POST-ICECAP

Patterns Of Survivors' Recovery Trajectories in the ICECAP Trial

PI: Drs. Sachin Agarwal and Clif Callaway

Start Time	End Time	Item	Presenter
12:30 PM	12:35 PM	Study Overview	Sachin Agarwal
12:35 PM	12:45 PM	Protocol	Clif Callaway
12:45 PM	12:50 PM	Training	Sachin Agarwal
12:55 PM	1:00 PM	Study Status	Natalie Fisher
1:00 PM	1:05 PM	Study Database	Elizabeth O’Donohue
1:05 PM	1:15 PM	Finance (Payments/Contracts)	Deneil Harney, Valerie Stevenson
1:15 PM	1:30 PM	Open Q&A	

Study Overview

Sachin Agarwal

Purpose and Rationale

- Trajectory of long-term recovery after cardiac arrest is not fully described
  - Only a few prospective, single cohorts
  - Many studies have enrollment biased towards higher-functioning survivors
- Anxiety, PTSD, fatigue are common even when physical recovery is good
  - Shared also by many survivors of critical care (PICS)
- Rehabilitation interventions may modify recovery
  - Often not paid by insurance “because of lack of evidence”
- Social determinants may modify recovery
  - Access to resources and environment contribute to disparities in recovery outcomes

Specific Aims

Clinical factors
Illness severity, critical care interventions

Inpatient rehabilitation
Versus outpatient rehab, no rehab or skilled nursing facility

Self reported Race/Ethnicity
Other individual SDOH, structural SDOH, psychosocial risk & resilience factors

Aim 1 →
Aim 2 →
Aim 3 →

Recovery

- **Functional Outcome**
- Cognitive Outcome
- Quality of Life

Who is eligible

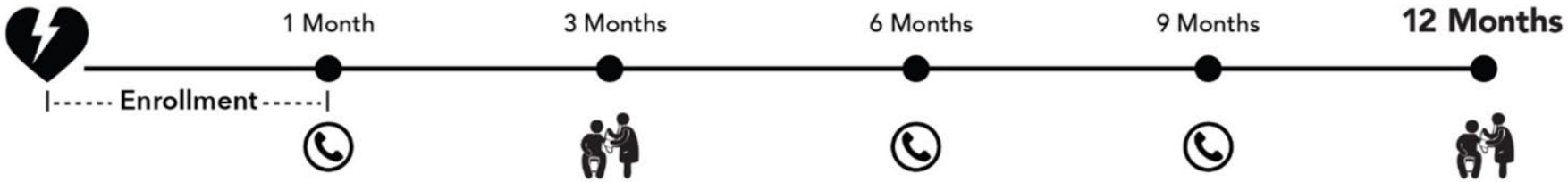
Inclusion

- Screened or Enrolled in ICECAP
- Age ≥ 18 years
- Coma after resuscitation from OHCA
- Received TTM
- Signed Informed Consent (may be LAR)
- Survives ≥ 30 days from cardiac arrest

Exclusion

- Neither English nor Spanish speaking
- Terminal non-cardiovascular illness
- Hospice as disposition
- Severe mental illness requiring urgent psychiatric care
- Pre-existing conditions that could confound outcome determination (e.g. dementia)
- Known inability to complete follow-up

What is the work



Consent Chart Review Intake Questionnaire	Questionnaire	Usual ICECAP Visit + Questionnaire	Questionnaire	Questionnaire	NIH ToolBox + Questionnaire

Protocol

Clif Callaway

POST-ICECAP

In-a-nutshell

Participant Eligibility

- ICECAP Participants are eligible
  - Must survive to 30 days after cardiac arrest

- ICECAP Screen Failures are eligible
  - Must survive to 30 days after cardiac arrest
  - Coma
  - Received some form of targeted temperature management (include fever prevention)

Participant Screening

- Approach anyone who is expected to survive their hospitalization after cardiac arrest-
  - Transferred to the inpatient floor after the ICU
  - Headed to LTAC or rehab or nursing home directly from ICU
  - Discharged from hospital, but still <30 days after cardiac arrest

- Best to get consent before their hospital discharge
  - Get consent well in advance of 30 days
  - Note: The participant is not “officially” enrolled until they survive to 30 days

HELP RESEARCH ON CARDIAC ARREST RECOVERY

Everyone's recovery journey is different.
We want to hear about yours!

POST- ICECAP

Patterns **O**f **S**urvivors' Recovery **T**rajectories in the **I**nfluence of **C**ooling Duration on **E**fficacy in **C**ardiac **A**rrest **P**atients

Sponsor: The National Institutes of Health

WHAT IS THIS STUDY ABOUT?

To understand how people recover after a cardiac arrest, both physically & mentally

WHO CAN PARTICIPATE?

- 18 years or older
- Speak English or Spanish
- Survived a cardiac arrest

WHAT IS INVOLVED?

- Meet with the research team at 1, 3, 6, 9, & 12 months by phone or in-person
- Answer questionnaires & complete puzzles

POST-ICECAP

Consent

- Eligible participants may provide informed consent at any time before the first POST-ICECAP evaluation at 1 month
- Please use electronic version of the consent form; it is the preferred way
- The consent is also available in Spanish
- In POST-ICECAP majority of the consents will be obtained from the patients, however certain patients with severe brain injury will be unable to follow commands at the time of consent. In those cases, the consent will be acquired from the LAR of the patient.

Participant Screening

- After consent, complete the baseline information
  - Chart review
  - Intake questionnaire

- Many of these data can be provided by caregiver or family
  - It may be easier to get when the participant is comatose or impaired

- Many of these data are stable over time
  - OK to ask questions over multiple visits
  - OK to get more complete data on follow-up visits if data are missing initially

Participant Screening – Chart Review

- EMS Code Review
- Medical History
- Laboratory Tests
- Pittsburgh Cardiac Arrest Category
  - Illness severity
- Hospital Discharge
- Hospital Summary
  - Treatment and TTM
  - Hospital procedures

Participant Screening – Questions

- Intake Questionnaire
  - Self-reported Demographics
  - Gender, Race, other minority status
  - Socioeconomic Status
  - Insurance Resources
- Experience of Discrimination Scale
- Premorbid PTSD Screening

Keeping Track of the Participant

- Get multiple points of contact
  - Participant Phone number
  - Participant Home address
  - Partner/spouse/roommate phone number
  - Phone numbers of other caregivers
  - Another family or friend who would know the whereabouts
  - Facebook or other social media

- Institutionalized participants
  - Partner/spouse/caregiver informant phone numbers and address

Keeping Track of Participant's Upcoming Visit

- WebDCU will send "Visit Due" notifications
- Create your Calendar reminders
  - Start arranging a visit 1 week or more in advance
  - Call the day before a visit
- Central Outcomes Team Tracking
  - The ICECAP team will remind you about 1 and 3-month ICECAP follow-up
  - The POST-ICECAP team will remind you about all non-ICECAP participants and all 6, 9, and 12-month follow-up

Visit – 1 month

Domains	Measures
Functional Status	Modified Rankin Scale
Neuropsychological Outcomes	BTACT
Psychological Deficits	Generalized Anxiety Disorder-2 (GAD-2) Patient Health Questionnaire-8 (PHQ-8) PTSD Checklist for DSM-V (PCL-5)
Interval Medical Events	Rehabilitation, Hospitalizations, Outpatients
If, Disorders of Consciousness	Disability Rating Scale

In-person Visits – 3 and 12 month

Domains	Measures
Functional Status	Modified Rankin Scale
Neuropsychological Outcomes	**NIH Toolbox,** BTACT
Health-related Quality of Life, IADL	**Neuro QoL, Modified Lawton-Brody IADL**
Psychological Deficits	Generalized Anxiety Disorder-2 (GAD-2) Patient Health Questionnaire-8 (PHQ-8) PTSD Checklist for DSM-V (PCL-5)
Interval Medical Events	Rehabilitation, Hospitalizations, Outpatients
Cardiac Function	**Kansas City cardiomyopathy**
Social Support	**ENRICHD Social Support**
If, Disorders of Consciousness	Disability Rating Scale

Phone Visits – 6 and 9 month

Domains	Measures
Functional Status	Modified Rankin Scale
Neuropsychological Outcomes	BTACT
Psychological Deficits	Generalized Anxiety Disorder-2 (GAD-2) Patient Health Questionnaire-8 (PHQ-8) PTSD Checklist for DSM-V (PCL-5)
Interval Medical Events	Rehabilitation, Hospitalizations, Outpatients
ADL, Fatigue, IADL	**Neuro-QoL Short Forms,** Modified Lawton-Brody IADL
Cardiac Function	Kansas City cardiomyopathy
Social Support	ENRICHD Social Support
If, Disorders of Consciousness	Disability Rating Scale

End of Study

- End of Study Form
  - Death
  - Withdraws from study
  - Finishes 12-month visit
  - Lost to follow-up – must discuss this during Operations call

- Vital Status Search
  - Participants with whom we lose contact before 12-months

Paying Participants

- We encourage to reimburse participants for time, inconvenience, parking, and travel
  - Use your institutional methods to arrange it
- The rate per visit should not exceed GSA per diem for your location
  - https://www.gsa.gov/travel/plan-book/per-diem-rates
- Note: Reimbursement $ come from your per-subject payments

Questions or Problems

- **For urgent issues:** Use ICECAP Hotline 1-833-4-ICECAP (1-833-442-3227)
- **For all non-urgent issues** related to Questionnaires or Instruments, NIH Toolbox/IT problems with iPADS: email is the preferred option POST-ICECAP-contact@umich.edu
- **Education** (training, website access, material development, technical support): Courtney Miller coraymon@med.umich.edu
- **WebDCU Support** (user account requests, technical support, CRF completion): Sara Meyer (843) 792-1599 butlers@musc.edu Liz O'Donohue (843) 876-1129 odonohue@musc.edu
- **Site Management:** Natalie Fisher brownnat@med.umich.edu
- **Hub Contracts and Site Payments:** Harney, Deneil dkolk@.umich.edu

Training

Sachin Agarwal

Education and Training

- Getting Started
- Protocol
- MOP
- Outcomes MOP
- >> Education and Training
- Advarra Documents
- Toolbox
- FAQs
- Contact

Clinical Trials / POST-ICECAP / Education and Training

POST-ICECAP

- Protocol
- MOP
- Outcomes MOP
- POST-ICECAP In a Nutshell
- Just In Time Training
  - mRS Certification
  - NIH Toolbox and Neuro QoL
  - Neuropsych Outcomes Training Certification "BTACT"
- Milestones and Payment

WebDCU

- POST-ICECAP Regulatory Parameters Document
  - Regulatory Document Management Training
  - Data Training
  - Investigator Agreement Form
  - Attestation of Local Education & Training v1
- SIREN WebDCU User Manual

POST-ICECAP

Just–In–Time Training

Components

- Modified Rankin Scale Training (ICECAP version)
- NIH Toolbox and Neuro QoL (ICECAP version)
- Neuropsych Outcomes Training (BTACT)
- Patient-reported Questionnaires
- Chart Review
- Recruitment and Retention Practices

Modified Rankin Scale Training

- mRS training is available through CCC and is identical to ICECAP.
- Use this direct link for mRS Training
- Training consists of watching a training video, then scoring vignettes.
- A certificate will be sent automatically via email upon passing.
- It is necessary to send certificate to the CCC or to upload it to WebDCU.
- The SIREN mRS certification is valid for two years.

NIH Toolbox and Neuro QoL

- There are no paper-pencil neuropsychology tests in POST-ICECAP
- ICECAP battery for NIH Toolbox and Neuro QoL will be administered at 3 and 12 month in-person visits
- Follow the Appendix A of the POST-ICECAP Outcomes Manual for training procedures
- Training modules are provided at this link
- For the POST-ICECAP study, it is necessary to send the ICECAP NIH Toolbox Training checklist to the CCC or to upload it to WebDCU.

Neuropsych Outcomes Training Certification

Brief Test of Adult Cognition by Telephone (BTACT)

- Training, Certification, Re-certification
- Examiner's Training Manual
- Administration Guide and Scoring Training Videos
- Certification Test: Vignette 1, Vignette 2
- Please send scanned copies of your scoring sheets at POST-ICECAP-contact@umich.edu for certification.

BTACT Administration Forms

- FORM A English (1, 6, 12 months visits)
- FORM B English (3, 9 months visits)
- FORM A Spanish (1, 6, 12 months visits)
- FORM B Spanish (3, 9 months visits)

Neuropsych Outcomes Training Certification

NIH SIREN
Emergency
Trials
Network

[Name]

[Institution Name]

This confirms that [Name] successfully completed the BTACT training on [Date].

IMPORTANT: Please submit this form in WebDCU to confirm completion of Neuropsych Outcomes Training.

This certification program was developed with NIH funding for the exclusive use in the POST-ICECAP study. Not valid for other external certification use.

Questionnaires

- All assessment related participant instructions and questions are to be read verbatim and no training is required.

Communal Learning for R & R

- A list of actions that have facilitated recruitment & retention
- We encourage sites to share their own best practices.
- A resource list of informational, support groups, and mental health resources for patients & families.

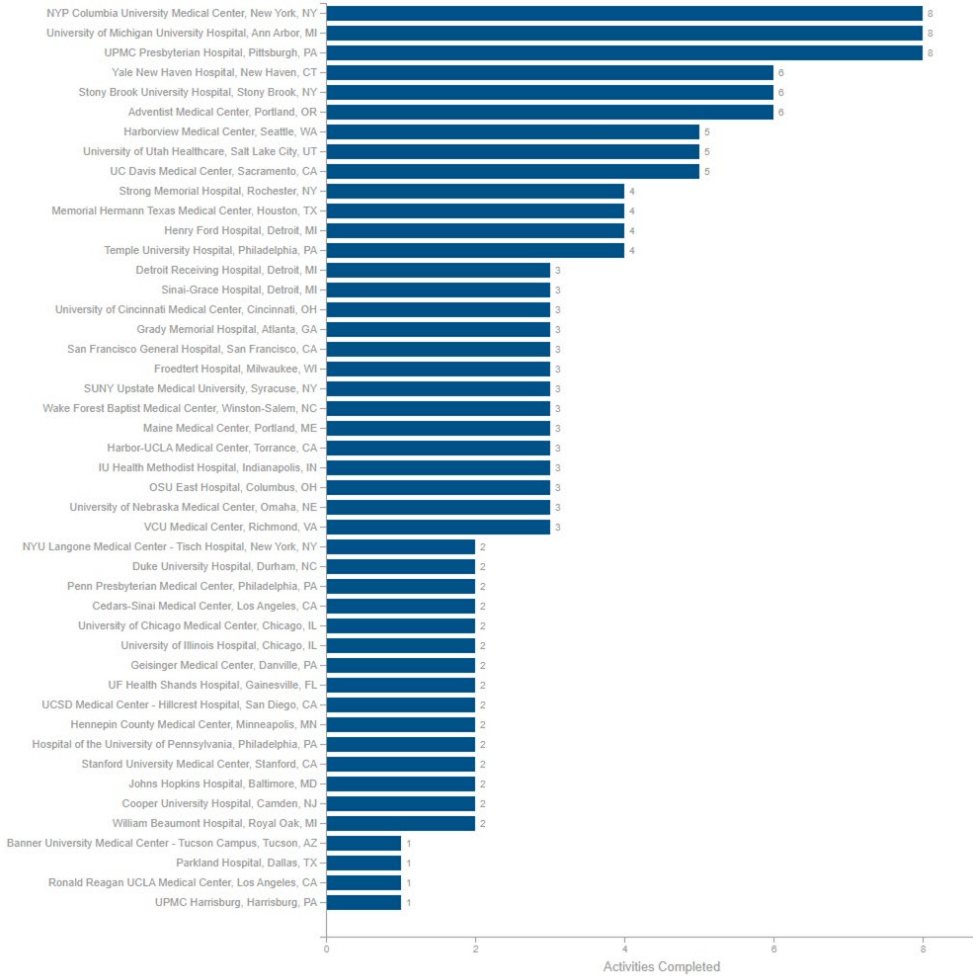
Study Status

Natalie Fisher

Site Start-Up Status

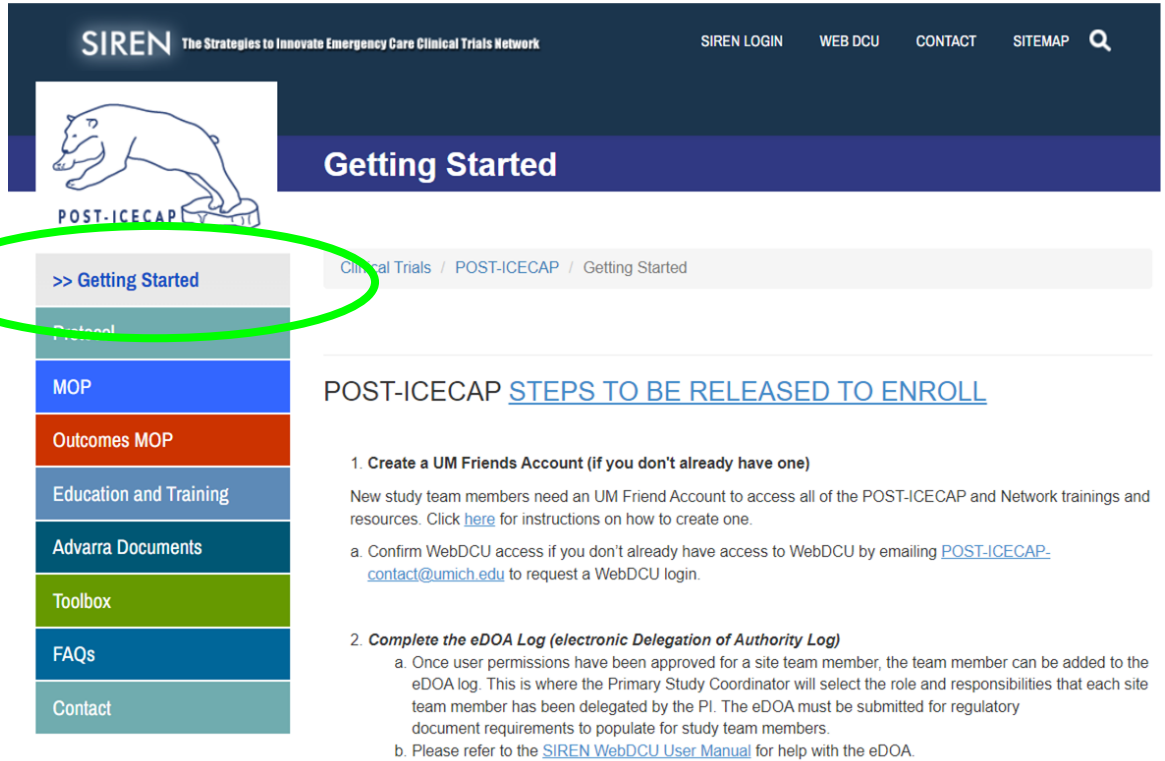
- 46 sites - Preparing
- 14 sites - Ceding Request to Local IRB
- 13 sites - Ceding Acknowledgement from Local IRB
- 5 sites - Undergoing cIRB Review
- 3 sites - Readiness Calls
- 2 site - cIRB Approval

Report: Site Readiness



POST-ICECAP

https://siren.network/clinical-trials/post-icecap



1. **Create a UM Friends Account**
2. **Complete the eDOA Log**
3. **Upload Regulatory Documents**
4. **Complete Central IRB Tables in WebDCU**
5. **Request Ceding**
6. **Support timely execution of POST-ICECAP contract**
7. **Complete the Readiness Checklist**

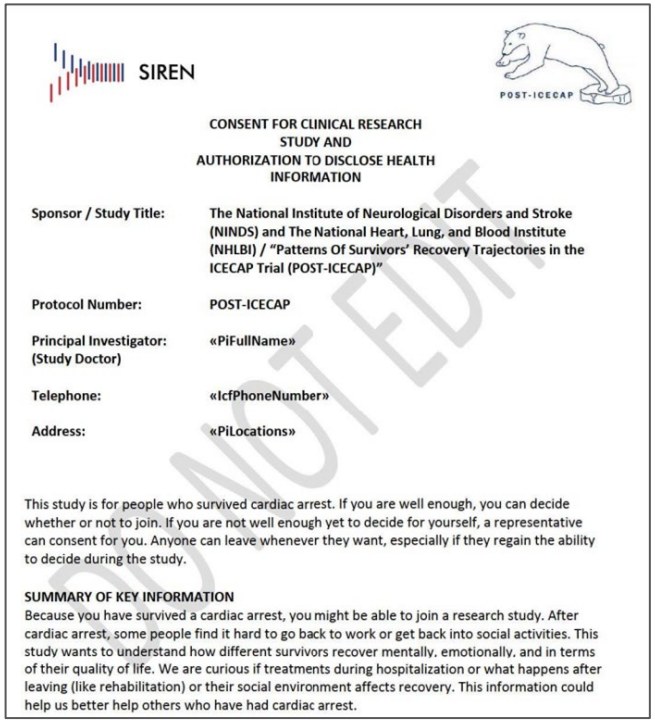
POST-ICECAP Regulatory Document Parameters

Outlines all regulatory and training requirements

- Site Documents
- People Documents
- cIRB Forms

POST-ICECAP ICF is Locked!

- Provide your local IRB with Master ICF (pdf)
- If your local IRB requests site-specific language not duplicative of main consent, let us know at the CCC.
- Email preferred language to POST-ICECAP-contact@umich.edu
- CCC works with you/local IRB until language is acceptable
- Site-specific language is add to the end of the consent (black box)



SIREN

POST-ICECAP

CONSENT FOR CLINICAL RESEARCH
STUDY AND
AUTHORIZATION TO DISCLOSE HEALTH
INFORMATION

Sponsor / Study Title:	The National Institute of Neurological Disorders and Stroke (NINDS) and The National Heart, Lung, and Blood Institute (NHLBI) / "Patterns Of Survivors' Recovery Trajectories in the ICECAP Trial (POST-ICECAP)"
Protocol Number:	POST-ICECAP
Principal Investigator: (Study Doctor)	«PiFullName»
Telephone:	«IcfPhoneNumber»
Address:	«PiLocations»

This study is for people who survived cardiac arrest. If you are well enough, you can decide whether or not to join. If you are not well enough yet to decide for yourself, a representative can consent for you. Anyone can leave whenever they want, especially if they regain the ability to decide during the study.

SUMMARY OF KEY INFORMATION

Because you have survived a cardiac arrest, you might be able to join a research study. After cardiac arrest, some people find it hard to go back to work or get back into social activities. This study wants to understand how different survivors recover mentally, emotionally, and in terms of their quality of life. We are curious if treatments during hospitalization or what happens after leaving (like rehabilitation) or their social environment affects recovery. This information could help us better help others who have had cardiac arrest.

Study Database

Liz O'Donohue

Chart Variables Specific to POST-ICECAP

- Link to CRF completion Guidelines

Contracts & Payments

Deneil Harney, Valerie Stevenson

Hub Post-ICECAP Contract Process

- Subrecipient forms
- Study Subcontracts are generated and distributed by the UM Contracts Office.
- Master Agreements and Riders
    - Master Agreements-”preamble”
    - Riders-trial specific
- Person listed on Master Agreement is on all Subcontracts.
    - Additional investigators can be added

19 - ACTIVE Hub Post-ICECAP Riders:

Cincinnati
Columbia
Emory
Harbor-UCLA
HFHS
Indiana
MCW
Nebraska
OHSU
Pittsburgh
Rochester
Tufts
UCSF
Utah
UW
VCU
Wake
Wayne
Yale

Start-up payment

A one-time payment of **$2,000** (inclusive of F&A costs) to support the effort and costs of site initiation will be paid to POST-ICECAP sites once they have:

- Completed required trainings
- Submitted regulatory documents
- Obtained required approvals
- Released to enroll subjects by the CCC
- Reads “ready” in WebDCU

Per-Participant Payments

There will be two per-patient payments.

- Payment 1 (after 3 months) up to $600 will be provided after:
  - All study CRFs required from enrollment through the 3 month visit are submitted and
  - Data free of queries.

- Payment 2 (at 12 months) up to $1400 will be provided after:
  - The End of Study (EOS) visit occurs within the timeline specified in the trial protocol,
  - All study CRFs required for the EOS visit are submitted and
  - Data free of queries.

- All payments are inclusive of F&A

Visit	Remote Visit	NIH Toolbox	Payment number	Payment in $
Enrollment/Intake Questions and 1 month	$0	$0	n/a	(no payment until 3 month visit)
3 month	$400	$200	**1**	$400 for the remote visit (3 months) with an additional $200 for NIH Toolbox at 3 months ($0, $400, or $600 possible) inclusive of F&A
6 months	$400	-	**2**	(paid at 12 months)
9 months	$400	-	**2**	(paid at 12 months)
12 month	$400	$200	**2**	$400 for the remote visit (12 months) with additional $200 for NIH Toolbox at 12 months ($0, $400, $600, $800, $1000, $1200, or $1400 possible) inclusive of F&A

Payment Process

- UM-CCC Payments are made to sites with active riders
- Payment “readiness” is visible in WebDCU
- UM-CCC generate the invoices for you
- Check information (payment date, amount, check number) is entered and visible in WebDCU

Open Q&A