

**A Message From The SATURN Study Team**

We hope that this message finds everyone in good health. The SATURN study team is excited to announce that 8 subjects have been enrolled since July. We wanted to congratulate the sites PIs and study coordinators for their work and getting SATURN off to a great start.

Best wishes,

**SATURN Shout-Out: *First Enrollments*****Congratulations to:**

- Beth Israel Deaconess Medical Center, Boston, MA
- Health Shands Hospital, Gainesville, FL
- Harborview Medical Center, Seattle, WA
- Prisma Health Greenville Memorial Hospital, Greenville, SC
- Oregon Health & Science University Hospital, Portland, OR
- Metro Health Hospital, Wyoming, MI

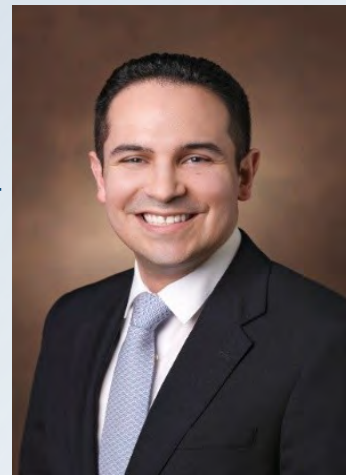
For enrolling and randomizing our first **SATURN subjects**

**Inside this issue**

- Acknowledgements
- Enrollment Guideline
- Screen Failures
- Follow Ups
- Reminders
- Status Update

## SATURN Coordinator Spotlight: Enrolling Coordinators

Franklin Echevarria **enrolled the first patient** for Health Shands Hospital. He is a clinical research coordinator at the University of Florida Health Shands Hospital Neurology Department. He currently serves as the lead coordinator of several StrokeNet studies including SATURN, sleepSMART and CREST-2. Before his current position, my entire focus was on researching neurodegenerative diseases in animal models. Aside from working with patients, Franklin's favorite part of clinical research is feeling a more direct contribution to patient healthcare outcomes. Outside of work, he currently enjoys spending time with his wife, dog, and cat, bingeing on Netflix and ordering takeout.



Ashley Pulido **enrolled the first patient for Prisma Health Upstate Greenville Memorial Comprehensive Stroke Center.** She is a research coordinator for the stroke center. Her favorite part of working in clinical research is making a meaningful impact in improving standard of care for patients and increasing their quality of life. Her interests in research are neurocritical and pulmonary care outcomes, especially in the realms of orphan disease. Outside of work, her hobbies include running, boating, fishing, and spending time with family.



## Coordinator Corner: *Consent Process Suggestions*

- Once a subject is identified, the PI/coordinator will approach the patient to introduce SATURN.
- During this process, coordinators should provide patients and/or their LAR with the consent document as well as a **provider study information sheet with PCP information (located in the WebDCU toolbox.)**
- This form can be sent via fax, EMR, or sent directly to the PCP if the patient approves.
- The study team can also opt to contact the PCP directly
- Patients should be given a few days to contact their PCP to inform them about the trial.
- Although formal approval from the PCP does not need to be documented, **we strongly encourage the study team to make sure that the PCP is aware of the study** and does not have strong objections to the subject's participation in the trial.
- This also ensures that an enrolled patient does not terminate the trial because the PCP advises the patient against it **after enrollment.**



## Site Enrollment Guide

SATURN amendment approved protocol and ICF v4

If your site has received an approved ICF v4: Notify local IRB as required and upload approval letter and ICF to WebDCU. Update COVID-19 impact assessment on WebDCU. Enrollment activities can begin.

Sites who have not yet submitted to the cIRB: Complete the ICF v4 template with site specific edits to submit for approval

Will your site be using remote consent?

**YES:** Update COVID impact assessment on WebDCU to indicate that the site will use remote consent. Work with the NCC on an amendment to edit ICF to include e-consent if applicable. NCC will submit on the site's behalf. Notify local IRB as required.

**NO:** Update COVID impact assessment to confirm that the site will not use remote consent. Notify NCC PM Kim Bernstein to submit cIRB amendment indicating that remote consent will not be used. Notify local IRB as required.

Sites with cIRB approved IDCv4 documents and approved remote consent amendments with local approval to reopen enrollment may be released to enroll. Sites will receive an email notification from WebDCU once enrollment may begin.



**Randomization**

Once it is determined that a patient meets eligibility criteria and informed consent is obtained investigators must:

- Log onto WebDCU
- Complete enrollment/randomization CRFs

After this the database will assign subjects to a group

The discontinue statin group will **stop** taking their statin

The continue statin group will continue to take the **same statin and dosage** that they were using at the time of ICH onset

## Follow Ups

- All follow-up assessments will be performed by centralized evaluators. A central adjudication committee blinded to treatment allocation will adjudicate all outcome events and imaging data.
- The patients will be followed up after 1,2, 3, 6, 9, 12, 18, and 24 months.
- Each follow up will be done over the phone with the option to also have video calls with cIRB approved Part 11 compliant software.
- Follow up visits include a SATURN follow up questionnaire, the T-MoCA, mRS, and EQ-5D.



## Logging Screen Failures

- Every patient admitted with ICH, but does not eligibility criteria is considered a screen failure & should be entered as a screen failure in WebDCU.
- Other types of hemorrhages (subdural, subarachnoid, or epidural) will not be considered for SATURN.
- Each patient is entered into a separate failure form on WebDCU.
- There is no screen failure log
- We encourage you to enter screen failures in real time or within 5 business days of screening

Q#	Screen Failure	Yes	No	Unknown
Q01	Enter all ICH patients that were admitted at your institution but do not meet eligibility criteria should be reported on this form			
A01	Assigned by WebDCU			
A02	Site			
A03	Assigned by WebDCU			
A04	Both ICH and Secondary Medical Center: Boston, MA			
A05	Screening date			
A06	Gender	<input type="checkbox"/> Male	<input type="checkbox"/> Female	
A07	Ethnicity	<input type="checkbox"/> Hispanic or Latino	<input type="checkbox"/> Not Hispanic or Latino	
A08	Race	<input type="checkbox"/> American Indian or Alaska Native	<input type="checkbox"/> Asian	
A09	Check all that apply	<input type="checkbox"/> Black or African American	<input type="checkbox"/> Native Hawaiian or other Pacific Islander	
A10	Other race	<input type="checkbox"/> White	<input type="checkbox"/> Unknown	
A11	Paternal informed consent prior to randomization	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Q01	Indication unclear	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Q02	Spontaneous lobar ICH confirmed by CT or MRI scan	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Q03	Using a statin drug at the onset of the qualifying ICH	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Q04	Randomization not by central and single stage of the study	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Q05	Paternal or legally authorized representative in the study after screening	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Q06	Empirical evidence			
Q07	Suspected secondary source for the qualifying ICH (such as an underlying cerebral aneurysm or tumor, systemic vascular infection, or hemorrhagic transformation of an infarcted infarct)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Q08	History of recent myocardial infarction attributed to coronary artery disease or unstable angina within the previous 5 months	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Q09	Current patients with history of myocardial infarction or coronary artery disease	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Q10	History of familial hypercholesterolemia	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Q11	Patients receiving empirical treatment without having evidence	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Q12	Known diagnosis of seizure disorders	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Q13	Ability to obtain informed consent	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Q14	Patients known or suspected of not being able to comply with the study protocol	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Q15	Due to alcoholism, drug dependency, or other chronic medical conditions, such as unable to adhere to the protocol specified visit assessments	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Q16	Life expectancy of less than 24 months due to non-related medical condition	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Q17	Pre-treated mRS greater than 3	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown

## Reminders

### Continuing Review

All SATURN sites who have received cIRB approval, or do so by 8/1/2020 must complete and return the continuing review forms. Highlighted are the necessary steps

- Complete the continuing review form
- Send a redacted copy of the last ICF that was completed prior to 8/1/2020.
- Have every PI complete the financial conflict of interest form
- All forms must be sent back to Kimberlee Bernstein at [gammk@ucmail.uc.edu](mailto:gammk@ucmail.uc.edu)

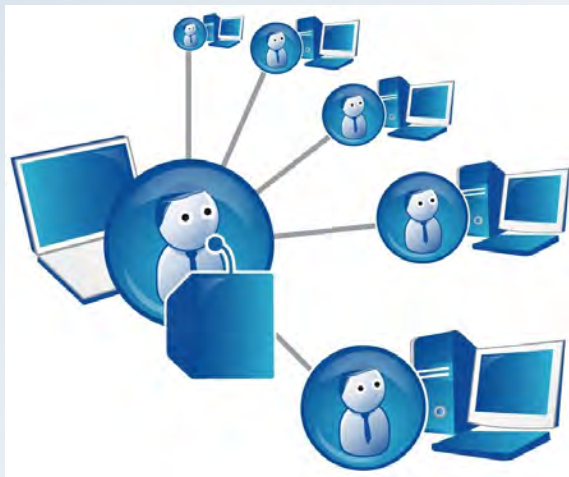


### Monthly Webinar

Please join us for our monthly SATURN PI/coordinator webinar on the last Thursday of every month at 12:30 PM.

Next Webinar: August 27th, 2020

<https://nihstrokenet.adobeconnect.com/trials/> -



### Got Questions?



E-Mail us at  
[SATURN@bidmc.harvard.edu](mailto:SATURN@bidmc.harvard.edu)

**24/7 Clinical Hotline**

**For urgent questions**

Call +1-617-667-7000 & ask  
to page beeper #39636 re: the  
SATURN Trial

SATURN Site Progress List				C	C					C	C				
8/3/2020				CTA	CIRB	CALL	REL	CTA execution / CIRB approval / Readiness CALL / Site RELEASED to enroll				CTA	CIRB	CALL	REL
<b>Canadian Sites</b>								<b>Stanford</b>							
Enfant-Jesus Hospital								Stanford University Medical Center							
Charles LeMoynes Hospital								El Camino Hospital, Mountain View Campus							
London Health Sciences Center								Oregon Health & Science University Hospital							
Ottawa Hospital								Mercy San Juan Medical Center							
University of Alberta Hospital								<b>U Chicago</b>							
University of Calgary - Foothills Campus								Froedtert Hospital							
Toronto Western Hospital								Central DuPage Hospital							
Health Sciences Centre								Loyola University Medical Center							
Montreal Neurological Institute and Hospital								Rush University Medical Center							
Centre de Sante et de Services Sociaux de Chicoutimi								<b>U Cincinnati</b>							
Thunder Bay Regional Health Sciences Centre								University of Cincinnati Medical Center							
Brandon Regional Health Center								University of Louisville Hospital							
Hamilton General Hospital								Miami Valley Hospital							
CIUSSS Hopital Fleurimont								OSU Wexner Medical Center							
Royal Columbian Hospital								<b>U Iowa</b>							
<b>Case Western</b>								University of Iowa Hospitals & Clinics							
WVU Healthcare Ruby Memorial Hospital								University of Nebraska Medical Center							
MetroHealth Medical Center								Sanford Medical Center Fargo							
Spectrum Health Hospitals Butterworth Hospital								<b>U Miami</b>							
UH Cleveland Medical Center								Tampa General Hospital							
<b>Columbia</b>								UF Health Shands Hospital							
NYP Columbia University Medical Center								Mayo Clinic - Jacksonville							
NYP Weill Cornell Medical Center								Jackson Memorial Hospital							
New York-Presbyterian Brooklyn Methodist Hospital								<b>U Michigan</b>							
Buffalo General Medical Center								University of Kentucky Hospital							
SUNY Upstate Medical University								Detroit Receiving Hospital							
St. Josephs Regional Medical Center								University of Michigan University Hospital							
<b>Mass General</b>								Mercy Health Saint Mary's							
Baystate Medical Center								McLaren Flint							
Tufts Medical Center								Metro Health Hospital							
Massachusetts General Hospital								<b>U Minnesota</b>							
UMass Memorial Medical Center								Regions Hospital							
Brigham and Women's Hospital								University of Minnesota Medical Center Hospital							
Beth Israel Deaconess Medical Center								United Hospital							
Lahey Hospital & Medical Center								University of Kansas Hospital							
Eastern Maine Medical Center								St. Cloud Hospital							
The University of Vermont Medical Center								<b>U Penn</b>							
<b>MedStar</b>								Abington Memorial Hospital							
University of Maryland Medical Center								Temple University Hospital							
UVA Medical Center								Hospital of the University of Pennsylvania							

**Mount Sinai**

The Mount Sinai Hospital	■ ■ ■ ■
NYU Langone Medical Center - Tisch Hospital	■ ■ ■ ■
Montefiore Medical Center	■ ■ ■ ■
NYU Langone Hospital - Brooklyn	■ ■ ■ ■

**MUSC**

Augusta University Medical Center	■ ■ ■ ■
Greenville Hospital System	■ ■ ■ ■
Moses H. Cone Memorial Hospital	■ ■ ■ ■

**Non Network**

Johns Hopkins Bayview Medical Center	■ ■ ■ ■
University of North Carolina Medical Center	■ ■ ■ ■

**U Washington**

Legacy Emanuel Medical Center	■ ■ ■ ■
PeaceHealth Sacred Heart Medical Center Riverbend	■ ■ ■ ■
Harborview Medical Center	■ ■ ■ ■
Overlake Hospital Medical Center	■ ■ ■ ■

**U Wisconsin**

Aurora St. Luke's Medical Center	■ ■ ■ ■
University of Wisconsin University Hospital	■ ■ ■ ■
Aurora BayCare Medical Center	■ ■ ■ ■

**UAB**

University of Alabama Hospital	■ ■ ■ ■
University of South Alabama University Hospital	■ ■ ■ ■

**UCLA**

Kaiser Permanente Los Angeles Medical Center	■ ■ ■ ■
University of New Mexico Hospital	■ ■ ■ ■
Long Beach Memorial Medical Center	■ ■ ■ ■
Cedars-Sinai Medical Center	■ ■ ■ ■
UC Irvine Medical Center	■ ■ ■ ■
Keck Hospital of USC	■ ■ ■ ■
Kaiser Permanente Fontana Medical Center	■ ■ ■ ■
Arrowhead Regional Medical Center	■ ■ ■ ■

**UCSD**

St. Joseph's Hospital and Medical Center	■ ■ ■ ■
UCSD Medical Center - Hillcrest Hospital	■ ■ ■ ■
Ochsner Medical Center - Main Campus	■ ■ ■ ■
Scripps Memorial Hospital La Jolla	■ ■ ■ ■

**UCSF**

San Francisco General Hospital	■ ■ ■ ■
UCSF Medical Center	■ ■ ■ ■
Eden Medical Center	■ ■ ■ ■

WellSpan York Hospital	■ ■ ■ ■
Thomas Jefferson University Hospital	■ ■ ■ ■
Lehigh Valley Hospital	■ ■ ■ ■

**U Pitt**

UPMC Presbyterian Hospital	■ ■ ■ ■
----------------------------	---------

**U Utah**

Swedish Medical Center	■ ■ ■ ■
University of Utah Healthcare	■ ■ ■ ■
Intermountain Medical Center	■ ■ ■ ■
St. Mary's Medical Center	■ ■ ■ ■

**UTHSC Houston**

St. David's Medical Center	■ ■ ■ ■
Baylor College of Medicine Medical Center	■ ■ ■ ■
OU Medical Center	■ ■ ■ ■
St. Luke's Baptist Hospital	■ ■ ■ ■
University Medical Center of El Paso	■ ■ ■ ■

**Wake Forest**

Wake Forest Baptist Medical Center	■ ■ ■ ■
Forsyth Medical Center	■ ■ ■ ■

**Washington University**

Saint Luke's Hospital of Kansas City	■ ■ ■ ■
OSF St. Francis Medical Center	■ ■ ■ ■
UAMS Medical Center	■ ■ ■ ■
Barnes Jewish Hospital	■ ■ ■ ■
Cox Medical Center South	■ ■ ■ ■

**Yale**

Hartford Hospital	■ ■ ■ ■
Rhode Island Hospital	■ ■ ■ ■
Yale New Haven Hospital	■ ■ ■ ■
North Shore University Hospital	■ ■ ■ ■

Completed ■

Scheduled ■

Pending ■