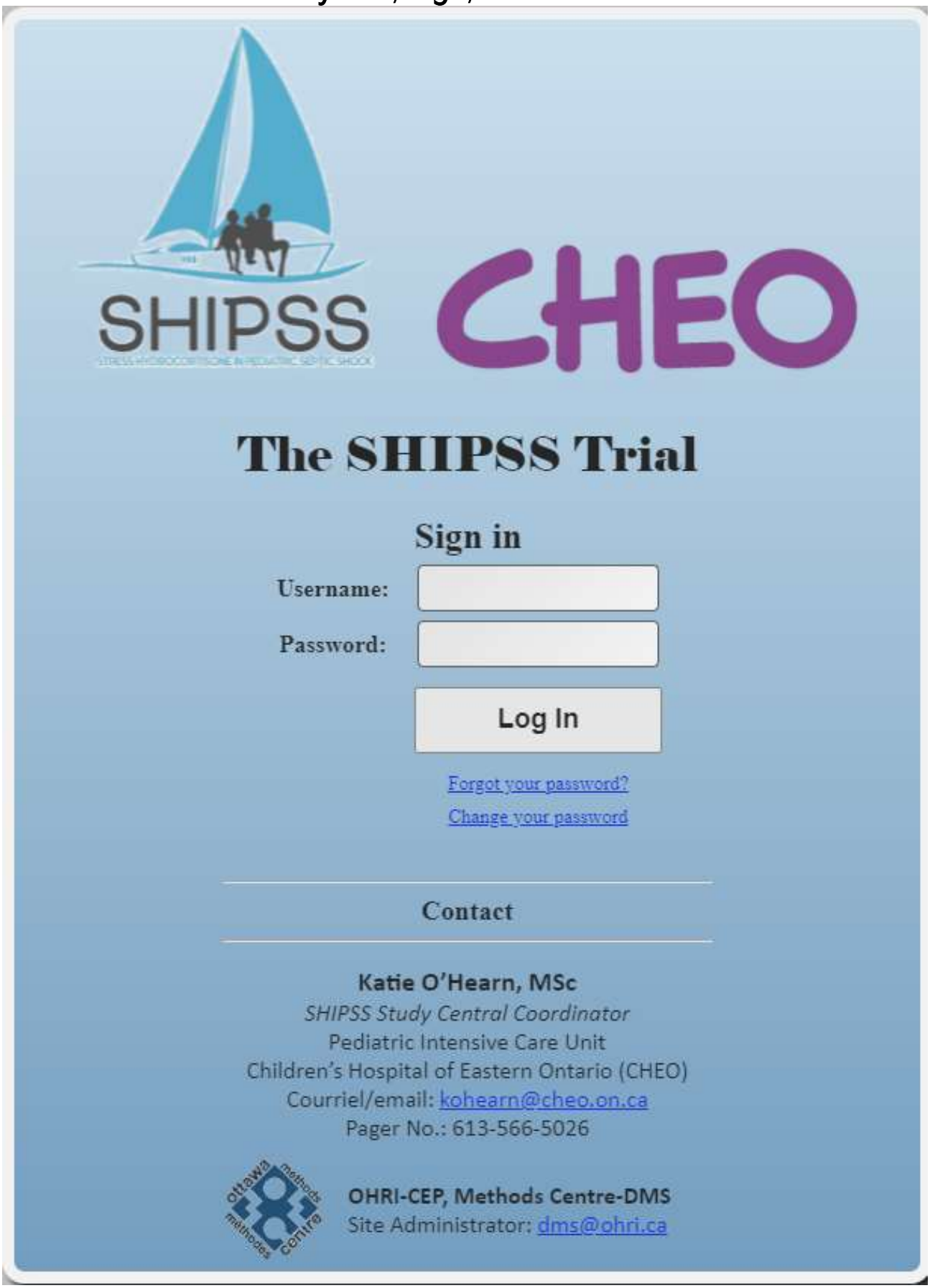
Secure login portal

Research study title, logo, and contact information



Participant list with search feature

Study Dashboard

SHIPSS
STRESS HYDROCORTISONE IN PEDIATRIC SEPTIC SHOCK

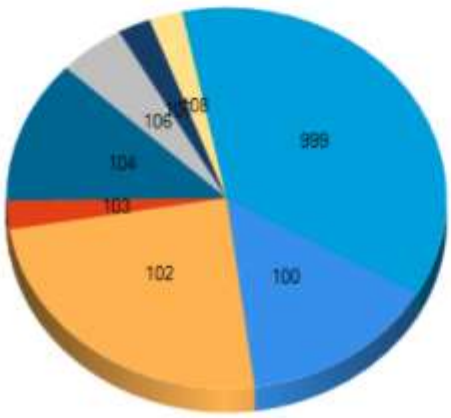
ome | Screening List | Randomization List | Resource Documents | Extract Data

SHIPSS Trial Dashboard

Stress Hydrocortisone in Pediatric Septic Shock (The SHIPSS trial).

Contact | Site List | Enrollment

Site	Site #	Total Enrolled
Children's Hospital of Eastern Ontario	100	6
London Health Sciences Centre	102	10
McMaster Children's Hospital	103	1
Ste Justine Children's Hospital	104	5
Centre hospitalier de l'Université Laval	106	2
Saskatoon Children's Hospital	107	1
Alberta Children's Hospital	108	1
TEST Site	999	15



An eligibility criteria checklist (IWRS)

SHIPSS
STRESS HYDROCORTISONE IN PEDIATRIC SEPTIC SHOCK

Log Out
User ID: TestRC
Site ID: 999

Home | Screening List | Randomization List | Resource Documents | Extract Data

SHIPSS TRIAL ELIGIBILITY CRITERIA

Screening No.: 999S *(###S###)* Screening Date:

Inclusion Criteria: To be randomized, participant must meet all of the inclusion criteria (Yes)
Note: In order to be screened, the participant must be receiving vasoactive-inotropic support

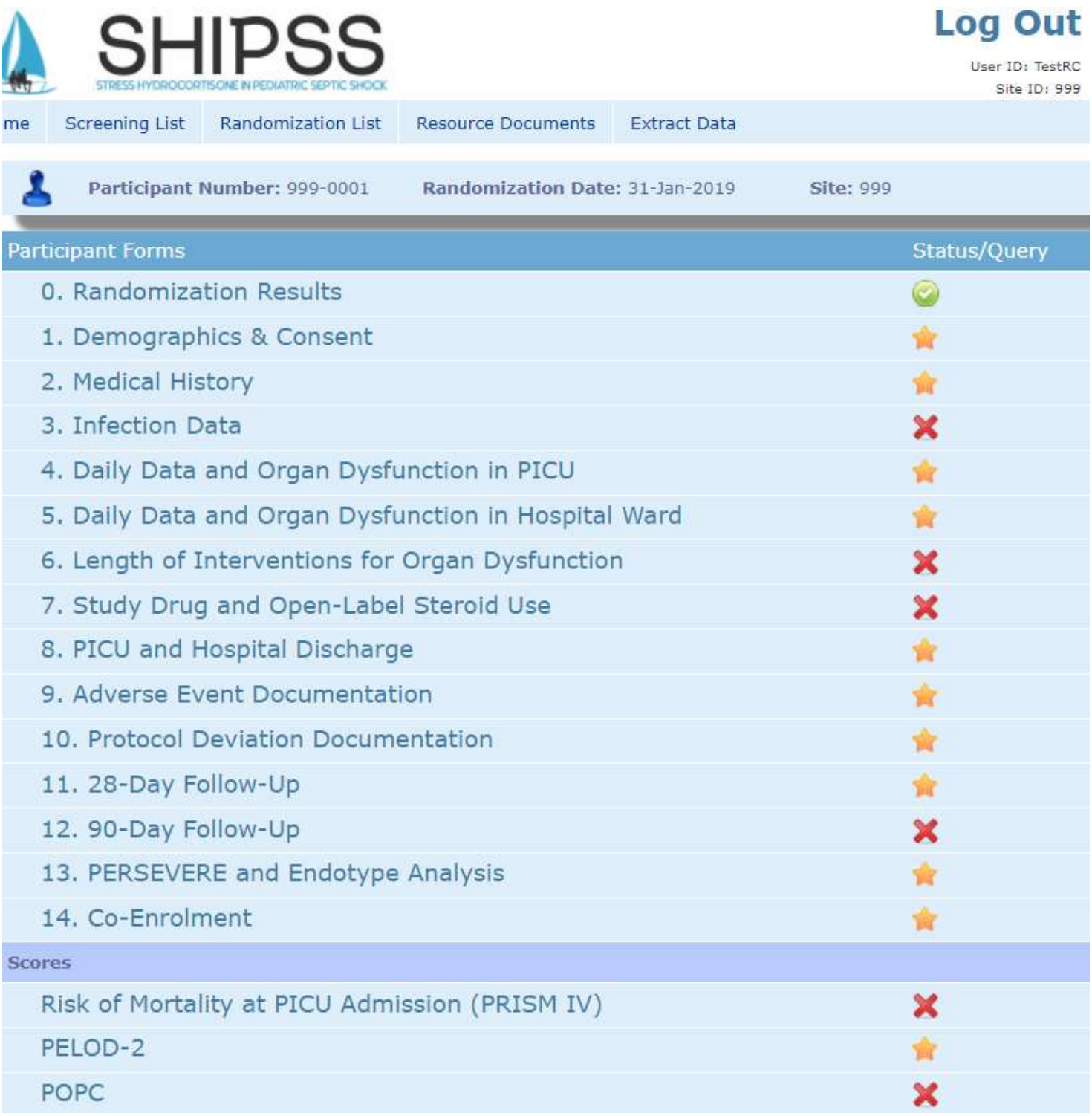
I1	Age is at least 1 month (with corrected gestational age ≥42 weeks), but less than 17 years and 8 months at the time of screening;	○ Yes	○ No
I2	A focus of infection has been documented or there is a strong suspicion of infection upon admission to PICU or for patients who develop septic shock during PICU stay, at the onset of the septic shock event;	○ Yes	○ No
I3	Surveillance cultures (e.g. blood, urine, cerebral spinal fluid, wound) and/or other microbial diagnostic tests have been obtained;	○ Yes	○ No
I4	One or more antimicrobials have been prescribed;	○ Yes	○ No
I5	Core temperature >38.5 C or <36.0 C or a change of ≥1.5 C from baseline core temperature or leukocytosis or leukopenia OR a left-shifted leukocyte differential with >10% immature granulocyte forms OR a neutrophil count of <0.5 X 10^9 cells per litre has been documented at least once within the last 24 hours;	○ Yes	○ No
I6	Treatment with a continuous infusion of vasoactive-inotropic agent(s) to maintain mean or systolic arterial blood pressure above the age-appropriate target set by the treating clinician;	○ Yes	○ No
I7	Administration of two or more vasoactive-inotropic agents OR epinephrine or norepinephrine infusion alone at greater than or equal to ≥0.10 mcg/kg/min for >1 hour;	○ Yes	○ No

Date and time that the participant met all inclusion criteria (start of 12-hour window for enrolment and administration of first dose of study drug);
Date: *(dd-mmm-yyyy)* Time: *(HH:mm,00:00 - 23:59, 24-hour)*

Exclusion Criteria: To be randomized, participant must not meet any of the exclusion criteria (No)

E1	All inclusion criteria have been present for > 12 hours;	○ Yes	○ No
E2	Attending physician expects to prescribe systemic corticosteroids for an indication other than septic shock;	○ Yes	○ No
E3	Participant has received any doses of systemic corticosteroids during treatment for sepsis;	○ Yes	○ No
E4	Enrolled concurrently in a competing interventional clinical trial (formal assessment to be conducted by SHIPSS Core Committee for each potential competing trial);	○ Yes	○ No

Participant form list with form status and query



Participant demographic form

Participant Number: 999-0001 **Randomization Date:** 31-Jan-2019 **Site:** 999

Form 1: Demographics and Consent Info

1 Date of birth: 01-Oct-2016 *(dd-mmm-yyyy)* Age: 26 *(months)* Gender: (•) Male ( ) Female

If your site does not allow you to collect date of birth, enter the patients age in months at the time of enrollment instead. If your site allows you to collect date of birth, you do not need to enter age in months.

2 PRISM IV Score: PRISM IV Score form

Consent: (Deferred Consent)

IF DEFERRED CONSENT WAS USED:

1 Reason deferred consent was used *(Check all that apply)*:

- [x] Parent(s)/guardian(s) not at beside
- [ ] Parent(s)/guardian(s) had not been updated on child's medical condition
- [ ] Care team did not want family approached at this time
- [ ] Insufficient time remaining in enrolment window
- [ ] Language barrier – translator required
- [ ] Patient in protective custody
- [ ] Other, specify

2 Was consent for continued participation obtained following enrolment via deferred consent: Yes, for full trial

3a Date & Time informed consent was obtained following enrolment via deferred consent: 07-Feb-2019 *(dd-mmm-yyyy)* 07:42 *(HH:mm 24-hour)*

DOCUMENTATION OF INFORMED CONSENT

Check Yes or No for each of the following questions to document the informed consent process for either a priori informed consent or for informed consent obtained following enrollment via deferred consent. If the answer to any question is "No", please explain in the comment box below.

Medical History form

Participant Number: 999-0001 **Randomization Date:** 31-Jan-2019 **Si**

Form 2: Medical History and Clinical Info

1	Past medical history: *(Check all that apply)*:	☐ Prematurity (< 37 weeks post-menstrual age) ☐ Asthma (prescribed bronchodilators or steroids) ☐ Other chronic steroid (glucocorticoid) therapy ☑ Bronchopulmonary dysplasia (BPD) ☐ Cystic fibrosis ☐ Metabolic disorder ☑ Diabetes
2	Immunodeficiency:	◉ Yes ○ No
	If immunodeficiency present, provide detail regarding cause:*(Check all that apply)*:	☐ Congenital immunodeficiency ☑ Hematopoietic stem cell transplantation ☐ Human immunodeficiency virus infection ☐ Malignancy with chemo-radiotherapy...
3	Any known genetic syndrome?	◉ Yes ○ No If Yes, name of syndrome: syndro

Residence/Disposition:

1	Residence/disposition: *(Check all that apply)*: (Primary residence of child over the past 12 months; if child is <1 year, primary residence since birth)	☐ Home with parents/guardian ☐ Home with outpatient rehabilitation program ☐ Home with skilled nursing ☐ Foster care ☑ Chronic care or rehabilitation facility

Admission:

1	Date of hospital admission:	13-Feb-2019 *(dd-mmm-yyyy)*
2	Date of arrival to PICU:	21-Jan-2019 *(dd-mmm-yyyy)*
3	Time of arrival to PICU:	11:22 *(HH-mm 24-hour)*

Data Extraction form

(Extract all study data to MS Excel 24/7/365)