Coordinator Conference Call Reminder

Just a reminder that the September conference call has been rescheduled to the following dates & times:

- Wednesday, September 23, 2015 at 2:00 PM EDT
- Thursday, September 24, 2015 at 11:00 AM EDT

You only need to participate in ONE of these calls. Please let us know if you have any suggestions for the agenda, and we would be happy to accommodate your requests. If you have any questions regarding the coordinator calls, please contact susan.mcintyre@sickkids.ca

Coming Up: Annual Coordinator Meeting

We have a great meeting planned for the CHSS annual study coordinator meeting on October 25-26, 2015 in Chicago. We are hoping to have each site represented by a coordinator! For those of you that have joined us before and asked that we provide CEU credits, we have been able to provide them without an increase to the registration fee. This is in thanks to the executive committee who has agreed to cover this cost. The final agenda should be ready for your review online in the coming week. As you know, a key part of research is the collection and submission of data by the coordinators. We view your attendance at this meeting as a step towards our goal of engaging each of the coordinators, and impressing upon you the vital role that you play in the success of CHSS studies. Please visit the CHSS website at chss.org and register online to reserve your hotel room at the Westin O'Hare. The deadline to receive the discounted rate for accommodations is October 2, 2015 at 5:00 pm Central Time. We look forward to seeing you in Chicago!

Children & Young Adults with CHD: Support Groups

We are reaching out to our institutional coordinators to see if we can compile a comprehensive list of support groups within each state/province. We plan to post this list to the CHSS website so that we can direct patients who are interested in connecting with other families, and peers, for additional support throughout their journey. Please send all support group information to ilina.ristevska@sickkids.ca if you haven't done so already.
REGULATORY CONNECTION REMINDER

As previously requested in the July 2015 newsletter:

Study Documentation Request to Participating Sites/Institutions
If you have not already done so, please provide a copy of the following to the CHSS Data Center for each CHSS research study in which your institution/site is participating (and the CHSS Data Center is the Coordinating Site for the study):

1. Institutional Review Board (IRB)/Research Ethics Board (REB)/Privacy Board
   (a) Initial IRB/REB approval of the study
   (b) IRB/REB approval of any amendments subsequent to the initial IRB/REB approval of the study
   (c) Any Privacy Board Approvals/Re-Approvals, as applicable [US sites only]
   (d) Current IRB/REB-approved Consent Forms/Assent Forms, and for US sites only: any separate HIPAA Authorization used for the study (as applicable)
   (e) Each IRB/REB re-approval/continuing approval of the study, subsequent to the initial IRB/REB approval of the study

2. Contract – Data Transfer Agreement (DTA)
   Please ensure that you have a fully executed DTA to cover all CHSS research studies in which your institution/site is participating (and CHSS Data Center is the Coordinating Site). A copy of the fully executed DTA needs to be on file at your institution/site, as well as at the CHSS Data Center.
   *For your convenience, the current DTA templates are located on our website: www.chssdc.org – these are general DTA templates (one template for US institutions; one template for Canadian institutions), set up to cover all CHSS Data Center research studies you are/may be participating in.

If you are not sure if your institution/site has provided the above-requested documents/ if you need to submit the requested documents/ if you have any questions regarding this, please contact: kathryn.coulter@sickkids.ca.

Please Note: There is no need to re-submit any documents that have already been submitted to the CHSS Data Center.

FALL WORK WEEKEND
The Fall Work Weekend has been finalized and is scheduled for the weekend of November 20 – 22nd, 2015.
SAVE THE DATE! Details to follow as the date nears.
We recently closed follow up on the IAA cohort with 51%. Currently, we are in the middle of follow up calls for TA and have sent out a data update request to those institutions involved in the study. If you have any current demographic or clinical updates on patients in any of these cohorts, please feel free to send us their information via Secure File Transfer, mail or fax.

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<tr>
<th>Current Enrollment Numbers</th>
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<tbody>
<tr>
<td>AAOCA</td>
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<td>Tricuspid Atresia</td>
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<td>LVOTO</td>
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¿HABLAS USTED INGLES?

When conducting annual follow up calls, we run into a common language barrier. Certain Spanish-speaking families have trouble completing their annual follow-up over the phone. We would like to ensure that this population is able to participate, therefore, we are asking coordinators if it is at all possible when enrolling Spanish-speaking families, to find out if they have an English-speaking relative or representative that they would like to designate in order to help complete the participants’ annual follow-up. The Spanish-speaking families that we have been in correspondence with normally have a designated individual for us to call in order to obtain follow up. We would like to maintain contact with the Spanish-speaking population through this method in the future and hope that you can help us!

TECHNICAL ASSESSMENT PROJECT

We are pleased to announce that the web-based TAP modules are now functional. The TPS ‘measures’ specific components of an operation (for example VSD closure and relief of RVOTO for Tetralogy of Fallot). The premise is that, by scoring different elements of the repair, an individual surgeon will gain insight into those parts of an operation they do very well, but might be able to improve on others. Please discuss this project with your member surgeon. The Data Center has received QI approval as well as approval from its legal department of the data sharing agreement. However, your institution may still require IRB approval or waiver before you can begin entering data. If this is the case, you will need the CHSS approval letter/protocol and the data sharing agreement located on the CHSS website:

www.chssdc.org/content/technical-assessment-project

Again, please inquire with your IRB as to what will be required prior to beginning participation.