Regulatory Document Approval Parameters for WebDCU™
ESETT

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, Primary SC, Secondary SC	People	Use date within document	Required - 5 yrs. from effective date	No	Required for all site personnel listed on the 1572 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	No	**Applies to HIPAA and HSP Certifications:** 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/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	No	
GCP Training	P.I., Co-I, Primary SC, Secondary SC, and other Data Collection/ Entry/Management Personnel	People	Use Source (date certification completed)	Use the date on Source or 3 years from effective date, whichever is earlier	No	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	Yes	Upload a copy of the current license into WebDCU™. Copies of online verifications are valid, unless a disclaimer is noted on the license.

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Protocol Training	P.I., Co-I, Primary SC, Secondary SC	People	Use date training provided	No – leave blank	No	Credit will be given to those in attendance at the Investigators Meeting. Training is also available in the ESETT Education and Training (www.esett.org) along with attestation. Study team members listed on the eDOA and/or 1572 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 ESETT database as "Protocol Training." (2) Attend a group training session conducted by the PI. .Upload an attendance sheet clearly identifying the date of the training and the team members present.
Regulatory Document Management Training	Team members maintaining regulatory compliance*	People	Use date training provided	No – leave blank	No	Regulatory document management training is available in the ESETT Education and Training (www.esett.org). Once the training is completed, an attestation will need to be completed using link provided on website. Upload the attestation into WebDCU™. 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 ESETT CRF data entry	People	Use date training provided	No – leave blank	No	CRF data training will be available in the ESETT Education and Training (www.esett.org). Once the training is completed, an attestation will need to be completed using link provided on website. Upload document as PDF in database. ESETT data entry accounts cannot be activated until the ESETT Data Training Certificate is uploaded to WebDCU™.
Pharmacy Data Training	Pharmacist, other study team personnel*	People	Use date training provided	No – leave blank	Yes	Pharmacy data training will be available in the ESETT Education and Training (www.esett.org). Once the training is completed, an attestation will need to be completed using link provided on website. Upload a PDF copy of the training attestation into WebDCU™. NOTE: Pharmacy User accounts cannot be activated until the ESETT pharmacy training is completed. *All study team members performing the following responsibility must complete the pharmacy data training: study drug accountability.
Sample Handling and Shipping Certification	Study team personnel*	People	Use Source	Required – Use Source	Yes	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: blood draw accountability.

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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	No	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 ESETT Toolbox.
CLIA	Site	Use source	Use source	No	CLIA certification is the only lab certification required.
FDA Form 1572	Site	Use date document was signed	No – leave blank	No	Provide source as a pdf attachment. NOTE: All study team members performing the following responsibilities MUST be on the 1572: overall responsibility for the trial, informed consent, AE/SAE reporting. All investigators should be listed as well.
ESETT Attestation of Study Team Education & Training	Site	Use date signature provided	No – leave blank	No	Each Spoke PI is required to sign an attestation form that he/she accepts responsibility of the protocol and training responsibilities for all personnel who might be involved with the treatment or assessment of ESETT subjects at their spoke. Please print the signature page of the current protocol and upload the PI signed and dated pdf attachment in WebDCU™.
EFIC Plan IRB Submission	Site	Use source date	Leave blank	No	Upload documentation that the EFIC plan has been submitted for IRB review. Acceptable documentation can include any IRB generated or else electronic application generated message indicating an application has been submitted for IRB review with the date of the submission. **If sharing** an EFIC submission with another site (NOTE: FWA indicates the same IRB of Record), you will need to: 1. Upload the applicable EFIC Plan Submission source again, for the additional site and 2. Add the following **note** to the record: "(site name) is the IRB of record for this site per FWA" For **IRB's deferring** to another sites EFIC plan submission (No FWA relationship): 1. Inform the CCC about it by submitting todkolk@umich.edu a **NETT Spoke Deferral of EFIC Process - letter to ESETT Leadership.** A template is available in the ESETT toolbox under: EFIC 2. Combine the deferral letter along with the EFIC Submission proof into a single PDF and upload. 3. Add the following **note** to the record: "IRB is deferring to (site's name) submitted EFIC Plan." Email dkolk@umich.edu for additional assistance.

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EFIC Plan IRB Approval	Site	Use source approval date	Leave blank	No	Combine the IRB accepted EFIC CC & PD plan and acknowledgment/approval letter from the IRB and upload. **If sharing** an EFIC Approval with another site (NOTE: FWA clearly indicates the same IRB of Record), you will need to: 1. Upload the applicable EFIC Plan Approval source again, for the additional site and 2. Add the following **note** to the record: "(site name) is the IRB of record for this site per FWA" For **IRB's deferring** to another sites EFIC Plan Approval (No FWA relationship): 1. Inform the CCC about it by submitting todkolk@umich.edu a **NETT Spoke Deferral of EFIC Process - letter to ESETT Leadership.** A template is available in the ESETT toolbox under: EFIC 2. Combine the deferral letter along with the relevant EFIC Plan into a single PDF and upload. 3. Add the following **note** to the record: "IRB is deferring to (site's name) approved EFIC Plan." Email dkolk@umich.edu for additional assistance.
Full Study IRB Application Submission (protocol v2)	Site	Use date of submission on document	Leave blank	No	Documentation that the protocol, version 2, was submitted to the IRB for all participating ESETT Spokes. Subsequent documentation that full applications for continuing review has 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. If your site is submitting for ESETT Protocol approval to your IRB for the first time using V2 of the protocol, the regulatory document parameter requirements for V1 apply – i.e., Include all formal correspondence with IRB, specifically any requested contingencies and investigator responses, which preceded final approval of the trial in one pdf.
IRB Approval (protocol v2)	Site	Use source approval date	Required – use source expiration date	No	Provide IRB approval of the protocol v3with clear documentation of the protocol version, approval date, and expiration date. Subsequent documentation of IRB approval at continuing review should also reside here. If your site is receiving approval for ESETT study for the first time using V2 of the protocol, include acknowledgment of receipt of EFIC results and receipt of the IND clinical hold lift letter at the time of initial IRB approval.
IRB Approved Informed Consent Form	Site	Use source approval date	Required - use source expiration date	No	Provide written documentation of the IRB approval of the Informed Consent Form(s) with clear documentation of the IRB approval date. Combine study Withdrawal Addendum with the ICF document and upload as a single PDF document. Prior to re/submitting to your IRB, your Informed Consent Form(s) must be approved by the CCC; please forward to esett-milestone@umich.edu Provide source in a pdf attachment explicitly showing IRB approval.
IRB Approved Assent Form	Site	Use source approval date	Required - use source expiration date	Yes	Provide written documentation of the IRB approval of the Assent Form(s) with clear documentation of the IRB approval date. Prior to submitting to your IRB, your Assent Form(s) must be approved by the CCC; please forward to esett-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	No	Provide written documentation of the IRB approval of the Consent Form(s) with clear documentation of the IRB approval date. Combine the study Withdrawal Addendum with the ICF document and upload as a single PDF document. Prior to submitting to your IRB, your Consent Form(s) must be approved by the CCC; please forward to esett-milestone@umich.edu Provide source in a pdf attachment explicitly showing IRB approval.
IRB Approved Informed Assent Form Non-English	Site	Use source approval date	Required - use source expiration date	No	Provide written documentation of the IRB approval of the Assent Form(s) with clear documentation of the IRB approval date. Prior to submitting to your IRB, your Assent Form(s) must be approved by the CCC; please forward to esett-milestone@umich.edu Provide source in a pdf attachment explicitly showing IRB approval.
IRB Approved LAR Notification Letter	Site	Use source approval date	Per institutional guidelines for re-approval of study documents	No	Provide written documentation of the IRB approval of the LAR notification letter with clear documentation of the IRB approval date. Provide source in a pdf attachment explicitly showing IRB approval.
IRB Study Communicat-ions	Site	Use source approval date	Use source expiration date, if applicable	No	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	No	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.
HSP Policy	Site	Use date of upload	Leave Blank	N	Provide within this entry the Human Subject Protection (HSP) and HIPAA training/certification policies for research as required at your site by local research administration office or site IRB policies. Combine HSP and HIPAA policy into one single PDF and upload. NOTE: **We need to see the interval (duration) of training/recertification (e.g. HSP training required every 3 years, etc.).

EFIC Documentation Collection [pathway: ESETT > EFIC (tab) > CC Form or PD Form (tables)]

	Instructions for WebDCU™
CC Form	This is a data entry form located in the ***ESETT*** Database/WebDCU™ and is used to report aggregate results by CC event. Resources for completing the CC Form are available in WebDCU™ WebDCU: ESETT > Toolbox > Project Documents For assistance in completing the CC Form contact Deneil Harney at: 734-232-2132 or dkolk@umich.edu
PD Form	This is a data entry form located in the ***ESETT*** Database/WebDCU™ and is used to report PD activity by event.

	Resources for completing the PD Form are available in WebDCU™ WebDCU: ESETT > Toolbox > Project Documents For additional assistance in completing the PD Form contact Deneil Harney at: 734-232-2132 or dkolk@umich.edu