

# **Stroke Hyperglycemia Insulin Network Effort (SHINE)**

## **Regulatory Requirements and Readiness Call Process**

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# SHINE Website and WebDCU Database

- **SHINE Website - <http://www.shinetrial.com>**
  - SHINE-related materials - protocol, regulatory parameters document, DOA, and readiness checklist.
  - Trainings - protocol, data, mRS, NIHSS, WebDCU
  - Obtain UMich Friends account for access requested from Joy Pinkerton (joypink@umich.edu), NETT Education coordinator
- **WebDCU Database - <https://webdcu.musc.edu/NETT>**
  - Complete WebDCU regulatory database training to request for access
  - Study personnel who will be uploading regulatory documents, randomizing, and/or entering subject data



# Document Type in WebDCU

- People Document: Document specific to an individual.
  - Examples include CV, License, NIHSS and mRS Certifications, HSP, HIPAA, etc.
- Spoke Document: Document that applies to a site.
  - Examples: IRB submittal, DOA log, pharmacy plan, etc.
- Use Regulatory Parameters Document for training requirements



# Required SPOKE Documents for Study Startup & Readiness Call

- FWA for your Institution
- CLIA Certification
- IRB Submittal Packet (include any contingency communications)
- IRB Study Approvals
- IRB-Approved Informed Consent Forms
- Delegation of Authority Log
  - Nursing staff do not need to be added to the DOA log or the Project Spoke Team Member (PSTM) table in WebDCU.

#upload all docs as PDFs in WebDCU



# Contd. **Required SPOKE Regulatory Documents**

- Nursing In-service Sign-in Sheet
- Pharmacy Plan
- Recruitment Plan
- Readiness Checklist\*

#Upload all docs as PDF in WebDCU.

\*Send readiness checklist to site manager.



# Readiness Checklist

- Confirms site's regulatory and logistical readiness
- Lists names of site participants attending the call
- Required at least 48 hours prior to the readiness call (RC) along with pharmacy orders/plan and recruitment plan.

\*Readiness Checklist template is on the SHINE website





# Readiness Call

- A Readiness Call (RC) is the SHINE Study Initiation Visit/Meeting (SIV/M).
  - Conducted via phone conference.
  - Evaluate and confirm site readiness for study activation



# Readiness call – Site Personnel

- Site personnel: Hub PI, Study PI, Primary SC, Pharmacist, and Nurse Champion.
- SHINE Readiness Call team: NETT PI, SHINE PIs, Project Director, Site Manager, and MUSC personnel.
- All participants will receive Readiness Call appointment





# Readiness Call – Scheduling

- Scheduling

- Contact Site Manager to set a “tentative” date.
- Tentative date is set to help sites finalize required site documents and trainings.

- Confirming the Call

- At least 48 hours prior to the call finalized pharmacy orders & plan, readiness checklist, and recruitment plan need to be sent/uploaded.
- Confirmation will be sent upon receipt of the final documents.

- Will be rescheduled if site is unable to meet the tentative call date.



# Readiness Call - Structure

- Confirm all regulatory documents in place for spoke and all study personnel
- Discuss recruitment plan
- Review pharmacy plan and study orders
- Walk through readiness checklist



# After Readiness call - Site Activation

- Following the Readiness Call, if there are action items, site personnel will help with resolution prior to site activation.
- In the absence of action items, site will be activated/released to enroll and will be notified via email.
- **Site - Activation**  
Site is released to **Active/Enrolling** status in WebDCU and can then screen and enroll/randomize.



# Preparing for Readiness Call

## – What Next?

- Set a tentative date for Readiness Call; update Site Manager regarding site readiness status
  - Upload final pharmacy orders/plan
  - Upload Recruitment plan
  - Obtain DOA signatures
  - Double check laptop connectivity in patient areas
  - Complete all trainings/upload docs.
  - Email completed Regulatory Checklist
- Send regulatory checklist, pharmacy plan/orders, and recruitment plan at least 24 hours prior to call



Questions?

