Regulatory Document Approval Parameters for WebDCU™
POINT

People Document Collection

REGULATORY REQUIREMENTS

Document	Person Role	Document Type	Effective Date dd/mmm/yyyy	Expiration Date dd/mmm/yyyy	Waived Y/N	Instructions for WebDCU™
CV	P.I., Co-I, Study Drug Recipient, Primary SC, Secondary SC	People	Use date within document	5 yrs. from effective date	N	Required for all site 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, Data Entry, Administrators	People	Use Source (date certification completed)	Site-specific	N	Please 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 WebDCU™ and you will receive a notification as that date nears. Please provide the corresponding HIPAA Certification for each study team member in a pdf attachment.
HSP Certification	P.I., Co-I, Primary SC, Secondary SC, Data Entry, Administrators	People	Use Source (date certification completed)	Site-Specific	N	Please 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 WebDCU™ and you will receive a notification as that date nears.. Please provide the corresponding HSP Certification for each study team member in a pdf attachment.
Medical License	P.I., Co-I, Primary Study Drug Recipient, Primary SC, Secondary SC	People	Use date license was issued. If date is not provided, use date of upload	Use Source (date license expires)	Y	Upload a copy of the current license into WebDCU™. Copies of online verifications are valid, unless a disclaimer is noted on the license. Provide source in a PDF attachment.
POINT Protocol Training	P.I., Primary SC	People	Use date training completed	Leave blank	N	Credit will be given to those who have completed the training. Once completed, a certificate will be provided; please provide source in a PDF attachment in WebDCU™.
POINT Enrollment Training	P.I., Primary SC	People	Use date training completed	Leave blank	N	Credit will be given to those who have completed the training. Once completed, a certificate will be provided; please provide source in a PDF attachment in WebDCU™.
POINT Data Training Certification	Data Entry	People	Use date training completed	Leave blank	Y	Provide POINT Data Training Certificate in a PDF file format in WebDCU™ for anyone assigned CRF completion or Data query resolution responsibility. WebDCU™ data entry access cannot be activated until the certificate is uploaded..

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POINT Regulatory Database Training Certification	Maintain Regulatory Documents	People	Use date training completed	Leave blank	Y	Provide POINT Regulatory Database Training Certificate in a PDF file format in WebDCU™ for anyone assigned responsibility for maintaining regulatory documents. WebDCU™ regulatory document access cannot be activated until the certificate is uploaded.
POINT Site Pharmacy Data Training Certification	Primary Study Drug/Device Recipient	People	Use date training completed	Leave blank	Y	Provide POINT Pharmacy Data Training Certificate in a PDF file format in WebDCU™ WebDCU™ pharmacy accounts can not be activated until the Site Pharmacy Data Training is uploaded.
NIHSS Certification	P.I., Co-I, anyone completing	People	Use date certification completed	Use Source (date certification expires)	Y	Certification is required for Investigators and Study Coordinators who will be completing the NIHSS assessment with subjects. Once completed, a certificate will be provided; please provide source in a PDF attachment in WebDCU™.
Physician Information form	P.I	People	Use source (date form completed	Leave blank	Y	Required for CRC sites. For NETT site-please waive.
Good Clinical Practice Certification	P.I., Co-I, Primary SC, Secondary SC, and others doing Data Collection/Entry	People	Use date certification completed	Use Source(date certification expires) or 3 years from effective date, whichever is earlier	N	A new National Institutes of Health (NIH) policy (NOT-OD-16-148) requires investigators, study coordinator, and data managers involved in the conduct, oversight, or management of NIH-funded trials be trained in GCP. This training requirement is in addition to (and does not replace) the basic required human subjects' training (e.g. CITI human subject's modules). The policy notes that training must be refreshed every 3 years. Follow your institutional policy for CGP training. Provide source in a PDF attachment.
ABCD2 Certification	P.I., Co-I, Primary SC, Secondary SC/anyone completing	People	Use date certification completed	Leave blank	Y	Certification is required for Investigators and Study Coordinators who will be completing the ABCD2 assessment with subjects. Once completed, a certificate will be provided; please provide source in a PDF attachment in WebDCU™.
Sample Handling and Shipping Certification	Study team personnel*	People	Use date certification was granted	Use Source (date certification expires)	N	Complete required training based on institutional requirements for drawing, preparing, storing, and shipping blood samples. Upload source in a pdf attachment in WebDCU. *All study team members performing this responsibility must complete this certification
mRS Certification	P.I., Co-I, Primary SC/anyone completing	People	Use date certification completed	Use Source (date certification expires)	Y	Certification is required for Investigators and Study Coordinators who will be completing the mRS assessment with subjects. Once completed, a certificate will be provided; please provide source in a PDF attachment in WebDCU™.

Spoke Document Collection

REGULATORY REQUIREMENTS

Document	Document Type	Effective Date dd/mmm/yy yy	Expiration Date dd/mmm/yy yy	Waived Y/N	Instructions for WebDCU™
IRB FWA	Spoke	Use source approval date, if a date is not provided, use date of upload into WebDCU	Use source expiration date	N	Each Hub must provide documentation of an IRB Federalwide Assurance (FWA). Upload a copy of the FWA to WebDCU™. The Federalwide Assurance (FWA) is how institutions attest that they will comply with federal rules governing the conduct of clinical trials.
POINT Full Study IRB Application Submittal* (Protocol Version)	Spoke	Use date of submission on document	Leave blank	N	Documentation that the full application has been submitted to the IRB for all participating POINT Hubs/ Spokes. This application should include results from the final Protocol, Package Insert for Clopidogrel, FDA IND Exemption Letter, Informed Consent Forms, and the DSMB plan (if applicable). This must be documented by uploading the confirmation of submittal and the full application into WebDCU. *Note – only the initial full application must be uploaded into WebDCU. For subsequent submissions (i.e. continuing renewal), only the IRB approval with documentation listing all documents reviewed and approved must be uploaded.

REGULATORY REQUIREMENTS

Document	Document Type	Effective Date dd/mmm/yy	Expiration Date dd/mmm/yyyy	Waived Y/N	Instructions for WebDCU™
POINT Protocol IRB Approval	Spoke	Use source approval date	Use source expiration date	N	Provide the IRB approval letter clearly documenting the protocol version and approval date. Continuing Renewals are posted here.
POINT IRB Approved Informed Consent Form(s)	Spoke	Use source approval date	Use source expiration date	N	Prior to submitting to your IRB, your Informed Consent Forms must be reviewed and approved by the CCC Once the CCC review is completed, please submit to your IRB for approval. In WebDCU™, provide written documentation of the IRB approval of the Informed Consent Forms with clear documentation of the IRB approval date. Provide source in a PDF attachment explicitly showing IRB approval.
Delegation of Authority Log	Spoke	Use Date uploaded in WebDCU	Leave Blank	N	This document type will be available and used for sites that have a local(institutional or country) requirement to maintain a paper DOA log.
Hub PI Attestation of POINT Retraining *required for NETT sites	Spoke	Use Signature	Leave Blank	N	Signed by Hub PI once re-training is completed.
Study Drug Destruction Policy	Spoke	Use source approval date	Leave Blank	Y	Provide institutional/pharmacy SOP that covers local guidelines for drug destruction on site.

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CLIA Certification	Spoke	Use source "approval date"	Use source expiration date	N	CLIA is required. Upload copies of the certificate to WebDCU™. If a current certificate is not yet available, a note from the lab can be uploaded in WebDCU until the official document is available.
HSP and HIPPA policies	Spoke	Use source approval date	Leave blank	Y	Required for NETT sites. For CRC sites-please waive. Provide HSP and HIPAA training/certification policies for research as required at your local research administration office or site IRB policies. Combine HSP and HIPAA policy into 1 single PDF and upload. NOTE; We need to see the interval/duration of training/recertification(e.g. HSP training required every 3 years, etc.)
Office of Research Integrity (ORI) Assurance *required for CRC sites	Spoke	Use source approval date	Use source expiration date.	N	Any site who has previously received a grant through NIH will already have established an initial assurance. If you have not established this assurance, or if you are unsure of your status, please contact Robin Parker at Robin.Parker@hhs.gov
POINT IRB Study Modification Notifications	Spoke	Yes use source "approval date"	Use source expiration date, if applicable	N	Written notification to the IRB of changes to study team; study materials; IRB acknowledgement of protocol deviations; or any document previously approved by a site's IRB (NOTE – IRB approval letters and consent forms are still posted to their respective entries.)
IRB Close-out Notification	Spoke	Yes use source "approval date"	Leave Blank	N	Written notification to the IRB of the study's closure at hub/spoke.
IRB Close-out Acknowledgment	Spoke	Yes use source "approval date"	Leave Blank	N	Written documentation of the IRB acknowledgment or approval of study's closure at hub/spoke.