data collection will take place.

**N. Drug(s):** NA  New use of approved drug  New drug  Other (explain)

**IND #:**

**Drug name:**

**Study Phase #:**

**Route of Administration:**

**Manufacturer:**

**How is drug supplied?**

**Dosing Regimen:**

**Possible side effects:**

**O. Device:** N/A  New use of approved device  New device  IDE #

**Sponsor's assessment of risk:** Non-significant risk device:  Significant risk

**Investigator's opinion of risk:** Non-significant risk device:  Significant risk

**Rationale for risk assessment:**

**P. Investigational Procedure:**

The information gathered will be added to information from other participants in this study and analyzed by the CHSS Data Center. Copies of the information gathered will be sent to the CHSS Data Center at the Hospital of Sick Children in Toronto, Canada. The information will be stored in a secure location, kept confidential, and entered into a password protected computer file maintained by the CHSS Data Center.

**Q. Financial Obligations:**

The study participant will not be paid to participate in this project. The participant's insurance carrier will be billed for the cost of care that is normally provided.

**R. Known and Potential Risks of Study Participation:**

1. State all known and potential risks to participants involved in this study, including risks to confidentiality

There are no known risks associated with participation in this study. All information will be maintained in a secure, confidential manner.

**2. How will all risks of study participation be managed and minimized, including risks from study procedures and drugs?**

All information will be maintained in a secure, confidential manner. Information is maintained in a locked file cabinet in a locked room with restricted access to CHSS Data Center appointed personnel. Data is stored within secure password protected computer files.

**3. Investigator's Assessment of Risk:** (according to 45 CFR Part 46 Subpart D)

- Category 1**  Research not involving greater than minimal risk.
- Category 2**  Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.
- Category 3**  Research involving greater than minimal risk and no prospect of direct benefit to the individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
- Category 4**  Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

**4. Provide statement explaining your choice:**

There are no known risks associated with participation in this study. Study is voluntary at all times and information is maintained in a secure and confidential manner.

**5. State the benefits of study participation:**

Information collected by this data center may contribute to the care of children in the future who have the same heart condition as those that participate in this study. The information may also improve the future management of study participants. There are no guarantees that participants will benefit from being members in this study.

**Project title:**

Congenital Heart Surgeons' Society (CHSS) Studies in Congenital Heart Disease

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**S. Signatures and Verification of Education:**

Once this project is approved, IRB approval will be obtained prior to any change in the protocol (other than that required for immediate subject safety) and I will report all serious adverse reactions, expected and unexpected, and protocol deviations to the IRB as required by 21 CFR 312.66.

Three copies of the consent form will be made for each subject. Signed consent forms will be available in the study records and the subject's medical record and the pharmacy, if applicable. One copy will be given to the subject or parent/guardian. I have verified that the consent form contains information for participants to contact a study representative at any time, 24 hours a day, 7 days a week.

The project has   x   has not \_\_\_\_\_ been funded, or contract is pending \_\_\_\_\_ at the present time.

I expect to begin work on this project on \_\_\_\_\_ .

**By signing below, each person involved in the conduct of this study agrees to comply with all applicable human subjects protections regulations and IRB and institutional policies relative to this research protocol.**

**Additionally, each person verifies they have read the hospital policy regarding education requirements for Responsible Conduct of Research and are in compliance with the policy. Proof of required education will be supplied to the IRB upon request.**

**Conflict of Interest (COI) Statement:**

A conflict of interest may exist if anyone involved in the conduct of the study (or their spouse or family member) has a personal interest that may influence or appear to influence the objective performance of his or her duties to the research study. This could include a personal interest to receive personal gain or special advantage, conflict of official duty, or any activity that appears to interfere or is likely to interfere in objective professional judgment.

**All actual and/or potential conflicts of interest must be reported.** Reportable activities include, but are not limited to, involvement with the sponsor or other entity that may be affected by the research such as: (1) any income (e.g., consulting or speaking fees, honoraria, gifts, or compensation in the form of equipment); (2) equity or financial interest (e.g., stocks, stock options, patents, licensing agreements, interests in non-publicly traded company); (3) serving as a director, board member, officer, partner, trustee, employee, or member of a scientific advisory board; or (4) having proprietary interest in the investigational product being tested or in a competing product. **Please refer to the Conflict of Interest Policy for additional examples and aggregate value that may not be exceeded.**

Each person involved in the conduct of this study (as defined in Sections C and D of this form) must indicate below whether a conflict of interest (potential or actual) exists for themselves, their spouse or dependents. In the event that such a conflict is identified, please provide the ORI with a copy of the most recent Conflict of Interest Statement describing the conflict. If the Conflict of Interest Statement has not been updated, please do so as described by the Conflict of Interest policy and submit a copy to ORI (with the original to Corporate Compliance).

*Please initial:*

No COI                      COI                      IRBECs

Signed \_\_\_\_\_  
**Principal Investigator** (required for submission)      Date \_\_\_\_\_

IRB #  
Date of original submission:  
Revision Date(s):

**Signatures of Sub-Investigators and Key Personnel:**

(Preferred for submission, required before final approval letter will be sent)

*Please initial:*

No COI

COI

IRBECs

		No COI	COI	IRBECs
_____	Date	_____	_____	_____
_____	Date	_____	_____	_____
_____	Date	_____	_____	_____
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_____	Date	_____	_____	_____
_____	Date	_____	_____	_____
_____	Date	_____	_____	_____

**Statement of Support and Signature of Department Manager or Section Chief:**

(Required for submission)

My signature below signifies my support of this study as presented in this document.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Dept. Manager or Section Chief

\_\_\_\_\_  
Name of Department/Section

RETURN THIS FORM TO:  
Office for Research Integrity  
Children's Mercy Hospital  
Suite 600, Hospital Hill Center

(Form Rev. 11/17/05, replaces version 9/15/05)

**The Children's Mercy Hospital Pediatric  
Institutional Review Board**

**Instructions for Submission of a New Protocol**

Each submission should include:

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- 5-minute presentation, followed by a 10-15 minute question and answer period, to the IRB when the submission is reviewed.

7/11/02

**The Children's Mercy Hospital Pediatric  
Institutional Review Board  
Protocol Submission Form**

---

**A. Project Title:** Pulmonary Conduit Study:  
Congenital Heart Surgeons' Society (CHSS) Studies in Congenital Heart Disease

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**B. Sponsor name/Protocol or Grant #:**  
The Congenital Heart Surgeons' Society (CHSS) Data Center  
Hospital for Sick Children, Toronto, Ontario, Canada

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**C. Primary Investigator:**  
**Address:**  
**Phone #:**  
**Email address:**

---

**D. Sub-Investigator(s):**  
**Coordinator(s):**

---

**E. Prior Scientific Review?** N  Y  By whom? CHSS research committee  
**Reviewed by other IRBs for this group of investigators?** N  Y  By whom?

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**F. Requested Review:** Full Committee  Expedited  Exempt

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**G. Study Objectives/Specific Aims:**

**Overall Goal:** To assemble a multi-institutional inception cohort of infants less than 2 years of age having pulmonary ventricle-pulmonary artery conduit placement.

**Objective 1:** To determine the best conduit for infants and young children.

**Objective 2:** To determine optimal conduit for replacement of previous conduits.

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**H. Background:**

The Congenital Heart Surgeons' Society (CHSS) is a group of 70 pediatric heart surgeons who meet once a year to discuss problems of mutual interest in patient management. The history of the group goes back to the early days of cardiac surgery in the mid 1950s, when 16 surgeons met annually to relate their early pioneering experience in operating on children with congenital heart defects.

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In 1985, Dr. John Kirklin and Dr. Eugene Blackstone proposed that the centers pool their experience in managing infants with rare congenital anomalies of the heart. Because these lesions are rare, the experience in even the largest

center was insufficient to provide generalized inferences. By combining the experience of many institutions, sufficient data could be accumulated in a relatively short time to allow meaningful analysis and to create new knowledge that could improve the care for children with congenital heart defects.

The initial data collection included information on babies in the first 2 weeks of life, born with complete transposition of the great arteries, and who were admitted to any one of the CHSS institutions. From 1985 to 1989, 985 newborns with transposition were entered into the newly established data center in Birmingham, Alabama. Subsequently, 7 other studies of neonates with specific congenital cardiac lesions have been initiated. The data center has entered over 4,000 babies from these series and maintains long term follow up information on the survivors. To date these studies have resulted in many presentations at national and international meetings and in 16 publications.

Data collection required the establishment of a Data Center, initially in Birmingham, Alabama. The personnel in the Data Center collated the information, collected reports from the various institutions, and entered all of the information into computerized data files. They also conducted an annual review to follow the progress of the babies entered in the study. The era of data collection for these patients was an important one because the surgical management of the neonates with transposition changed dramatically from an atrial or inflow redirection to an outflow or arterial operation. The former was not performed until age of 3 to 18 months, whereas the arterial switch operation was performed routinely in the first two weeks of life. The data analysis on these patients has resulted wealth of information in 7 publications to date.

The success of data collection in the transposition babies led to 6 subsequent studies of infant groups including pulmonary atresia intact septum, pulmonary stenosis, interrupted aortic arch, coarctation, critical aortic stenosis, and aortic atresia and most recently tricuspid atresia.

In 1997, the Data Center moved from Birmingham, Alabama to the Hospital for Sick Children in Toronto. The Data Center employs 3.5 full-time people and has two physicians/surgeon-consultants.

---

### **I. Study Design:**

CHSS is a group of 70 pediatric heart surgeons enrolling patients at 45 participating institutions throughout North America and South America.

---

### **J. Subject Selection Criteria:**

**Recruitment of Subjects:** All patients presenting to our hospital that meet the listed inclusion and exclusion criterion will be eligible for the study. Patients will enter the system via their referral lines and will be funneled to the cardiology section. The primary investigator, or his designee in his absence will obtain informed permission. This will be done at the time the patient is identified as eligible for the study.

Informed permission will be obtained in writing from the parent(s) or legal guardian prior to participation of any minor child. The purpose and nature of the study along with the procedures, possible benefits, and potential risks are verbally explained to the parent and/or potential subject in age appropriate language. A copy of the permission document is provided to the parent for review and all questions are answered. At the point that the parent/subject appears to understand the information, written permission is obtained if the parent/subject agrees to participate. A copy of the signed and dated permission form is provided to the parent/subject, one copy is placed in the patient's medical record, and the original will be maintained in the subject's confidential study records.

**Expected Sample Size: Total study:** Past enrollments in this study indicate an average of 2 enrollees per month. Total sample size will be dependent upon length of time that the study is left open which is determined by the CHSS research committee.

**CMH only:** Based upon referral area and published incidence of the study population, we could expect to enroll approximately 24 patients per year.

**Inclusion Criteria:** 1) Valved conduit implant at age < 2 years at CHSS member institution. Date of first implant AFTER January 1, 2002.

AND 2) Survival to hospital discharge after conduit insertion

AND 3) First pulmonary ventricle-pulmonary artery conduit placement

**Exclusion Criteria:** 1) Single ventricle RV-PA Conduit

2) Non-valved Conduit

3) VSD fenestrated or not closed.

**K. Study Groups:** (include information regarding randomization procedures, treatment groups, etc)

N/A

**L. Observations/Measurements:** Following receipt of informed permission a patient enrollment form is completed for enrollment into the study (See attached Patient Enrollment form). Information gathered will be obtained from existing data and records, diagnostic testing and surgical interventions will not be altered in any way. At yearly intervals, specially trained personnel from the Children's Mercy Hospital or CHSS may call and/or mail a letter to the family and child, checking on the child's clinical progress and obtaining additional follow-up information and records (See attached Follow-up form).

## **M. Confidentiality of Subjects and Data**

### **1. What subject identifiers are used in:**

#### **a. study documents to funding agency**

Name

Address

Parent's Name

Birth Date

Social Security Numbers

Telephone Numbers

Medical Record Numbers

#### **b. study documents retained at CMH**

Name

Address

Parent's Name

Birth Date

Social Security Numbers

Telephone Numbers

Medical Record Numbers

### **2. Where will data be stored and how will confidentiality be maintained?**

Data is collected by the Cardiovascular Surgery Research Coordinators from the patient's medical record. Data is maintained in the Cardiovascular Surgery department in locked file cabinets devoted to study records in a locked room. Each study participant is assigned a corresponding study number that is used for all analysis purposes. Information will be stored in a secure location, kept confidential, and specific variables will be entered into a secure, password protected computer file. These data files are restricted to the study investigators.

The hospital utilizes a HIPAA data use agreement with the Congenital Heart Surgeon's Society to maintain the highest level of confidentiality for all participants. Data is mailed to the CHSS Data Center where it maintained in locked file cabinets in a locked room devoted to study records. Each study participant is assigned a corresponding study number that is used for all analysis purposes. Information will be stored in a secure location, kept confidential, and specific variables will be entered into a secure, password protected computer file and access to the data files are restricted to the CHSS Data Centre employees. Data analysis, review, and published results are all performed in an unidentified manner.

**3. Who will have access to data?**

Data files are restricted to the study investigators and CHSS Data Center employees.

**4. Will tissue/blood samples be stored beyond the end of the study?** Y  N  NA

- a. If yes, explain, and specify what subject identifiers will be retained on the samples:
- b. Is this clearly stated in the consent form?

**5. What will happen to data and samples if subject withdraws prior to completing study?**

Data previously collected will be maintained. No further data collection will take place.

---

**N. Drug(s):** NA  New use of approved drug  New drug  Other (explain)

IND #:

Drug name:

Study Phase #:

Route of Administration:

Manufacturer:

How is drug supplied?

Dosing Regimen:

Possible side effects:

---

**O. Device:** N/A  New use of approved device  New device  IDE #

Sponsor's assessment of risk: Non-significant risk device:  Significant risk

Investigator's opinion of risk: Non-significant risk device:  Significant risk

Rationale for risk assessment:

---

**P. Investigational Procedure:**

The information gathered will be added to information from other participants in this study and analyzed by the CHSS Data Center. Copies of the information gathered will be sent to the CHSS Data Center at the Hospital of Sick Children in Toronto, Canada. The information will be stored in a secure location, kept confidential, and entered into a password protected computer file maintained by the CHSS Data Center.

---

**Q. Financial Obligations:**

The study participant will not be paid to participate in this project. The participant's insurance carrier will be billed for the cost of care that is normally provided.

---

**R. Known and Potential Risks of Study Participation:**

**1. State all known and potential risks to participants involved in this study, including risks to confidentiality**

There are no known risks associated with participation in this study. All information will be maintained in a secure, confidential manner.

**2. How will all risks of study participation be managed and minimized, including risks from study procedures and drugs?**

All information will be maintained in a secure, confidential manner. Information is maintained in a locked file cabinet in a locked room with restricted access to CHSS Data Center appointed personnel. Data is stored within secure password protected computer files.

**3. Investigator's Assessment of Risk:** (according to 45 CFR Part 46 Subpart D)

- Category 1**  Research not involving greater than minimal risk.
- Category 2**  Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.
- Category 3**  Research involving greater than minimal risk and no prospect of direct benefit to the individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
- Category 4**  Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

**4. Provide statement explaining your choice:**

There are no known risks associated with participation in this study. Study is voluntary at all times and information is maintained in a secure and confidential manner.

**5. State the benefits of study participation:**

Information collected by this data center may contribute to the care of children in the future who have the same heart condition as those that participate in this study. The information may also improve the future management of study participants. There are no guarantees that participants will benefit from being members in this study.

---

**Project title:**

Congenital Heart Surgeons' Society (CHSS) Studies in Congenital Heart Disease

---

**S. Signatures and Verification of Education:**

Once this project is approved, IRB approval will be obtained prior to any change in the protocol (other than that required for immediate subject safety) and I will report all serious adverse reactions, expected and unexpected, and protocol deviations to the IRB as required by 21 CFR 312.66.

Three copies of the consent form will be made for each subject. Signed consent forms will be available in the study records and the subject's medical record and the pharmacy, if applicable. One copy will be given to the subject or parent/guardian. I have verified that the consent form contains information for participants to contact a study representative at any time, 24 hours a day, 7 days a week.

The project has   x   has not \_\_\_\_\_ been funded, or contract is pending \_\_\_\_\_ at the present time.

I expect to begin work on this project on \_\_\_\_\_ .

**By signing below, each person involved in the conduct of this study agrees to comply with all applicable human subjects protections regulations and IRB and institutional policies relative to this research protocol.**

**Additionally, each person verifies they have read the hospital policy regarding education requirements for Responsible Conduct of Research and are in compliance with the policy. Proof of required education will be supplied to the IRB upon request.**

**Conflict of Interest (COI) Statement:**

A conflict of interest may exist if anyone involved in the conduct of the study (or their spouse or family member) has a personal interest that may influence or appear to influence the objective performance of his or her duties to the research study. This could include a personal interest to receive personal gain or special advantage, conflict of official duty, or any activity that appears to interfere or is likely to interfere in objective professional judgment.

**All actual and/or potential conflicts of interest must be reported.** Reportable activities include, but are not limited to, involvement with the sponsor or other entity that may be affected by the research such as: (1) any income (e.g., consulting or speaking fees, honoraria, gifts, or compensation in the form of equipment); (2) equity or financial interest (e.g., stocks, stock options, patents, licensing agreements, interests in non-publicly traded company); (3) serving as a director, board member, officer, partner, trustee, employee, or member of a scientific advisory board; or (4) having proprietary interest in the investigational product being tested or in a competing product. **Please refer to the Conflict of Interest Policy for additional examples and aggregate value that may not be exceeded.**

Each person involved in the conduct of this study (as defined in Sections C and D of this form) must indicate below whether a conflict of interest (potential or actual) exists for themselves, their spouse or dependents. In the event that such a conflict is identified, please provide the ORI with a copy of the most recent Conflict of Interest Statement describing the conflict. If the Conflict of Interest Statement has not been updated, please do so as described by the Conflict of Interest policy and submit a copy to ORI (with the original to Corporate Compliance).

*Please initial:*

No COI                      COI                      IRBECs

Signed \_\_\_\_\_  
**Principal Investigator** (required for submission)      \_\_\_\_\_  
Date \_\_\_\_\_

IRB #  
Date of original submission:  
Revision Date(s):

**Signatures of Sub-Investigators and Key Personnel:**

(Preferred for submission, required before final approval letter will be sent)

*Please initial:*

No COI

COI

IRBECs

_____	_____	_____	_____	_____
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	Date			
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	Date			

---

**Statement of Support and Signature of Department Manager or Section Chief:**

(Required for submission)

My signature below signifies my support of this study as presented in this document.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Dept. Manager or Section Chief

\_\_\_\_\_  
Name of Department/Section

RETURN THIS FORM TO:  
Office for Research Integrity  
Children's Mercy Hospital  
Suite 600, Hospital Hill Center

(Form Rev. 11/17/05, replaces version 9/15/05)

**The Children's Mercy Hospital Pediatric  
Institutional Review Board**

**Instructions for Submission of a New Protocol**

Each submission should include:

- The original and 4 copies of “Request for Approval of Investigation Involving Human Subjects”
- 5 copies of the complete human subjects protocol. (Information in the submission form must correspond accurately with the protocol.)
- 5 copies of the grant application, if different from the protocol (in most instances the human subjects protocol will be contained within the grant proposal)
- 5 copies of the proposed permission/assent form in the recommended format
- 2 copies of the Investigators’ Drug Brochure or any applicable information sheets
- 5 copies of any proposed advertisements or other recruitment materials
- 2 copies of the Primary Investigator’s CV (if applicable, see below)

The committee will not review incomplete or inadequate submissions. Please provide double-sided copies whenever possible. Upon request, the IRB office will preview documents prior to final submission to assist with wording and form completion.

**Instructions for Completing the Request for  
Approval of Investigation Involving Human Subjects**

This form is intended to be used in its electronic form so that each section can be expanded or reduced to accommodate your submission. Please use font size 11 or greater to complete the form. Questions regarding the form should be directed to Kathy Johnson, RN, CCRC (816-234-3905) or Amy Leavell (816-234-3813). Most sections should be self-explanatory and require succinct responses. Because the IRB uses a “Primary reviewer system, only 3 members of the committee will receive the full protocol and all other reviewers will receive the submission form and permission assent form only. Therefore, it is important that the submission form contain all the important information. The following details may be helpful.

- Section C - The primary investigator must be a UMKC faculty member and/or staff member at Children’s Mercy Hospital or at an affiliated institution of either. A current curriculum vita is one that is dated within the past two years. Do not send a CV with each submission, only if this is the first time you have submitted a project for review to this IRB.
- Section G - Most projects require full committee review. If you are requesting expedited review or an exemption, refer to 45 CFR 46.101 (b), and 45 CFR 46.109-111.
- Section S – Risks of routine care items may not need to be included in the permission/assent, unless required for other reasons.
- Section N - If samples are to be stored for future use, explain how the samples will be identified, the expected length of storage, what is the expected use, whether additional consent will be required for subsequent use.
- Section O - Provide information for all investigational drugs directly involved in meeting the objectives of your study. Medications used to treat potential adverse events or that are part of routine care do not need to be detailed in this section.
- Section T – As of January 1, 2001, investigators and all key personnel involved in the conduct of the study are required by hospital policy to have “Responsible Conduct of Research” education. Protocols that list investigators who do not have the required credits will not be reviewed. Contact the Office for Research Integrity (816-234-3879) for details.
- 5-minute presentation, followed by a 10-15 minute question and answer period, to the IRB when the submission is reviewed.

7/11/02

**The Children's Mercy Hospital Pediatric  
Institutional Review Board  
Protocol Submission Form**

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**A. Project Title:** Tricuspid Atresia Study:  
Congenital Heart Surgeons' Society (CHSS) Studies in Congenital Heart Disease

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**B. Sponsor name/Protocol or Grant #:**  
The Congenital Heart Surgeons' Society (CHSS) Data Center  
Hospital for Sick Children, Toronto, Ontario, Canada

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**C. Primary Investigator:**  
**Address:**  
**Phone #:**  
**Email address:**

---

**D. Sub-Investigator(s):**  
**Coordinator(s):**

---

**E. Prior Scientific Review?** N  Y  By whom? CHSS research committee  
**Reviewed by other IRBs for this group of investigators?** N  Y  By whom?

---

**F. Requested Review:** Full Committee  Expedited  Exempt

---

**G. Study Objectives/Specific Aims:**

**Overall Goal:** To assemble a multi-institutional inception cohort of patients with Tricuspid Atresia and normally related great arteries.

**Objective 1:** To determine the impact of patient characteristics and management algorithms on outcomes of the Fontan track for infants with Tricuspid Atresia.

Examples of risk factors to be examined:

- Impact of staging
- Types of Fontan connection
- Impact of fenestration

Examples of outcomes:

- Mortality
- Morbidity - short-term i.e. post-op complications, effusions, arrhythmias, length of ICU stays
- long-term i.e. protein losing enteropathy, thrombotic complications, arrhythmias, and ventricular failure.

**Objective 2:** To examine the overall health status and quality of life of patients with Tricuspid Atresia.

---

**H. Background:**

The Congenital Heart Surgeons' Society (CHSS) is a group of 70 pediatric heart surgeons who meet once a year to discuss problems of mutual interest in patient management. The history of the group goes back to the early days of

cardiac surgery in the mid 1950s, when 16 surgeons met annually to relate their early pioneering experience in operating on children with congenital heart defects.

Congenital heart disease affects 8 of every 1000 newborn children. There are over 100 congenital defects that may deform the heart, and these defects may occur singly or in various permutations and combinations. Not every newborn child with congenital heart disease will require heart surgery, but about 50% do need surgery either in the newborn period, later in life or both. Improvement in the medical and surgical care during the past 40 years has changed the outlook for these children and 50% of patients with congenital heart disease are now adults.

In 1985, Dr. John Kirklin and Dr. Eugene Blackstone proposed that the centers pool their experience in managing infants with rare congenital anomalies of the heart. Because these lesions are rare, the experience in even the largest center was insufficient to provide generalized inferences. By combining the experience of many institutions, sufficient data could be accumulated in a relatively short time to allow meaningful analysis and to create new knowledge that could improve the care for children with congenital heart defects.

The initial data collection included information on babies in the first 2 weeks of life, born with complete transposition of the great arteries, and who were admitted to any one of the CHSS institutions. From 1985 to 1989, 985 newborns with transposition were entered into the newly established data center in Birmingham, Alabama. Subsequently, 7 other studies of neonates with specific congenital cardiac lesions have been initiated. The data center has entered over 4,000 babies from these series and maintains long term follow up information on the survivors. To date these studies have resulted in many presentations at national and international meetings and in 16 publications.

Data collection required the establishment of a Data Center, initially in Birmingham, Alabama. The personnel in the Data Center collated the information, collected reports from the various institutions, and entered all of the information into computerized data files. They also conducted an annual review to follow the progress of the babies entered in the study. The era of data collection for these patients was an important one because the surgical management of the neonates with transposition changed dramatically from an atrial or inflow redirection to an outflow or arterial operation. The former was not performed until age of 3 to 18 months, whereas the arterial switch operation was performed routinely in the first two weeks of life. The data analysis on these patients has resulted wealth of information in 7 publications to date.

The success of data collection in the transposition babies led to 6 subsequent studies of infant groups including pulmonary atresia intact septum, pulmonary stenosis, interrupted aortic arch, coarctation, critical aortic stenosis, and aortic atresia and most recently tricuspid atresia.

In 1997, the Data Center moved from Birmingham, Alabama to the Hospital for Sick Children in Toronto. The Data Center employs 3.5 full-time people and has two physicians/surgeon-consultants.

---

### **I. Study Design:**

CHSS is a group of 70 pediatric heart surgeons enrolling patients at 45 participating institutions throughout North America and South America.

---

### **J. Subject Selection Criteria:**

**Recruitment of Subjects:** All patients presenting to our hospital that meet the listed inclusion and exclusion criterion will be eligible for the study. Patients will enter the system via their referral lines and will be funneled to the cardiology section. The primary investigator, or his designee in his absence will obtain informed permission. This will be done at the time the patient is identified as eligible for the study.

Informed permission will be obtained in writing from the parent(s) or legal guardian prior to participation of any minor child. The purpose and nature of the study along with the procedures, possible benefits, and potential risks are verbally explained to the parent and/or potential subject in age appropriate language. A copy of the permission

document is provided to the parent for review and all questions are answered. At the point that the parent/subject appears to understand the information, written permission is obtained if the parent/subject agrees to participate. A copy of the signed and dated permission form is provided to the parent/subject, one copy is placed in the patient's medical record, and the original will be maintained in the subject's confidential study records.

**Expected Sample Size: Total study:** Past enrollments in this study indicate an average of 1 enrollee every other month. Total sample size will be dependent upon length of time that the study is left open which is determined by the CHSS research committee.

**CMH only:** Based upon referral area and published incidence of the study population, we could expect to enroll approximately 6 patients per year.

**Inclusion Criteria:** 1) Diagnosis of Tricuspid Atresia with normally related great arteries and VSD  
AND  
2) Age < 3 months at time of diagnosis  
AND  
3) Admitted to CHSS institution after January 1, 1999. (birthdate after October 1, 1998)

**Exclusion Criteria:** 1) Patients with AV discordance/Double Outlet  
OR  
2) First intervention at non-CHSS institution  
OR  
3) Age > 3 months at time of diagnosis.

**K. Study Groups:** (include information regarding randomization procedures, treatment groups, etc)  
N/A

**L. Observations/Measurements:** Following receipt of informed permission a patient intake form is completed for enrollment into the study (See attached Patient Intake form). Information gathered will be obtained from existing data and records, diagnostic testing and surgical interventions will not be altered in any way. At yearly intervals, specially trained personnel from the Children's Mercy Hospital or CHSS may call and/or mail a letter to parent and child, checking on the child's clinical progress (See attached Follow-up form).

## **M. Confidentiality of Subjects and Data**

### **1. What subject identifiers are used in:**

#### **a. study documents to funding agency**

Name  
Address  
Parent's Name  
Birth Date  
Social Security Numbers  
Telephone Numbers  
Medical Record Numbers

#### **b. study documents retained at CMH**

Name  
Address  
Parent's Name  
Birth Date  
Social Security Numbers  
Telephone Numbers  
Medical Record Numbers

### **2. Where will data be stored and how will confidentiality be maintained?**

Data is collected by the Cardiovascular Surgery Research Coordinators from the patient's medical record. Data is maintained in the Cardiovascular Surgery department in locked file cabinets devoted to study records in a locked room. Each study participant is assigned a corresponding study number that is used for all analysis purposes. Information will be stored in a secure location, kept confidential, and specific variables will be entered into a secure, password protected computer file. These data files are restricted to the study investigators.

The Hospital utilizes a HIPAA data use agreement with the Congenital Heart Surgeon's Society to maintain the highest level of confidentiality for all participants. Data is mailed to the CHSS Data Center where it maintained in locked file cabinets in a locked room devoted to study records. Each study participant is assigned a corresponding study number that is used for all analysis purposes. Information will be stored in a secure location, kept confidential, and specific variables will be entered into a secure, password protected computer file and access to the data files are restricted to the CHSS Data Center employees. Data analysis, review, and published results are all performed in an unidentified manner.

**3. Who will have access to data?**

Data files are restricted to the study investigators and CHSS Data Center employees.

**4. Will tissue/blood samples be stored beyond the end of the study?** Y  N  NA

**a. If yes, explain, and specify what subject identifiers will be retained on the samples:**

**b. Is this clearly stated in the consent form?**

**5. What will happen to data and samples if subject withdraws prior to completing study?**

Data previously collected will be maintained. No further data collection will take place.

**N. Drug(s):** NA  New use of approved drug  New drug  Other (explain)

**IND #:**

**Drug name:**

**Study Phase #:**

**Route of Administration:**

**Manufacturer:**

**How is drug supplied?**

**Dosing Regimen:**

**Possible side effects:**

**O. Device:** N/A  New use of approved device  New device  IDE #

**Sponsor's assessment of risk:** Non-significant risk device:  Significant risk

**Investigator's opinion of risk:** Non-significant risk device:  Significant risk

**Rationale for risk assessment:**

**P. Investigational Procedure:**

The information gathered will be added to information from other participants in this study and analyzed by the CHSS Data Center. Copies of the information gathered will be sent to the CHSS Data Center at the Hospital of Sick Children in Toronto, Canada. The information will be stored in a secure location, kept confidential, and entered into a password protected computer file maintained by the CHSS Data Center.

**Q. Financial Obligations:**

The study participant will not be paid to participate in this project. The participant's insurance carrier will be billed for the cost of care that is normally provided.

**R. Known and Potential Risks of Study Participation:**

**1. State all known and potential risks to participants involved in this study, including risks to confidentiality**

There are no known risks associated with participation in this study. All information will be maintained in a secure, confidential manner.

**2. How will all risks of study participation be managed and minimized, including risks from study procedures and drugs?**

All information will be maintained in a secure, confidential manner. Information is maintained in a locked file cabinet in a locked room with restricted access to CHSS Data Center appointed personnel. Data is stored within secure password protected computer files.

**3. Investigator's Assessment of Risk:** (according to 45 CFR Part 46 Subpart D)

- Category 1**  Research not involving greater than minimal risk.
- Category 2**  Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.
- Category 3**  Research involving greater than minimal risk and no prospect of direct benefit to the individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
- Category 4**  Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

**4. Provide statement explaining your choice:**

There are no known risks associated with participation in this study. Study is voluntary at all times and information is maintained in a secure and confidential manner.

**5. State the benefits of study participation:**

Information collected by this data center may contribute to the care of children in the future who have the same heart condition as those that participate in this study. The information may also improve the future management of study participants. There are no guarantees that participants will benefit from being members in this study.

**Project title:**

Congenital Heart Surgeons' Society (CHSS) Studies in Congenital Heart Disease

---

**S. Signatures and Verification of Education:**

Once this project is approved, IRB approval will be obtained prior to any change in the protocol (other than that required for immediate subject safety) and I will report all serious adverse reactions, expected and unexpected, and protocol deviations to the IRB as required by 21 CFR 312.66.

Three copies of the consent form will be made for each subject. Signed consent forms will be available in the study records and the subject's medical record and the pharmacy, if applicable. One copy will be given to the subject or parent/guardian. I have verified that the consent form contains information for participants to contact a study representative at any time, 24 hours a day, 7 days a week.

The project has   x   has not \_\_\_\_\_ been funded, or contract is pending \_\_\_\_\_ at the present time.

I expect to begin work on this project on \_\_\_\_\_ .

**By signing below, each person involved in the conduct of this study agrees to comply with all applicable human subjects protections regulations and IRB and institutional policies relative to this research protocol.**

**Additionally, each person verifies they have read the hospital policy regarding education requirements for Responsible Conduct of Research and are in compliance with the policy. Proof of required education will be supplied to the IRB upon request.**

**Conflict of Interest (COI) Statement:**

A conflict of interest may exist if anyone involved in the conduct of the study (or their spouse or family member) has a personal interest that may influence or appear to influence the objective performance of his or her duties to the research study. This could include a personal interest to receive personal gain or special advantage, conflict of official duty, or any activity that appears to interfere or is likely to interfere in objective professional judgment.

**All actual and/or potential conflicts of interest must be reported.** Reportable activities include, but are not limited to, involvement with the sponsor or other entity that may be affected by the research such as: (1) any income (e.g., consulting or speaking fees, honoraria, gifts, or compensation in the form of equipment); (2) equity or financial interest (e.g., stocks, stock options, patents, licensing agreements, interests in non-publicly traded company); (3) serving as a director, board member, officer, partner, trustee, employee, or member of a scientific advisory board; or (4) having proprietary interest in the investigational product being tested or in a competing product. **Please refer to the Conflict of Interest Policy for additional examples and aggregate value that may not be exceeded.**

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*Please initial:*

No COI                      COI                      IRBECs

Signed \_\_\_\_\_  
**Principal Investigator** (required for submission)      \_\_\_\_\_  
Date

**Signatures of Sub-Investigators and Key Personnel:**

(Preferred for submission, required before final approval letter will be sent)

*Please initial:*

**No COI                  COI                  IRBECs**

	Date			
	Date			
	Date			
	Date			
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	Date			
	Date			
	Date			

**Statement of Support and Signature of Department Manager or Section Chief:**

(Required for submission)

My signature below signifies my support of this study as presented in this document.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Dept. Manager or Section Chief

\_\_\_\_\_  
Name of Department/Section

RETURN THIS FORM TO:  
 Office for Research Integrity  
 Children's Mercy Hospital  
 Suite 600, Hospital Hill Center

(Form Rev. 11/17/05, replaces version 9/15/05)

## **PARENTAL PERMISSION AND CHILD ASSENT TO PARTICIPATE IN A RESEARCH STUDY AT THE CHILDREN'S MERCY HOSPITAL**

### **Congenital Heart Surgeons' Society (CHSS) Studies in Congenital Heart Disease**

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#### **WHO IS DOING THIS STUDY?**

This study is being conducted by The Children's Mercy Hospital's Cardiovascular Surgery Department. Dr. Gary Lofland, Primary Investigator, is in charge of this study. Dr. Gary Lofland and Dr. James O'Brien, Jr. are the Cardiovascular surgeons involved in this study. Lisa Barth, RN, MSN, MC-CNS; Lisa Laddish, RN, BSN; Kathleen O'Grady, RN, MSN, MC-CNS; and Stacy Reynolds, RN, CPNP, are the Cardiovascular Surgery Advanced Practice Nurses that coordinate the study activities at Children's Mercy Hospital. Pamela Dennis, RN, MA, CRNFA, Jennifer Swihart, RN, RRT, CCRC and Marcy Tarrants assist in study related activities as assigned by the surgeons and the advanced practice nurses. Vicki Headley, RN, RNC and Kathi Welch, RN, CPN; are nurse clinicians who may assist with the study.

The Congenital Heart Surgeons' Society (CHSS) has contracted with The Children's Mercy Hospitals and Clinics to do this study. The study personnel will not receive any personal financial benefits as a result of your decision.

We are asking your child to be in this research study. Please read the information below and ask questions about anything that you do not understand before you make a decision.

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#### **WHY IS THIS STUDY BEING DONE?**

The Congenital Heart Surgeons' Society (CHSS) collects information on individuals with congenital heart disease from many different centers around the United States and Canada. This information is kept in a registry. Because individuals with congenital heart disease have many different, and sometimes rare, conditions, compiling information from multiple centers gives us better information on how those who have congenital heart disease are doing, both in the short-term and the long-term, as well as which factors are associated with better or worse outcomes. The CHSS data center helps surgeons and cardiologists change their practices and helps them to give families accurate information about their family member's heart defect.

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#### **WHO CAN BE IN THIS STUDY?**

We are asking your child to participate in this study because he or she was born with a specific Congenital Heart Disease. About 70 surgeons will be enrolling children in this study at 45 different institutions.

The Children's Mercy Hospitals and Clinics will enroll approximately 2 patients per month in various CHSS studies.

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#### **WHAT WILL HAPPEN TO MY CHILD IN THIS STUDY?**

If you agree for your child to participate in this study, your child's diagnostic testing and surgery will not be altered in any way. Information regarding your child's hospitalization will be sent to the CHSS data center. Information such as your and your child's name and address, your child's diagnosis, social security number, pediatrician's name and address, medical and surgical reports, copies of echocardiograms, chest x-rays, and cardiac catheterizations will be entered into a password protected computer database. At intervals, healthcare professionals from the Children's Mercy Hospital or CHSS may call and/or mail a letter to you/your child, checking on your child's clinical progress. This letter is a survey that you will be asked to complete and return regarding your child's clinical progress. They may ask questions about the medication your child is receiving, and surgery or procedures conducted during the year. These data will be analyzed together with data from other children with the same diagnosis from centers around the country to determine the impact of patient characteristics, as well as treatment strategies on patient outcomes and to examine the overall health status and

quality of life of these children. The results will form the basis for scientific publication and will be presented at CHSS and other meetings. Each participant will be in this study indefinitely.

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### **WHAT ARE THE RISKS OF THE STUDY?**

There are no foreseeable risks in this study. If you agree for your child to participate in this study, your child's diagnostic testing and surgery will not be altered in any way. All records associated with your child's participation in this study will be strictly confidential within the registry. His or her name will not be released to any outside individuals or used in any publications.

There may be risks we don't know about right now. We will tell you about any new information that might change your decision to keep your child in the study.

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### **WHAT ARE THE BENEFITS OF BEING IN THIS STUDY?**

Information collected by this data center may contribute to the care of children in the future who have the same heart condition as your child. The information may also improve the future management of your child. However, at this time there are no guarantees that your child will benefit from participation in this study.

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### **WHAT ABOUT EXTRA COSTS?**

You will not have to pay anything extra if your child is in this study.

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### **WHAT ABOUT CONFIDENTIALITY?**

Your child has rights regarding the privacy and confidentiality of his or her health information. When health information includes identifiers (like names, addresses, phone numbers and social security numbers) that link it directly to an individual, it is called protected health information (PHI). Federal laws require that PHI be kept secure and private. In certain situations, federal law also requires that you approve of how your child's PHI is used or disclosed. A research study is one of those situations.

By signing this permission/assent form, you are permitting the following people to have access to your child's medical record and use your child's PHI for the research purposes described in this form:

- The research team, which includes the study personnel listed on this form and other persons involved in this study at Children's Mercy Hospitals and Clinics;
- The Congenital Heart Surgeons' Society and their designees;
- The Institutional Review Board at Children's Mercy Hospitals and Clinics;
- Federal regulatory agencies such as the Office for Human Research Protections.

Information about your child that is obtained during this study will be recorded in a research record. Information in the research record will be sent to the sponsor. This record will

- Include your and your child's name, address and telephone number, your child's medical record number, hospital account number, social security number and date of birth.

The research record is separate from your child's medical record. Information from your child's medical record may also be recorded in the research record. By signing this permission/assent form, you are allowing your child's information to be recorded in the research record. You are also permitting your child's research record to be shared with everyone listed above.

We will also keep a research file that stays in the Cardiovascular Surgery research office. That file may include documents that have your and your child's name, address and telephone number, your child's medical record number, hospital account number, social security number and date of birth.

The persons and groups listed above are required by federal law or by contract to keep any PHI in your child's research record secure and private. While confidentiality cannot be guaranteed, it will be protected to the greatest extent possible. There also may be some situations where laws require the release of your child's PHI. If your child's PHI is shared with an organization that is not required to comply with federal privacy laws, your child's health information is no longer considered protected and may be used and shared freely by that organization.

You may choose not to sign this permission/assent form and not have your child participate in the study. You may cancel your permission to use and share your child's PHI at any time by contacting the study personnel listed on this form or The Children's Mercy Hospital Medical Records Correspondence Department in writing. If you cancel your permission, your child may no longer participate in this study. If you cancel your permission, no more information will be recorded in your child's research record for study purposes. Your child's PHI that has already been collected for the study may still be used, however. Unless you cancel your permission, your child's PHI may continue to be recorded and used until the study is finished. Some information about the study may be included in your child's medical record. Any study information recorded in your child's medical record will be kept there indefinitely. In the case of a side effect or bad event, your child's entire medical record may need to be reviewed. Unless stated elsewhere in this form, you may not have access to your child's research record or test results.\

Results of this study may be made public. Your child will not be identified in any publications or presentations.

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#### **WHAT ARE THE ALTERNATIVES TO BEING IN THIS STUDY?**

The alternative to this study is not to participate. All tests and procedures will be performed regardless of participation in this study.

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#### **WHAT ARE MY CHILD'S RIGHTS AS A STUDY PARTICIPANT?**

Being in a research study is voluntary. Your child does not have to be in a study to receive care for his/her congenital heart defect. If you choose not to have your child participate, there will be no penalty or loss of benefits to which your child is otherwise entitled.

You may withdraw your child from the study at any time without penalty or loss of benefits to which your child is otherwise entitled.

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#### **WHO SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

Dr. Gary Lofland is in charge of this study. You may call him at (816) 234-3580 with questions at any time during the study. You may also call Marcy Tarrants, the study coordinator, at (816) 234-3580 with any questions you may have.

You may also call the Chair of the Pediatric Institutional Review Board (IRB) at (816) 234-3879 with questions about injury or your child's rights as a research subject. The IRB is a group of people who review studies to protect the rights of research subjects.

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#### **SPONSOR AND INSTITUTIONAL RESPONSIBILITIES**

It is not the policy of The Children's Mercy Hospital or the Congenital Heart Surgeons' Society to compensate research participants if the research results in injury. The hospital will provide facilities and medical attention to participants if needed.



\_\_\_\_\_  
Signature (Witness)

\_\_\_\_\_  
Date

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**NON-ENGLISH SPEAKING PARTICIPANTS**

Short form in Spanish given to parent/legal guardian.

Name of Person Providing Oral Translation \_\_\_\_\_

Relationship of Translator to Subject, Parent or Authorized Consenting Party \_\_\_\_\_

## DATA USE AGREEMENT

THIS DATA USE AGREEMENT (“Agreement”) is entered into this \_\_\_\_ day of \_\_\_\_\_, 2006 (Effective Date”) by and between \_\_\_\_\_ (“Hospital”) and \_\_\_\_\_ (“Data Recipient”).

WHEREAS, Hospital and Data Recipient wish to enter into or have entered into an oral or written arrangement or arrangements (collectively “Arrangement”) whereby Hospital may give Data Recipient Protected Health Information (“PHI”) as defined in 45 CFR §164.501 that is in the form of a Limited Data Set as defined in 45 CFR §164.514 (e) (2);

WHEREAS, Hospital is obligated under the Health Insurance Portability and Accountability Act of 1996 and the standards set forth at 45 CFR Parts 142, 160, 162, and 164 (collectively “HIPAA”) to safeguard PHI and ensure that Data Recipient maintains the integrity of PHI and uses and discloses PHI in accordance with HIPAA; and

WHEREAS, Data Recipient understands and acknowledges that the terms of this Agreement shall govern the use and disclosure of PHI disclosed to, provided by, received by, or created by Data Recipient in the course of providing the services under the Arrangement.

NOW, THEREFORE, the parties agree as follows:

1. Use and Disclosure Obligations. Data Recipient agrees to use and disclose PHI only to the extent necessary to perform its specific obligations under the Arrangement. Data Recipient agrees not to use or further disclose PHI other than as permitted or required by the Arrangement or this Agreement, or as required by law.
2. Safeguards. Data Recipient will use appropriate safeguards to prevent the use or disclosure of PHI other than as provided for in the Arrangement and this Agreement.
3. Reporting Obligation. Data Recipient will report to Hospital any use or disclosure of PHI of which Data Recipient becomes aware that is not permitted by the Arrangement or this Agreement.
4. Agents and Subcontractors. Data Recipient will ensure that any agents, including subcontractors, to whom it provides PHI agree to the same restrictions and conditions that apply to Data Recipient with respect to such information.
5. Identification of Individuals. Data Recipient agrees that it will make no attempt to identify or contact the individual to whom the PHI pertains unless such identification or contact is required by law.
6. Indemnification. Data Recipient shall indemnify and hold harmless Hospital from and against any and all losses, expense, damage or injury that Hospital may sustain as a result of, or arising out of a breach of this Agreement by Data Recipient or its agents or subcontractors, including but not limited to any breach or security or unauthorized use or disclosure of PHI.
7. Termination. Hospital may immediately terminate this Agreement, the Arrangement and access to PHI if Hospital becomes aware of any breach of this Agreement.

8. Miscellaneous.

- a. No Other Modifications. Except to the extent inconsistent with this Agreement, the Arrangement shall remain in full force and effect with no further modifications.
- b. Relationship of Parties. None of the provisions of this Agreement are intended to create or shall be deemed to create any relationship between the Parties other than that of independent parties contracting with each other solely for the purposes of effecting the provisions of this Agreement and any other Arrangement between the Parties.
- c. Ownership of Information. PHI created for or received from Hospital is, and will remain, the property of Hospital unless otherwise specified under the terms of the Arrangement. Data Recipient agrees that it acquires no ownership rights to or title in any PHI.
- d. No Third Party Beneficiaries. Nothing express or implied in this Agreement is intended to confer, nor shall anything herein confer, upon any person or entity other than the individual who is the subject of the PHI, the Hospital or Data Recipient and their respective successors and assigns, any rights, remedies, obligations or liabilities whatsoever.
- e. Successors and Assigns. This Agreement shall be binding on the parties and their successors, but neither party may assign the Agreement without the prior written consent of the other, which consent shall not be unreasonably withheld.
- f. Waiver. No change, waiver or discharge of any liability or obligation hereunder on any one or more occasions shall be deemed a waiver of performance of any continuing or other obligation, or shall prohibit enforcement of any obligation, on any occasion.
- g. Severability. In the event that any provision of this Agreement is held by a court of competent jurisdiction to be invalid or unenforceable, the remainder of the provisions of this Agreement shall remain in full force and effect.
- h. Modification to Comply with Law. The Parties acknowledge that state and federal laws relating to the security and privacy of PHI are rapidly evolving and that modification of this Agreement may be required to provide for procedures to ensure compliance with such developments. The Parties specifically agree to take such action as is necessary to implement the standards and requirements of HIPAA. The Parties understand and agree that Hospital must receive satisfactory written assurances from Data Recipient that Data Recipient will adequately safeguard all PHI. Upon request of either party, the other party agrees to promptly enter into negotiations concerning the terms of a modification to this Agreement embodying written assurances consistent with the standards and requirements of HIPAA. Hospital may terminate the Arrangement and access to PHI upon thirty (30) days written notice in the event: (1) Data Recipient does not

promptly enter negotiations to modify this Agreement when requested by Hospital under this section; or (2) Data Recipient does not enter into a modification of this Agreement providing assurances regarding the safeguarding of PHI that Hospital, in its sole discretion deems sufficient to satisfy the standards and the requirements of HIPAA.

- i. Amendment. This Agreement may be amended or modified only in writing signed by the Parties.
- j. Notice. Any notices required under this Agreement shall be deemed provided if sent by first class United States mail, postage prepaid, to Data Recipient at Data Recipient's last known address and to Hospital as follows:

To Hospital: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

With a Copy to: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

- k. Interpretation. This Agreement shall be governed by the laws of the State of \_\_\_\_\_ and interpreted as broadly as necessary to implement and comply with HIPAA. The Parties agree that any ambiguity in this Agreement shall be resolved in favor of a meaning that complies and is consistent with HIPAA.
- l. Survival. The respective rights and obligations of Data Recipient under this Agreement shall remain in force until all PHI provided by or created for Hospital is destroyed or returned to Hospital.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the day and year first written above.

Hospital: \_\_\_\_\_ Data Recipient: \_\_\_\_\_  
 Signature: \_\_\_\_\_ Signature: \_\_\_\_\_  
 Print Name: \_\_\_\_\_ Print Name: \_\_\_\_\_  
 Title: \_\_\_\_\_ Title: \_\_\_\_\_