

Hyperbaric Oxygen Brain Injury Treatment Trial (HOBIT) Finance Overview

ClinicalTrials.gov: [NCT02407028](https://clinicaltrials.gov/ct2/show/study/NCT02407028)
NIH Project Number: [1U01NS095926-01A1](https://www.nih.gov/record/1U01NS095926-01A1)

Hubs and spokes (designated by rectangles) represent enrollment sites. Circles are coordinating entities. Dotted lines represent optional relationships. Dashed lines represent Hub-spoke complexes. Number of blue "award sites" is established by number of individual NIH enrollment hub awards. Steering Committee includes all "award site" PI's (including multiple PI's) with only one vote per award site. Green "hubs" are affiliated with "award sites" but have their own master agreement with the CCC. Which sites within a hub-spoke complex are "hubs" is determined locally, but are typically distinguished by the "hub" being an institution that has its own spokes. Ancillary Hub/spokes are typically contracted by the Trial Prime if brought on for a single trial, or by the CCC if expected to participate in multiple trials (including those already participating in multiple trials).

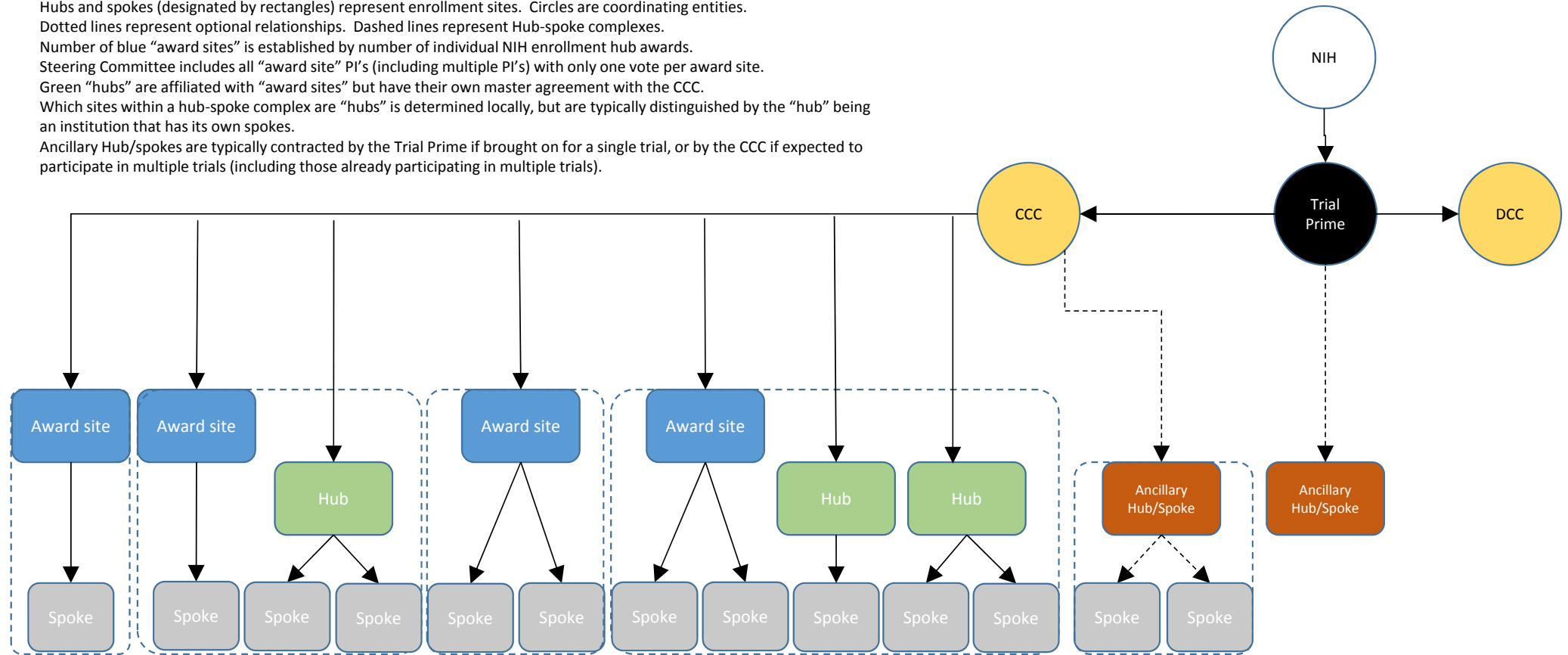


Illustration of proposed contractual relationships in SIREN

Master Agreement

- Provide overarching terms for SIREN trials
- Executed only once
- Date reflects entire SIREN award period
- Trials are riders to the Master Agreement

Start-up Payment

- \$2000 (inclusive of F&A costs)
- Paid to each performance site
- Site has completed the required trainings, submitted regulatory documents
- Released by the Clinical Coordinating Center to enroll subjects.

Patient Simulation

- A one-time payment of \$1500 (inclusive of F&A costs) will be provided to each performance site after the submission of the clinical simulation video per the instructions outlined in the HOBIT manual of procedures.

Control Group

- Up to \$10,000 (inclusive of F&A costs)
 - **Payment 1- \$6500:** Subject enrollment, treatment and data entered into the CRFs.
 - **Payment 2- \$3500:** Completion of 6-month follow up visit and data entered into the CRFs.

10-treat tier

- Up to \$20,000 (inclusive of F&A costs)
 - **Payment 1**
 - **\$1500**: Subject enrollment
 - **\$1000*** number of completes treatment (up to \$10,000)
 - **\$5000**: data entered into the CRFs.
 - **Payment 2**
 - **\$3500**: Completion of 6-month follow up visit and data entered into the CRFs.

Invoicing

- CCC generates invoices based on information in WebDCU
- Copies of invoices sent to contracted sites
- Payment information entered into database
- Process transparent to all



https://webdcu.musc.edu/nett/ListRecord.asp?theFormID=1259

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Regular Entry Web Slice Gallery

Valerie STEVENSON Sign Out



List: Subject Payment

Help

Center = emory

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Page Actions

#	Subject	Center	Site	Payment Name	Payment Status	Date First Ready	Invoiced On	Paid On	Check Issued On	Amount
1	2434	Emory	Children's Healthcare of Atlanta at Egleston, Atlanta, GA	ESETT Payment 1	Ready	27-Jan-2018	06-Feb-2018			
2	2435	Emory	Children's Healthcare of Atlanta at Egleston, Atlanta, GA	ESETT Payment 1	Ready	27-Jan-2018	06-Feb-2018			
3	2441	Emory	Children's Healthcare of Atlanta at Egleston, Atlanta, GA	ESETT Payment 1	Ready	15-Feb-2018				
4	1005	Emory	Grady Memorial Hospital, Atlanta, GA	ESETT Payment 1	Paid	19-Feb-2016	29-Feb-2016		14-Mar-2016	7500
5	1008	Emory	Grady Memorial Hospital, Atlanta, GA	ESETT Payment 1	Paid	19-Feb-2016	29-Feb-2016		14-Mar-2016	7500
6	1012	Emory	Grady Memorial Hospital, Atlanta, GA	ESETT Payment 1	Paid	19-Feb-2016	29-Feb-2016		14-Mar-2016	7500
7	1016	Emory	Grady Memorial Hospital, Atlanta, GA	ESETT Payment 1	Paid	04-Feb-2016	29-Feb-2016		14-Mar-2016	7500
8	1026	Emory	Grady Memorial Hospital, Atlanta, GA	ESETT Payment 1	Paid	03-Feb-2016	29-Feb-2016		14-Mar-2016	7500
9	1027	Emory	Grady Memorial Hospital, Atlanta, GA	ESETT Payment 1	Paid	20-Feb-2016	29-Feb-2016		14-Mar-2016	7500
10	1042	Emory	Grady Memorial Hospital, Atlanta, GA	ESETT Payment 1	Paid	25-Feb-2016	29-Feb-2016		14-Mar-2016	7500
11	1044	Emory	Grady Memorial Hospital, Atlanta, GA	ESETT Payment 1	Paid	26-Feb-2016	05-Apr-2016		08-Apr-2016	7500
12	1045	Emory	Grady Memorial Hospital, Atlanta, GA	ESETT Payment 1	Paid	26-Feb-2016	05-Apr-2016		08-Apr-2016	7500
13	1056	Emory	Grady Memorial Hospital, Atlanta, GA	ESETT Payment 1	Paid	18-Mar-2016	13-Jun-2016		27-Jun-2016	7500
14	1062	Emory	Grady Memorial Hospital, Atlanta, GA	ESETT Payment 1	Paid	06-Apr-2016	13-Jun-2016		27-Jun-2016	7500
15	1084	Emory	Grady Memorial Hospital, Atlanta, GA	ESETT Payment 1	Paid	04-May-2016	13-Jun-2016		27-Jun-2016	7500
16	1108	Emory	Grady Memorial Hospital, Atlanta, GA	ESETT Payment 1	Paid	23-Jun-2016	27-Jun-2016		18-Jul-2016	7500
17	1109	Emory	Grady Memorial Hospital, Atlanta, GA	ESETT Payment 1	Paid	01-Jun-2016	27-Jun-2016		18-Jul-2016	7500
18	1113	Emory	Grady Memorial Hospital, Atlanta, GA	ESETT Payment 1	Paid	15-Jun-2016	27-Jun-2016		18-Jul-2016	7500
19	1116	Emory	Children's Healthcare of Atlanta at Egleston, Atlanta, GA	ESETT Payment 1	Paid	16-Jun-2016	27-Jun-2016		18-Jul-2016	7500
20	1120	Emory	Grady Memorial Hospital, Atlanta, GA	ESETT Payment 1	Paid	02-Jul-2016	08-Aug-2016		19-Aug-2016	7500

All information is generated based on data currently in the database. Data may not be verified or validated. The report is generated to assist in trial operations only, and is not valid to support any statistical analysis of study data. Unless noted, the Data Coordination Unit (DCU) assumes no responsibility for the use of this report. This report may contain protected health information covered by the Health Insurance Portability and Accountability Act (HIPAA). You are prohibited from disclosing this information without the specific written consent of the person to whom it pertains. Anyone using this data specifically assumes responsibility for maintaining the confidentiality of the protected data.

No.	Item Description	Data Value
1	Subject	1008
2	Center	Emory
3	Site	Grady Memorial Hospital, Atlanta, GA
4	Payment Name	ESETT Payment 1
5	Payment Status	Paid
6	Status Date	14-Mar-2016 (dd-mmm-yyyy)
7	Date First Ready	19-Feb-2016 (dd-mmm-yyyy)

8 Payment Condition Check
Payment Condition Check

No.	A. Condition	B. Value	C. Date
8-1	All Required and Data Entered CRFs through End of Study Visit are Submitted	Passed	16-Feb-2018 4:03AM
8-2	All DCRs through End of Study Visit are Responded	Passed	16-Feb-2018 4:03AM
8-3	End of Study Visit is Posted	Passed	16-Feb-2018 4:03AM

Payment Activity

9	Invoiced By	
10	Invoiced On	29-Feb-2016 (dd-mmm-yyyy)
11	Paid	<input type="radio"/> No <input checked="" type="radio"/> Yes
12	Paid By	
13	Paid On	
14	Check Issued By	
15	Check Issued On	14-Mar-2016 (dd-mmm-yyyy)
16	Amount	7500
17	Check No	3704185
18	Note	

Last updated by Janice OSOWSKI on 23-Mar-2016 12:15PM