



## **Common Questions and Answers about the Revisions to the Pulmonary Conduit Study**

1) **Why did the data entry system change?**

As of January 5<sup>th</sup> 2005 we have enrolled 160 patients into the study. However, the data entry is incomplete:

- About one-third of the patients that have been assigned study numbers have no data entry.
- We have no way of validating the data in the Data Center. If we do see an aberrant value in a file, the only way of confirming the entry is to contact the person in the CHSS institution.
- Follow-up of these patients is very difficult because many are followed at a non-CHSS institution or their follow-up may be unknown within the CHSS institution as it may be done entirely by Cardiology.

2) **What has stayed the same and what has changed about this study?**

The Goals and Objectives for this study have remained the same. The way in which the data is processed has changed. Institutions will no longer be entering patient data over web-based database.

Each institution will now send the CHSS Data Center copies of reports extracted from the child's health records. The list of requested reports has been added to the PATIENT ENROLLMENT FORM. This form is posted on the CHSS Data Center website ([www.chssdc.org](http://www.chssdc.org)).

3) **Do I have to wait for the Data Center to assign a study number before I can send the data?**

Institutions no longer have to wait for a study number to be assigned. When a patient who meets the criteria is consented, the Enrollment form is completed and sent to the CHSS Data Center along with the requested reports.

This can be done by FAX ( 416-813-8776) or by courier.

4) **What about the patients who have already been enrolled on the web-based data base. What information do I need to send the CHSS Data Center?**

Each institution that has already enrolled patients on the web-based database will be sent a list of their current study patients. For each of these patients, we are asking for copies of the reports as listed on the revised PATIENT ENROLLMENT FORM under "What needs to be sent...".

5) **Who will be contacting the patients for their Follow-up and when will this happen?**

Each center will be asked for permission for the CHSS Data Center to be able to contact the patients directly for a scheduled follow-up each year. This is the way we have conducted follow-up for all the other CHSS studies. Providing the patient's consent form allows contact by the CHSS Data Center and the institutions agrees, the patients will have yearly Follow-up by the CHSS Data Center. This will benefit those patients who are not being followed on a regular basis by their enrolling institution.

6) **Our Institution consent form does not state that the CHSS Data Center can contact our families, what do we do?**

The institutions may choose to amend their consent form to allow the CHSS Data Center to contact the patient's family directly for scheduled follow-up. These patients will need to be re-consented with the amended consent form.

**OR**

Institutions may choose to contact the families directly on behalf of the CHSS Data Center. In this case, the CHSS Data Center will prepare pre-printed follow-up forms for the institutions to complete and return.

7) **We would rather the CHSS Data Center do the follow-up for the families:**

If the Consent form needs to be amended to allow this change, the CHSS Data Center will assist those institutions with the follow-up until permission is obtained from the patient.

8) **Will these protocol changes affect the time period for enrolling new patients?**

No, please refer to the Inclusion Criteria on the PATIENT ENROLMENT FORM for details about enrolment.

9) **Where can I get more information?**

You can contact Geraldine Cullen-Dean, Study Coordinator at 416-813-8477, email: [gcdean@sickkids.ca](mailto:gcdean@sickkids.ca), and visit the CHSS Data Center website for regular updates: [www.chssdc.org](http://www.chssdc.org)