Stroke Hyperglycemia Insulin Network Effort (SHINE) Trial Training & Regulatory Requirements

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SHINE Site Manager

Types of Documents in WebDCU

- **People Document:** A document that is specific to an individual.
  - Linked to a specific study team member in WebDCU
  - The same document can occasionally apply to more than one person but must be uploaded for each person separately

Types of Documents in WebDCU

- **Spoke Document:** A document that is not specific to an individual, but that applies to either a site generally or to several individuals at a site.
  - Regulatory Parameters document provides instructions for deferred documents

Overview of Required Regulatory Documents

Study Team Members – People Documents

Document	Required for:
CV	PI, Co-Is, Primary/Secondary SCs, Lead Pharmacist
HIPAA Certification	PI, Co-Is, Primary/Secondary SCs
HSP/CITI Certification	PI, Co-Is, Primary/Secondary SCs
Medical License	PI, Co-Is, Primary/Secondary SCs (if licensed), Lead Pharmacist
SHINE Protocol Training	PI, Co-Is, Primary/Secondary SCs
SHINE Data Training	Primary/Secondary SCs
SHINE Investigator's Agreement	PI, Co-PI
NIHSS Certification	PI, Co-Is, Primary/Secondary SCs who will perform assessment
mRS Certification	PI, Co-Is, Primary/Secondary SCs who will perform assessment

Overview of Required Regulatory Documents

Clinical Team Members – Spoke Training Documents

Document	Purpose:
SHINE Nursing Inservice Sign-in Sheet	Documentation of site-specific training of clinical nursing staff who will be managing the SHINE protocol
SHINE Pharmacy Plan	Documentation of the site's logistical plan for notifying pharmacy of a SHINE subject, preparing/labeling of the first and subsequent bags of insulin/saline, and maintenance of the study protocol over the treatment period.

Overview of Required Regulatory Documents

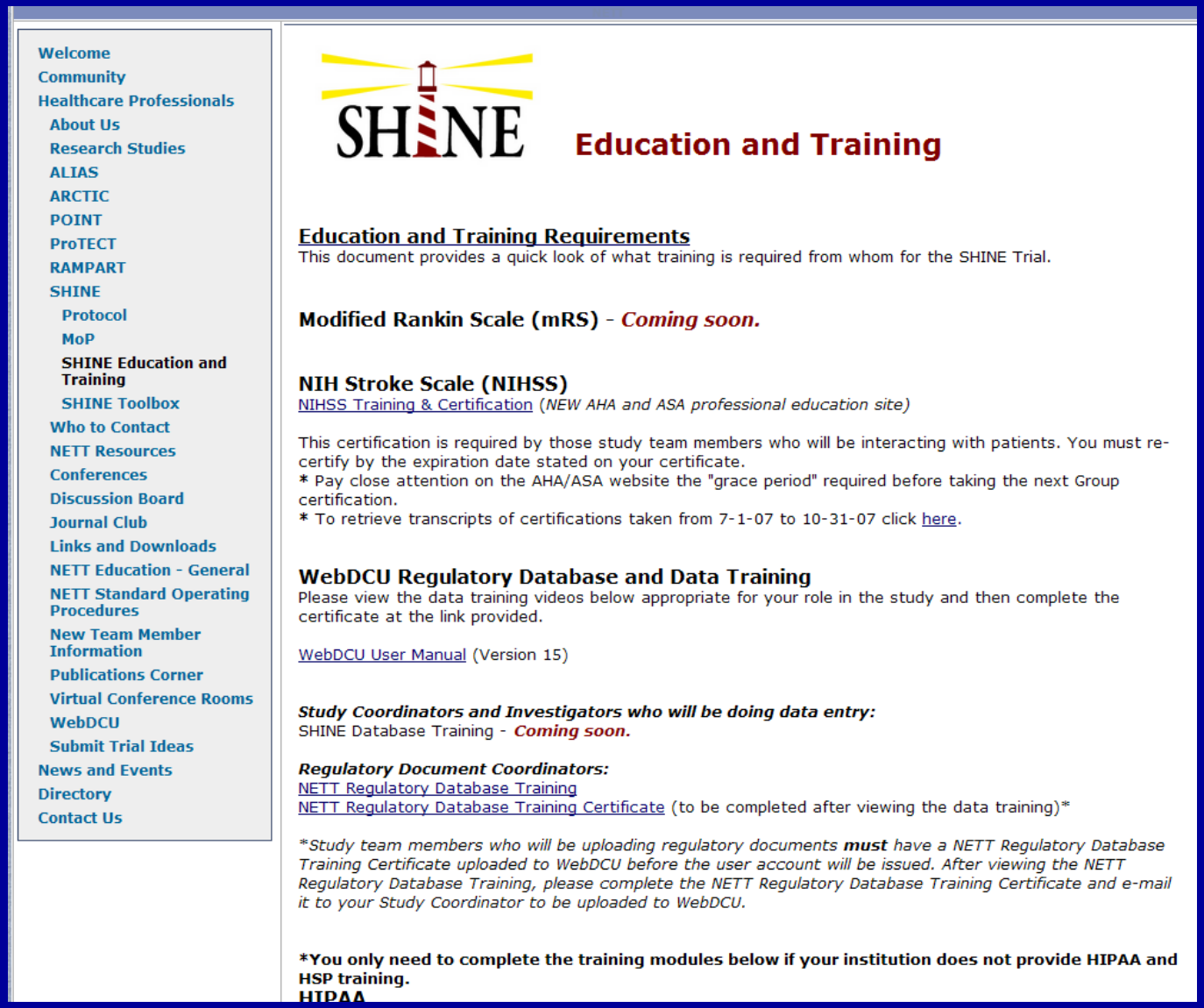
General Regulatory Requirements – Spoke Documents

- Institutional FWA
- IRB Applications & Correspondence
  - IRB Application Submittals
    - These should include the text of the application
    - Only the cover page of supplemental materials (e.g., protocol, CRFs, MOP) need to be included
  - IRB Study Approvals
  - IRB-Approved Informed Consent Forms
    - Please send ICFs to shine-milestones@umich.edu for approval prior to IRB submittal
  - IRB Study Modification Notifications (e.g., SAEs, Protocol Deviations, Personnel Changes)
  - IRB Close-Out Notification
  - IRB Close-Out Acknowledgement
- Delegation of Authority Log
- CLIA Certification

SHINE

Training Resources

http://www.SHINEtrial.com



REMEMBER!

There are two main websites you will be using:

- SHINE Website: http://www.SHINEtrial.com (also accessible via http://nett.umich.edu)
  - Requires UMich Friends Account
  - Access must be requested through Joy Pinkerton (joypink@umich.edu)
- WebDCU: https://webdcu.musc.edu/nett/
  - Requires WebDCU regulatory database training prior to granting initial access
  - Access only needed by those who will be uploading regulatory documents or entering subject data
  - SHINE database is in progress – access will be granted when it is operational

Helpful hint: Use the same email address for both your UM Friends Account and your WebDCU access to reduce confusion, especially if you are just starting out with the systems.

SHINE

New Personnel/Personnel Changes

- Study team members must be listed on the Delegation of Authority Log – keep the DOA log on WebDCU current!
- Study team members must be assigned roles in WebDCU Project Spoke Team Member table
- Regulatory Parameters Document lists specific requirements
- Nursing staff and pharmacy staff (with the exception of the lead pharmacist/pharmacy contact) do not need to be added to the DOA log or the Project Spoke Team Member table.

Regulatory Readiness

- Site should notify that CCC that they are regulatory ready after IRB approval is received and all regulatory docs are uploaded
- CCC will confirm the presence of all required documents and schedule a readiness call with key personnel from the SHINE team, the site study team, and the NETT CCC.
- Site will complete a Readiness Checklist and provide it to the CCC for review prior to the readiness call.
- Following the call, if no action items are required, the site will be notified that they are released to begin enrollment.
- If action items are required, these must be resolved prior to being released to enroll under SHINE.