Minimally **I**nvasive **N**euroendoscopic **U**ltra-Early **T**argeted ICH **E**vacuation (MINUTE)

Study Coordinator Training

Study Chairs:

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Mount Sinai

MINUTE Study Contacts

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National Data Management Center (NDMC)	Data Managers – WebDCU CRF and data-related questions.	Susanna Steinmuller (crestett@musc.edu) Jordan Stallings (stallinj@musc.edu)
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Learning Goals

The coordinator will learn:

- ❑ Site activation/readiness process
- ❑ Screening Criteria
- ❑ Consenting Process (ICF or eConsent)
- ❑ Study Imaging
- ❑ WebDCU™
- ❑ Subject Visits
- ❑ Study Payments
- ❑ Toolbox Resources

Site Activation Process

➔ **cIRB** approval must be obtained & **CTA** is executed.

➔ WebDCU™ **DoA** is completed and approved.

- The team must include the **PI, Surgical PI & PSC**. Other team members may be added as desired.
- More than one role can be assigned on DOA (e.g., PSC and Administrator). Tasks are assigned as needed.

➔ All team member **training** has been completed and attestation forms or certificates have been uploaded into the WebDCU™ regulatory database.

- This includes all required people documents.
- The surgical PI must complete the one-day, in-person surgical training, watch the 5 SCUBA educational modules, and submit 4 non-trial cases.

➔ Confirm availability of **neuroendoscopic evacuation supplies**, Viz AI or Rapid **AI screening tool(optional), & 24/7 staff coverage.**

➔ **Readiness call** has been completed.

- Project Manager will arrange the readiness call.
- The site PI, surgical PI, and primary coordinator must be on the call.

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Screening & Consent

- ❑ I/E Criteria
- ❑ Study Workflow
- ❑ Baseline Imaging Requirement
- ❑ Screen Failures
- ❑ The Consent Process
  - ❑ Subject Consent
  - ❑ eConsent
  - ❑ Using an LAR

Screen Failures

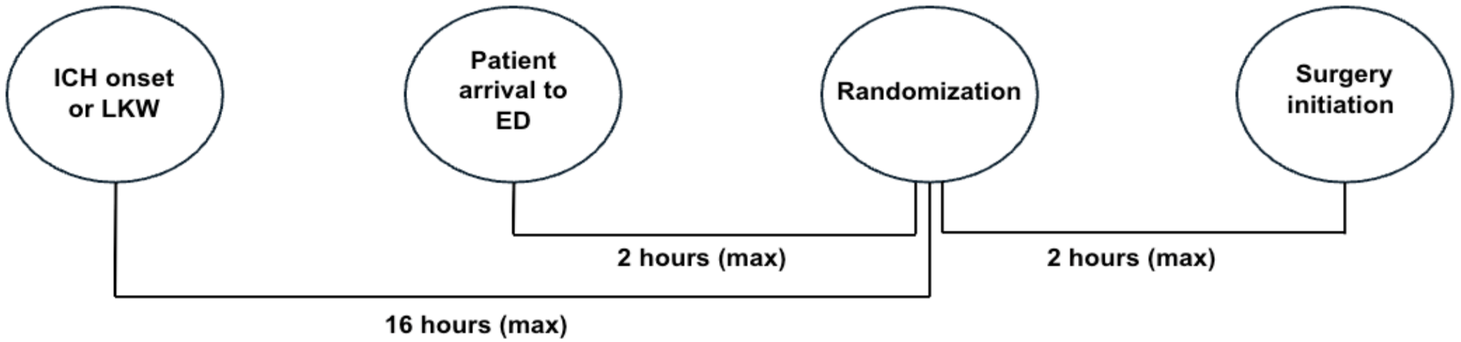
Where?
- The Screen Failure Log in WebDCU™ will be utilized.

Who to enter into the screening log?
- Patients with an imaging confirmed BGH who present within 16 hours of ICH onset or LKW.

When to enter?
- Within **5** days of screening (real-time, not monthly)

What information to enter?

- Demographics
- Screen failure details
- Eligibility criteria
- Enter as much information as possible on the screen failure log. In other words, sites should enter all of the known reasons for ineligibility.



The Consenting Process & eConsent in REDCap

- Informed consent is an ongoing process in which qualified study staff explain the study's purpose, procedures, risks, benefits, and participant rights to the potential participant and/or their legally authorized representative.

- The informed consent process should encompass the following:
  - A copy of the ICF for the potential participant &/or family to review.
  - Disclosure to potential participant the information that is needed to make an informed decision.
  - Ensuring the potential participant understands what has been disclosed
  - Promotion of decision to participate is voluntary

- All research activities will take place after the ICF has been signed by the participant or LAR.

- Signed informed consent documents (unredacted) are required to be uploaded to WebDCU for remote monitoring within 5 days.

- The MINUTE ICF will be available as an eConsent form in REDCap. The eConsent process must be approved by the cIRB.

- We highly recommended your site to use the eConsent. Having the eConsent available on your site's tablet is a more efficient and error-free process of obtaining the patient or LAR's consent.

  - The patient or LAR may sign the eConsent.
  - Before having access to an eConsent, your site must be approved by submitting the "Implementation Form" to the cIRB that indicates your desire to use the eConsent and/or remote consent.
  - Your eConsent will be produced in the REDCap platform using your cIRB approved documents.
  - Two administrative users at each site, the PSC and typically another coordinator, will be provided a user ID, a user guide and training to use the REDCap platform.
  - Any one who is delegated the responsibility to obtain consent on the DOA may and your site-specific eConsent link to consent participants.

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The Consenting Process -LAR

- An LAR is a *Legally Authorized Representative* that can act to make decisions on behalf of another person.

- An LAR can be but is not limited to:
  - Spouse
  - Legal Guardian
  - Adult child
  - Parent

- **Does the subject have the cognitive capacity to decide about study participation?** This assessment should be made by a study investigator and documented in the subject's records.

- ⛔ **No**, then LAR signs and dates:
  - **Reconsent is needed when subject regains capacity.**
- ✅ **Yes**, the subject signs and dates the ICF.

- If the subject is physically incapable of signature, illiterate, visually impaired, or signing a short form consent, utilize witness of consent process and signature.

- All research activities will take place after the ICF has been signed by the participant or LAR.

- Many patients with severe BGH may be neurologically impaired and incapacitated. In such cases, the LAR will be approached for consent.

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The Consenting Process - Non-English–Speaking Participants

- Informed consent will be conducted in a language understood by the patient or their LAR.
  - An IRB-approved translated ICF will be used whenever available
  - A qualified medical interpreter (in person, phone, or video) will assist with the consent discussion
  - If a translated consent form is not available, consent may be obtained using the IRB-approved short-form consent process
- The consent process will be fully documented, and copies of signed forms will be provided to the participant or LAR
- Please refer to StrokeNet SOP ADM 26 Consenting Non-English Speaking or Literacy-Challenged Participants

Scenario	Forms Used	Who Signs
Fully Translated ICF available (e.g. Spanish)	IRB-approved fully translated ICF **(Bilingual Research Staff on DOA)**	Patient or LAR, Person Obtaining Consent **(must be certified to consent in this language)**
	IRB-approved fully translated ICF + English ICF **(Interpreter-assisted consent)**	• Patient or LAR (Translated ICF), • Person Obtaining Consent (English ICF), • Interpreter (documentation as required by local institution)
No fully translated ICF available + Interpreter-assisted (Short-Form Consent)	Short-Form Consent (in participant's language) + Full ICF (English)	• Patient or LAR (Short Form), • Person Obtaining Consent (English ICF), • Impartial & Bilingual Witness (Short Form + English ICF), • Interpreter may act as Impartial Witness
Witnessed consent (patient can consent but cannot sign)	ICF + Witness Signature	Witness(Full ICF), Person Obtaining Consent (Full ICF), Patient or LAR (may make their mark)

Randomization

- After confirmation that **all inclusion and exclusion criteria** are met and **informed consent** has been obtained, randomization should proceed.

- **Before Randomization:**
  - **Subject Enrollment** must be completed in **WebDCU™** to populate the Subject's CRF Binder. **Eligibility and Randomization** case report forms must be completed for randomization. All other forms can be data entered later to avoid delaying study intervention.
  - Randomization is targeted to occur **within 120 min of arrival** to the treating/enrolling hospital's ED.
  - Baseline imaging & consent will need to be uploaded as soon as possible. The uploading of the ICF does not need to happen prior to randomization, just obtaining consent.
  - Randomization will take into account the following variables: **ICH-onset-to-randomization window (<8 hours vs. 8-16 hours); ICH volume at baseline (20-40 cc vs. >40 cc); and IVH (present vs absent)**.

- Delegated team member can randomize the subject in WebDCU™.
  - The subject is randomized to a treatment assignment.
  - The study intervention should be initiated **within 120 minutes** of randomization.
  - Notify the appropriate team members in real time and initiate treatment according to the participant's randomization assignment.

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Measures to Minimize Bias

- MINUTE is an on-label study with **blinded end-point outcome assessment**; participants, treating providers, and site investigators are not blinded to treatment assignment.
- Full blinding is not feasible because treating clinicians, clinical staff, and research teams must know the treatment to provide care and appropriately manage and report adverse events.
- Study follow-up outcome assessments will be performed by **independent, blinded investigators** certified in modified Rankin Scale (mRS) assessment.
- Blinded assessors will not have been involved in the participant's clinical care and will be unaware of randomization status; the coordinator will ensure a large Band-Aid is placed on each patient's forehead to prevent scar-related unblinding.
- Outcome assessors will record their best guess of treatment allocation and their confidence level to evaluate the effectiveness of blinding.

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Study Imaging Requirement

Time Point	Control: Standard Medical Management	Intervention: SCUBA Procedure
Screening (before treatment arm is known)	A baseline CT & vascular imaging (e.g., CTA, MRA, DSA)	
Day 0: Baseline	A stability CT scan at approximately **4–8 hours**	An **immediately post-evacuation** CT scan, which replaces the standard stability scan
Day 1	A **24-hour CT** scan to confirm stability	
Unscheduled	Any unscheduled brain imaging, either: • collected **within 72 hours** of randomization, or •related to an AE/SAE during entire study participation	

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Study Imaging Reminders

- Within 7 days of patient discharge:

  All imaging MUST be uploaded to the imaging portal

  Complete the Imaging Collection form in WebDCU

  Inform the Imaging Project Manager of any delays!
- Make sure you are well-acquainted with your site process for ordering and obtaining imaging from your radiology department

- *Sites should also know their site process for obtaining external imaging if they expect to receive many transfer patients*
- Upload imaging as you receive it; do not need to wait!

Study Imaging Upload

- All imaging must be in native, **uncompressed DICOM** format.
- If your institution requires you to remove PHI prior to upload, make sure the **date and time of image acquisition is intact**
- **Google Chrome** is the preferred browser
- Do not close screen until upload completes
- Full upload Instructions are found in the MINUTE Imaging MOP in WebDCU.

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WebDCU™

- ❑ Data Collection Guidelines
- ❑ Document Parameter Guidelines
- ❑ User Manual
- ❑ Training

Data Collection Guidelines

- ❏ The Data Collection Guidelines, published by NDMC, is a booklet to guide you through entering data into WebDCU™.
- ❏ The booklet will be added to the WebDCU™ toolbox for the MINUTE study.
- ❏ All data is to be entered into the subject's binder in WebDCU™ within 5 days of data collection.
- ❏ **Subject Enrollment** must be completed in **WebDCU™** to populate the Subject's CRF Binder. **Eligibility and Randomization** case report forms must be completed for randomization. All other forms can be data entered later to avoid delaying study intervention.
- ❏ Screen Failures are entered into WebDCU™ as they occur, not monthly.
- ❏ Site payments are contingent upon complete subject data being entered into WebDCU™.

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Regulatory Document Parameter Guidelines

- The Document Parameter Guidelines is a document that guides you in the requirements of your regulatory documents that are uploaded to WebDCU™ and also contained in your site regulatory files. These include but are not limited to:

Site Documents	
cIRB Approval	cIRB Approved ICF
cIRB Approved Translated ICF	Protocol Signature Page
Local IRB Acknowledgement	Site-specific BOR, if applicable
Site-specific HIPAA, if applicable	Translated copy of BOR &/or HIPAA, if applicable
cIRB Approved Translated Short Form ICFs	cIRB Approved Administrative Amendments, when applicable
	HIPAA Authorization for Screening

People Documents	
CV	Medical/Professional License
HSP Training Certificate	GCP Training Certificate
NIHSS Training Certificate	mRS Training Certificate
Protocol Training Attestation(Quiz)	Study Coordinator Training Attestation(Quiz)
ABC/2 Method Attestation	Surgical PI: One-Day In-Person Surgical Training (Attestation/Approval Form)
Core Lab Imaging Upload Training	Surgical PI: Five Educational Modules (Attestation)
	Surgical PI: Four Non-Trial Case Submissions (Approval Form)

This document is stored in the WebDCU™ toolbox under your StrokeNet studies.

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WebDCU™ User Manual

The WebDCU™ User Manual is your go-to guide for working with our clinical trial management system.

The manual will cover the following and more:

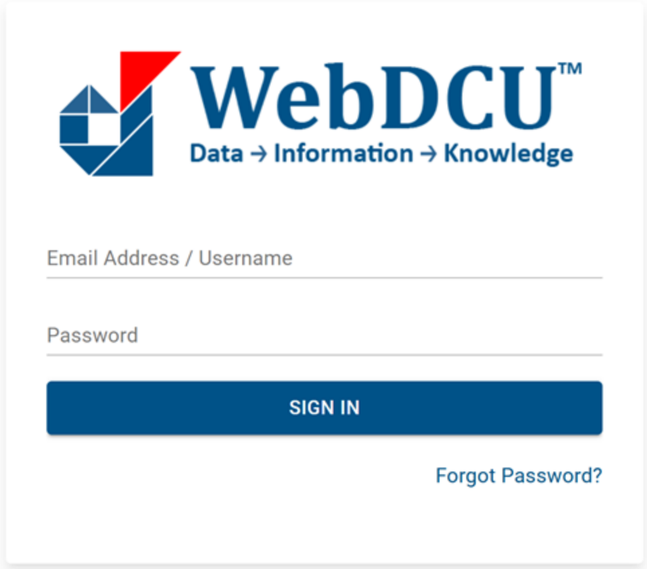
- ❏ Logging in & out
- ❏ Uploading Regulatory Documents
- ❏ Project Documents, i.e. Protocol, Data Collection Guidelines, Regulatory Document Parameters, Current CTCAE version and other imperative trial documents
- ❏ Data Entry Instructions
- ❏ Instruction Documents
- ❏ Regulatory Documents
- ❏ Core Lab Imaging Documents
- ❏ Tools for Site & Subjects

The WebDCU™ User Manual is available in the WebDCU™ toolbox.

WebDCU™ Training

Training for WebDCU™ is in the WebDCU™ training center located on the login page. No WebDCU™ login is needed to access the training center.

https://webdcu.musc.edu/DCUApp/Login



Subject Visits

- In-hospital (Screening, Day 0 Baseline, Day 1, Day 7 or Discharge)
- Day 30,
- Day 90,
- Day 180,
- Day 365

Subject Visits (In-hospital)

Screening

I/E Criteria	Demographics	Medical History	Medication Review
Pregnancy Test	SOC Lab Results	Diagnostic CT Head	Diagnostic CTA or MRA
Informed Consent	NIHSS	GCS	mRs

Day 0: Baseline

Randomization	Endoscopic Evacuation#	CT Head	AE	SAE	Concomitant Meds

Only for SCUBA arm

Day 1: 24 ± 6 hrs after Randomization

SOC Lab Results	CT Head	NIHSS	GCS
AE	SAE	Concomitant Meds	

Day 7 or discharge (± 1 day), whichever comes first

SOC Lab Results	NIHSS	GCS
AE	SAE	Concomitant Meds

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Subject Visits

Day 30 ± 7 Days	mRS	SAE	Concomitant Meds	
Day 90 ± 30 Days	mRS	SAE	Concomitant Meds	
Day 180 ± 30 Days	mRS	SAE	EuroQol-5D (Quality of Life)	Concomitant Meds
Day 365 ± 30 Days or Study Exit/Completion	mRS	SAE	EuroQol-5D (Quality of Life)	Concomitant Meds

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Adverse Events Assessing & Reporting

- ❑ Assessing for Adverse & Serious Adverse Events
- ❑ Reporting AEs/SAEs in WebDCU™ & Timeline
- ❑ Unanticipated Events/Protocol Deviations

Assessing for Adverse & Serious Adverse Events

The SC plays a key role in the discovery of any Adverse Event (AE) or Serious Adverse Event (SAE). If an AE/SAE is discovered during time spent with the subject or medical record review, the SC should obtain all data and present to the PI/SubI for assessment of the AE/SAE.

The PI is responsible for assessing any AE or SAE that occur with their subjects. This task can also be delegated to the site SubI(s).

The PI should assess for the following:

- ❑ Severity
- ❑ Relationship to Study Intervention
- ❑ Relatedness to ICH
- ❑ Anticipated or Unanticipated
- ❑ Action taken regarding study intervention
- ❑ Other actions taken
- ❑ Outcome

Documentation of any AEs should be maintained at the site in the subject's research binder, with PI acknowledgement, and reported in WebDCU™.

Reporting AEs/SAEs in WebDCU™ & Timeline

Reporting of an AE/SAE on WebDCU™

1. Enter the subject's CRF binder
2. Click on your subject number
3. Click on F104 Adverse Event CRF
4. Enter the data following the questions in the form
    a. Please make sure to answer Q3, "Serious", yes or no

Reporting Timeline

- ❑ SAEs (unanticipated or at least possibly related to the procedure): **within 24 hours** from discovery. The SAE report does not have to be completed but at least started and submitted.
- ❑ SAEs (not unanticipated, unrelated or unlikely to be related to the procedure): **within 3 business days**
- ❑ Non-serious AEs: **within 5 business days** of discovery

★ Reference Anticipated Events list in the Manual of Procedures.

Unanticipated Events/Protocol Deviations

Unanticipated events (UEs) are those that are unexpected and may involve an increased risk of harm to the research subject. These may also include protocol deviations.

Examples of UEs:

- ❏ Consent form errors, i.e., not using a witness when applicable, using incorrect version, etc.
- ❏ Subject not meeting inclusion criteria for study
- ❏ Out of window visit, i.e., incorrect specimen draw time
- ❏ Non-compliance by site or subject
- ❏ Researcher error
- ❏ Breach of confidentiality, i.e., sending unsecured email with PHI

- ★ UEs will be captured in WebDCU™ on the CRFs and the Prime PI will monitor these events in aggregate.
- ★ UEs that increase risk or constitute serious noncompliance will also be reported via WebDCU™ on the UAE/PD Form and reported to the CIRB per the NCC PM.

Toolbox Resources – Manuals & Protocols & Regulatory Documents

Protocol

- The most current version of the protocol will be maintained in the toolbox.

Manuals

- All current MOPs are available in the toolbox; these include:
  - Protocol MOP
  - Imaging

Regulatory Documents

All PRIME approval letters will be added to the WebDCU™ toolbox which include:

- Initial approval letter for the study
- All modification letters
  - PRIME approval letters will also be emailed to the site.

Toolbox Resources – Instruction Documents

All instructional documents will be made available in the toolbox, these include but are not limited to:

- Frequently Asked Questions (FAQ List)
- How to create a digital signature
- Site Readiness Checklist
- Preparing PDFs for Upload into WebDCU™
- Enrollment, Randomization & Visit Checklists

Toolbox Resources – Tools for Sites & Subjects

The WebDCU™ Toolbox will also contain many tools for the sites and subjects. All subject tools will be cIRB approved prior to uploading into the toolbox. These tools may include, but are not limited to:

- ❑ Inclusion/Exclusion Criteria Card
- ❑ Study Brochure
- ❑ Information Video for Patients/Families (will be posted on NIHStrokeNet.org -> MINUTE website)
- ❑ ICH Medical Management Recommendations/Guidelines
- ❑ Visit scheduler
- ❑ Data Collection Guidelines
- ❑ Follow-up Visit Checklist
- ❑ Wallet card
- ❑ UAE/PD Checklist
- ❑ Lost-to-follow letter to subject

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Thank you! 👏 😊

Thank you for your time! Please take the coordinator training quiz in REDCap. Here's the link: https://redcap.link/minutecoordinatorquiz.

- By completing this quiz, you are confirming you have reviewed the training slide deck.
- You must answer at least 11 out of 13 questions correctly to receive a passing score. A PDF will be generated at the conclusion of this test and sent to the email address entered below.
- That PDF must be uploaded to WebDCU to document your training.
- A separate attestation form is not required for protocol or coordinator training.

Email Ally Qi, ally.qi@mountsinai.org if you have any questions regarding this material.