



Congenital Heart Surgeons' Society Data Center
Our Research Saves Lives

CHSS Coordinator Newsletter

CHSS Study Amendments

Overview of Amendments

There have been two sets of amendments:

First Set

1. AAOCA - Protocol Version 3 - 29 Jun 2015
2. LVOTO - Protocol Version Date: 30 Jun 2015
3. TA - Protocol Version Date: 01 Jul 2015
4. Addition of accompanying documents, both study specific AND generic

Second Set

1. AAOCA - Protocol Version 4 - 22 Sep 2015
2. LVOTO - Protocol Version Date: 22 Sep 2015
3. TA - Protocol Version Date: 22 Sep 2015
4. CHSS Studies (non-enrolling)- Protocol Version Date: 22 Sep 2015
 - o Addition of/and revisions to current accompanying documents, both study-specific **AND** generic

AAOCA Amendment: Protocol Version 3 - 29 Jun 2015

- To further detail/clarify current processes, and add process changes (e.g., use of Consent for Release of Medical Information; use of CHSS Data Center Registration Form);
- Added current process of welcoming parents/guardians of new subjects and new subjects enrolled into the study;
- Privacy, Security, Confidentiality sections reworded/updated for further clarify

Note: SickKids Scientific Peer Review recommendations, resulted in updates to the following sections of the Protocol: Follow-Up, Confidentiality

LVOTO Amendment: Protocol 30 June 2015

- To further detail/clarify current processes, and add process changes (e.g., use of Consent for Release of Medical Information; use of CHSS Data Center Registration Form);
- Now including waiver/alteration to include deceased subjects;
- Added current process of welcoming parents/guardians of new subjects enrolled into the study;
- Confidentiality and Security section added to further detail processes;
- Risk Assessment section added;
- Statistical Analysis section revised;
- Publications section added

Note: SickKids Scientific Peer Review recommendations, resulted in updates to the following sections of the Protocol: Background, Study Population, Study Design, Follow-up, Outcomes/Follow-up, and Statistical Analysis

TA Amendment: Protocol 01 July 2015

- A newly created TA protocol (Version Date: 08 June 2015) was created to describe our current processes, containing the essential elements per standard protocol requirements in observational research
- Revisions to that version were made, after SickKids Scientific Peer Review and prior to submission to SickKids REB (resulting in Protocol Version Date: 01 Jul 2015)
- Those further updates to the protocol include:
 - The process of welcoming newly enrolled, CHSS registered participants;
 - Revisions in Statistical Considerations section

AAOCA, LVOTO, TA Amendments: June/July 2015

- Coordinators were notified via email on September 30th regarding SickKids REB approval of the amendments for TA, AAOCA, and LVOTO studies
- Approved documents were posted on the website at that time
- Some participating institutions chose to submit the above mentioned amendments to their IRB/REB shortly after the September 30th notification
- The majority of participating institutions did not submit their amendments at that time and instead decided to await the second round of amendments initiated in September, thus only dealing with one submission instead of two

AAOCA, LVOTO, TA Amendments: September 2015

These amendments were initiated to streamline the Follow Up and other processes outlined below:

Previous Version

1. AAOCA: Protocol Version 3 – 29 Jun 2015
2. LVOTO: Protocol Version Date: 30 Jun 2015
3. TA: Protocol Version Date: 01 Jul 2015
4. CHSS non-enrolling Study Cohorts: Protocol Version Date: 2013 10 23

Updated Version

1. AAOCA: Protocol Version 4 – 22 Sep 2015
2. LVOTO: Protocol Version Date: 22 Sep 2015;
3. TA: Protocol Version Date: 22 Sep 2015
4. CHSS non-enrolling Study Cohorts: Protocol Version Date: 22 Sep 2015

- Numerous (revised and/or new) accompanying documents (some study-specific; some generic: for use in AAOCA, LVOTO, TA, and CHSS non-enrolling Study Cohorts) Version Date range: Sep to Dec 2015

Revisions to AAOCA, LVOTO and TA protocols:

- To further detail/clarify current processes and add process changes (e.g. addition of questionnaires for annual follow-up);
- Clarification with respect to consent process, to include authorization, as applicable;
- Clarification of process of welcoming subjects into the study when they consent for themselves to continue participation

- Clarification with respect to obtaining consent for release of medical information
- Privacy section: further details provided with respect to the transfer of information to the CHSS DC
- References: PedsQL references added as well as other minor administrative changes in text

CHSS non-enrolling Study Cohorts Amendment - Protocol 22 Sep 2015

Revisions to Protocol:

- To clarify that this is the protocol for the non-enrolling CHSS study cohorts (closed to enrollment), that are in follow-up phase only (see separate Appendices in the protocol, addressing details of each of these cohorts)
- To further detail/clarify current processes, and add process changes (e.g., addition of Questionnaires for annual follow-up);
- Clarification with respect to consent process, including the role of the CHSS Data Center with respect to the consent process (specifically, obtaining consent from parents/guardians and subjects who are eligible to provide consent, in cases where the subjects are no longer followed by the institutions where they were originally enrolled into the study in or before the year 2000);
- Clarification with respect to obtaining consent for release of medical information;
- Confidentiality section: further details provided with respect to the current processes, including the transfer of information to the CHSS Data Center;
- References: PedsQL references added;
- Other minor administrative changes in text

SickKids REB Approval granted for:

- AAOCA
- LVOTO
- TA
- CHSS non-enrolling cohort studies (amendments initiated in September 2015) in January 2016

Where to find Documents

Current SickKids REB Approved documents are posted on the website. To locate study documents please click [here](#) and choose a specific study from the menu.

Approval was also obtained for 50 PedsQL™ Inventories (these are not posted on the website, as they are copyright protected materials). We've outlined specific processes in the document PedsQL™ Quality of Life and Cardiac Module Inventories... Age & Consent/Assent Status (Version Date: 22 Oct 2015)

What Documents will I find?

1. (7) Protocol Amendment Summary Documents (under the applicable specific study section)
 - Information from these Summary documents may be used if needed for your IRB/REB amendment submissions
2. Current SickKids REB-approved Protocols:
 - Clean copy: needed for IRB/REB submission;
 - Track changes copies, if needed for IRB/REB submission, *and*
 - Current accompanying documents (some 'study-specific'; some 'generic'): as needed for IRB/REB submission (as applicable)

Note:

- Some documents are *study-specific* [applicable only to that one Study (and listed under that Study specifically on the website)], and
- Some documents are *generic* (i.e., current SickKids REB-approved for use for all the following studies: CHSS non-enrolling cohorts; TA; LVOTO; AAOCA)
 - The *generic* documents can be accessed only through each of the above-noted Study sections, which links up with the 'generic documents for enrollment, registration & follow up' section
- If your institution is participating in, or would like to participate in, any of the studies, you may copy the documents, as needed, for your own IRB/REB initial or amendment submissions, as applicable (except for the consent/assent documents and related cover letters, which are posted for *reference only*; for those documents: you may adapt the text if you wish and make it specific to your own institution (as applicable), for submission to your IRB/REB for review/approval)

Study Documents NOT Posted to Website

PedsQL™

- PedsQL™ Inventories will be (or have been) sent to you, under separate cover, for IRB/REB submission, as needed
- These PedsQL™ Inventories may only be used for your IRB/REB submission for the above-noted studies (***may not*** be used by sites to administer the PedsQL™;

may not be used for any other purpose)

Amendment Instructions Document

- An Amendment Instructions document for each of the amended studies (AAOCA; LVOTO; TA; CHSS non-enrolling Cohorts) was sent to participating institutions (in Feb 2016)
- For the study/ies your institution is participating in: please submit the(se) amendment(s) to your IRB/REB on or by 07 Mar 2016)

Tracking Amendment Approval

You will receive email communications, on an approximately monthly basis, or as needed, to track your amendment progress up to your IRB/REB amendment approval. Please submit a copy of your IRB/REB amendment approval document(s) [including any approved revised consent (and authorization, as applicable) and assent forms] directly to [Kathryn](#), as soon as obtained from your IRB/REB.

Consent/Assent and/or Re-Consent/Re-Assent

- After receiving your IRB/REB amendment approval, if you are required to re-consent your study participants/parents-guardians, and/or re-assent (or obtain assent), please obtain this ASAP thereafter
- Then submit most recent re-consent; re-assent (or assent) signed documents, via secure file transfer or via secure courier, to the CHSS Data Center, ASAP, but no later than **01 August 2016**
- Your IRB/REB amendment approval letter, signed consent/assent documents [and/or pertinent explanations (e.g., written re-consent/re-assent is not required, as implied consent is sufficient for Questionnaire completion; or assent is not applicable, as Subject lacks capacity to provide assent)] will be used/reviewed by the CHSS Data Center to determine what Annual Follow-up Questionnaires are to be administered by CHSS Data Center
- Please also refer to the 'generic' document: PedsQL™ Quality of Life and Cardiac Module Inventories ... Age & Consent/Assent Status (Version Date: 22 Oct 2015) for further process and examples of explanations
- Submission of the above-noted documentation and adherence to these timelines

are very important, to keep the Annual Follow-up timelines on schedule for 2016

Upcoming AVSD Study Amendment

Revisions to the AVSD Study have been made to address the processes already addressed and approved in the other studies and have been submitted to SickKids REB for renewal and approved. You will be notified when SickKids REB Approval is granted for this AVSD Study Amendment

Questions?

If you have any questions or comments about these study amendments or processes, or about navigating the website to obtain study documents, or required timelines, please contact:

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