Regulatory Document Approval Parameters for WebDCU™
SHINE

People Document Collection

REGULATORY REQUIREMENTS						CCC APPROVAL PARAMETERS
Document	**Person Role**	**Document Type**	**Effective Date** dd/mmm/yyyy	**Expiration Date** dd/mmm/yyyy	**Waived Y/N**	**Instructions for WebDCU™** Please upload all documents in **pdf** format to WebDCU™.
CV	P.I., Co-I, Pharmacist, Primary SC, Secondary SC	People	Use date within document	Required - 5 yrs. from effective date	N	Required for all site personnel listed on the DOA and any other personnel who are directly involved in the study. Document must have a date. Signature is not required. Provide source in a pdf attachment.
HIPAA Certification	P.I., Co-I, Primary SC, Secondary SC	People	Use Source (date certification completed)	Site-specific	N	**Applies to HIPAA and HSP Certifications:** Follow the local institutional policies for completion and ongoing maintenance of these certifications. If your institution requires re-training and provides an expiration date for the certification, enter this date into WebDCUTM and you will receive a notification as that date nears. Provide the corresponding HIPAA/HSP Certification for each study team member in a pdf attachment.
HSP Certification	P.I., Co-I, Primary SC, Secondary SC	People	Use Source (date certification completed)	Site-specific	N	
GCP Training	P.I., Co-I, Primary SC, Secondary SC, and other Data Collection/ Entry/Management Personnel	People	Use Source (date certification completed)	Use date on Source or 3 years from effective date, whichever is earlier	Y	A new National Institutes of Health (NIH) policy (NOT-OD-16-148) requires investigators, study coordinators, and data managers involved in the conduct, oversight, or management of NIH-funded clinical trials be trained in Good Clinical Practice (GCP). This training requirement is in addition to (and does not replace) the basic required human subjects' protection training (e.g., CITI human subject's modules). The policy notes that GCP training should be refreshed at least every three years. Follow your institutional policy for GCP training.
Medical License	P.I., Co-I, Pharmacist, Primary SC, Secondary SC	People	Use Source "issuance date," if no date, use date uploaded	Required – Use Source	Y	Upload a copy of the current license into WebDCU™. Copies of online verifications are valid, unless a disclaimer is noted on the license.
NIHSS Certification	P.I., Co-I, Primary SC, Secondary SC	People	Use date certification was granted	Use Source (date certification expires)	Y	Certification is required for Investigators and Study Coordinators who will be completing the NIHSS assessment with subjects. Training will be available on SHINE Education and Training (www.shinetrial.org). Upload a copy of the training certification in pdf format in WebDCU.

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mRS certification	P.I., Co-I, Primary SC, Secondary SC	People	Use date certification was granted	Use Source (date certification expires)	Y	Certification is required for Investigators and Study Coordinators who will be completing the mRS assessment with subjects. Training will be available on the SHINE Education and Training (www.shinetrial.org). Upload a copy of the training certification in pdf format in WebDCU.
SHINE Investigator's Agreement	P.I.	People	Use date document was signed	Leave blank	N	Document must have a date and signature of the site PI. Provide source in a pdf attachment.
Regulatory Document Management Training	Primary SC, other study team personnel*	People	Use date training provided	N – leave blank	N	Regulatory document management training is available in the SHINE Education and Training (www.shinetrial.org). Once the training is completed, an attestation can be completed using link provided. Upload the SHINE Regulatory Training document and access will then be granted for new user accounts. *All study team members maintaining regulatory compliance.
Data Training	Primary SC, anyone who will be doing SHINE CRF data entry	People	Use date training provided	N – leave blank	N	CRF data training will be available in the SHINE Education and Training (www.shinetrial.org). Once the training is completed, an attestation will be completed and uploaded. SHINE data entry accounts cannot be activated until the SHINE Data Training document is uploaded to WebDCUTM.
Protocol Training	P.I., Co-I, Primary SC, Secondary SC	People	Use date training provided	No – leave blank	N	Credit will be given to those in attendance at the Investigators Meeting and protocol training sessions/webinars conducted periodically. Training is also available in the SHINE Education and Training page (www.shinetrial.org) along with attestation. Study team members listed on the eDOA are required to complete the protocol training. There are two options to choose from. (1) View the video and/or slides. When finished, complete the attestation with name and date for each team member and upload in database as "Protocol Training." (2) Attend a group training session. .Upload an attendance sheet clearly identifying the date of the training and the team members present.
ISPOT STUDY						
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ISPOT Training	Team members with this responsibility	People	Use date certification was granted	Leave Blank	Y	Training is available on the SHINE Education web page for ISPOT. Upload a PDF copy of the training certification into WebDCU.
Sample Handling and Shipping Certification	Team members with this responsibility	People	Use date certification was granted	Use Source (date certification expires)	Y	Complete required training based on institutional requirements for drawing, preparing, storing, and shipping blood samples. Upload source in a pdf attachment in WebDCU. Mandatory for anyone performing ISPOT tasks, even if not specified as required by role.

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Spoke Document Collection

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FWA	Site	Use source approval date, if a date is not provided, use date uploaded	Required – use source expiration date	N	Each Hub must provide documentation of a Federal wide Assurance (FWA). Upload a copy of the FWA to WebDCU™. Please see FWA process document in the SHINE Toolbox.
CLIA	Site	Use source	Use source	N	CLIA certification is the only lab certification required.
HSP Policy	Site	Use date of upload	Leave Blank	N	Provide the NETT-CCC with Human Subject Protection (HSP) and HIPAA training/certification policies for research as required by your site's research administration office or site IRB. Combine HSP and HIPAA policy into one single PDF and upload in this entry. NOTE: **We need to see within the pdf the interval (duration) of re/certification (e.g. HSP re-training required every 3 years, etc.).
SHINE Nursing In-service Sign-in Sheet	Site	Use date signature provided	N – leave blank	N	Please document inservices done with clinical nurses by having attendees sign in. These nurses do not need to be listed in WebDCU; however, this document should provide evidence that adequate training has been conducted on site.
Full Study IRB Application Submission (protocol v2)	Site	Use date of submission on document	Leave blank	N	Documentation that the protocol v2 was submitted to the IRB for all participating Spokes. Subsequent documentation that full applications for continuing review have been submitted to the IRB should also reside here. Acceptable documentation can include any IRB generated or electronic application message indicating an application has been submitted for IRB review and the date the submission was received.
IRB Approval (protocol v2)	Site	Use source approval date	Required – use source expiration date	N	Provide IRB approval of the protocol v2 with clear documentation of the protocol version and approval date. Subsequent documentation of IRB approval at continuing review should also reside here
IRB Approved Informed Consent Form V3.0 (for protocol V2.0)	Site	Use source approval date	Required - use source expiration date	N	Provide written documentation of the IRB approval of the Informed Consent Form(s) with clear documentation of the IRB approval date. Prior to re/submitting to your IRB, your Informed Consent Form(s) must be approved by the CCC; please forward to shine-milestone@umich.edu Provide source in a pdf attachment explicitly showing IRB approval.

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IRB Approved Informed Consent Form Non-English	Site	Use source approval date	Required - use source expiration date	N	Provide written documentation of the IRB approval of the Consent Form(s) with clear documentation of the IRB approval date. Provide source in a pdf attachment explicitly showing IRB approval.
IRB Study Modification Notification	Site	Use source approval date	Leave Blank	N	Written notification to the IRB of changes to study team; study materials; or any document previously approved by a site's IRB (NOTE – IRB approval letters, consent forms and other documents specified above are still posted to their respective entries.)
PI Attestation of Retraining	Site	Use signature date	Leave Blank	N	Site PI is required to sign the attestation form after site team has completed all retraining tasks (Per study requirements and NETT SOP). Upload signed attestation in WebDCU. Each spoke site that has not enrolled a subject in 6 months is required to complete retraining.
SHINE Pharmacy Plan	Site	Use date of upload into WebDCU	Leave blank	N	Please include the process for drug preparation and dispensing at each respective Spoke. Will be reviewed by the NETT-CCC.
SHINE Recruitment Plan	Site	Use date of upload into WebDCU	Leave blank	N	Please write in prose of ½-2 pages an individualized recruitment plan that captures the strategies proven or intended for your site by imagining tracing a possible SHINE patient from presentation to the ED through completion of final handoff to receiving RN on the bedding floor. Please include all aspects of the process you feel are relevant to successful recruitment at your site. See guidance document in SHINE Toolbox for specific areas to address in the plan.
IRB Close-out Notification	Site	Y - use source approval date	Leave blank	N	Written notification to the IRB of the study enrollment closure at hub/site
IRB Close-out Acknowledge-ment	Site	Y- use source approval date	Leave blank	N	Written documentation of the IRB acknowledgment or approval of study's closure at hub/site