



## Heat Loss Prevention Trial Newsletter #8

Next HeLP Trial Investigator meeting will take place during the Pediatric Academic Societies' Annual Meeting on May 6<sup>th</sup> at 1700hrs in Toronto, Ontario, Canada. Location to be announced.

Welcome to our eighth HeLP Trial Newsletter. The purpose of the newsletter, as always, is to keep you up to date on trial-related information and share with you the great work our HeLP Trial participating centers are doing.

We will be having an investigator's meeting during PAS that is being held here in Toronto, the main coordinating center for the HeLP Trial. We are excited to be hosting this conference in our beautiful city. Because many of our participating sites will not be sending members to PAS, we will host a web conference in late May to update you all on the progress of the trial.

If you are attending PAS, we hope to see you at the investigator meeting. If you have any questions about Toronto or would like ideas of where to eat or what to see, please let Maureen know.

### Institutional Consent Update

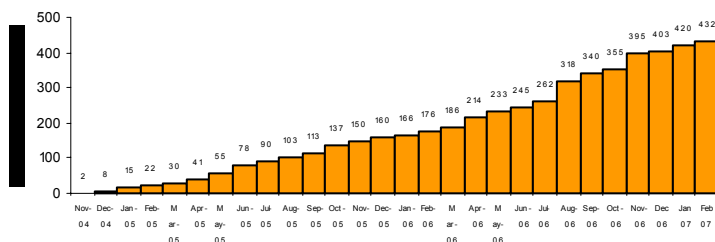
Currently 3 US centers are enrolling HeLP Trial infants under Institutional Consent (IC) or a waiver of consent. There are many different ways to apply the use of IC. If you are interested in pursuing IC, all forms necessary for IRB/HREB application are available on the HeLP Trial Website. If you are interested in applying to your IRB for IC please contact Maureen so we can guide you through the process.

### Randomization

As of the beginning of March, **432 infants** have been enrolled: **417 infants** in the main study and **15 infants** in the <24 week gestation pilot study.

Congratulations to Albert Einstein Medical Center who enrolled the 400<sup>th</sup> infant.

HeLP: Cummulative Patient Enrollment



### Study Materials

HeLP Trial materials. Please let Maureen know when you are running low on thermometers, wraps, and randomization cards so she can arrange to have supplies shipped to you.

### Web conference

We will have our next HeLP Trial web conference in May. Stay tuned for more info.

Previous web conferences are available on the HeLP Trial website.

The audio and presentation are available at:

<http://www.vtoxford.org/protected.aspx?p=research/help/education.htm>

### First Interim Analysis

Many randomized controlled trials have interim analyses to ensure participant safety - if there is overwhelming evidence that a treatment causes or prevents harm, then a study may be stopped prematurely. Our first interim analysis will take place when we have reached 25% enrollment (421). We expect to reach that number by the end of March. The data on the infants will be sent to Edmonton for blinded analysis then on to our Data and Safety Monitoring Board (DSMB) for blinded review. Blinding is used to ensure that bias does not affect how the data are interpreted. We expect to have a report from them by September. If there is a compelling safety reason to stop our study, we will alert you to this immediately. We are not expecting this - the more likely scenario is that the study will continue until we reach our sample size. In the meantime, the DSMB will be releasing their bi-annual monitoring report in the next few weeks. We will send the report out on the helptrial listserve.

### Reminders

- **Remember to fax your randomization cards, even if you do not have VON #, ASAP after delivery to 802 865 9613. Receiving randomization cards on time allows us to keep track of enrollment numbers more accurately.**
- **Remember to inform Karla at VON asap when a VON number becomes available for a HeLP Trial infant.**

### FAQ

**Question:** How do I answer the question 14 on Form 6: Age when oxygen last discontinued when the infant is going home on oxygen?

**Answer:** Please tick off not applicable. For question 15: Respiratory Support at 36 weeks corrected age or discharge, tick off oxygen vial head box or low flow nasal cannula.

VON HeLP Trial website: <http://www.vtoxford.org/home.aspx?p=research/help/index.htm> (login: help trial; password: \*babywrap8\*)

HeLP Trial Principal Investigators:

Maureen Reilly: [maureen.reilly@sunnybrook.ca](mailto:maureen.reilly@sunnybrook.ca)

Sunita Vohra: [svohra@ualberta.ca](mailto:svohra@ualberta.ca)

VON:

Karla Ferrelli: [karla@vtoxford.org](mailto:karla@vtoxford.org)

Fax: 802 865 9613

HeLP Trial Coordinating Center:

Tel : 416 323 6400 x 3033, Fax 416 323 6011