

Source documents and signature requirements

- StrokeNet monitors will verify that data entered in WebDCU matches the site source documentation.
- All source documentation should be attributable.
 - Recall ALCOA
 - *Examples:* wet ink, email, e-signature, EMR notes.
- StrokeNet monitors *always* verify signatures on the following CRFs (though not limited to):
 - F126: End of Study Form
 - F101: Eligibility
 - F104: Adverse Event
 - Why?
 - These are considered the highest risk

F126 Requires Wet Ink Signature

- **F126 End of Study***

- The PI as denoted on eDOA in WebDCU must sign this form.
 - Sub-I is not acceptable.
- Qd (First/Last name of reviewing site PI) and Q12 (Date of site PI review and affirmation) are **required** in WebDCU and must match the source, i.e. the printable paper CRF.
- The paper source must have the PIs wet-ink signature and date.
 - But why wet ink on paper? The PI signature and date affirm the review and the accuracy of the information reflected in all the case report forms (in WebDCU) for this study participant.

***At this time**, PIs are NOT able to electronically sign CRFs in WebDCU at the end of the study.

F101 and F104- Signature Expectations

- **F101 Eligibility** – Investigator signature is required to confirm a subject met all eligibility criteria prior to randomization.
 - Investigator must be delegated responsibility C (Determine eligibility) on eDOA in WebDCU.
 - Qd (First/Last name of investigator confirming eligibility) is **required** in WebDCU and must match the source.
 - The source must have a wet-ink signature *or* equivalent documentation, i.e. e-mail, EMR, Adobe electronic signature.

- **F104 Adverse Event** – Investigator signature is required to confirm that, at a minimum, an investigator assessed the grade (Q02), seriousness (Q03), and relatedness (Q04).
 - Investigator must be delegated responsibility F (Assess adverse events) on eDOA in WebDCU.
 - Qd (Last name of reporting site investigator) and Q19 (Date of reporting site investigator signature) are **required** in WebDCU and must match the source.
 - The source must have a wet-ink signature *or* equivalent documentation, i.e. e-mail, EMR, Adobe electronic signature.

Q&A Source Documentation

Q: *Who can enter data (including F101, F104, F126) into WebDCU?*

A: Any study team member who has the appropriate permission on the eDOA (i.e., “Responsibility E-Complete Case Report Forms”).

Q: *If the PI enters the data into WebDCU (using their login), is this considered an acceptable signature?*

A: F126- NO! There must be a paper source with the PI’s wet ink signature and date.

A: F101, F104- If your site allows direct data entry, then this is acceptable. However, we would not recommend that the eCRF be the sole source.

Q&A Source Documentation

Q: *Is it okay to print completed eCRFs and have the investigator sign off on those?*

A: Yes, but remember, the source document must match what's entered in WebDCU.

Q: *Does each individual inclusion/exclusion criteria on F101 need to be listed for source documentation?*

A: No, but it's recommended that your site document that the investigator reviewed every inclusion/exclusion criteria.

Example:

“We print out of the eligibility criteria (F101), which is completed by the PSC. In the EMR, the PI completes an enrollment note stating “Patient met all the inclusion criteria of trial and none of the exclusion criteria. Is this sufficient in terms of capturing that the PI reviewed all I/E criteria and confirmed eligibility?”

A: Yes, the EMR note is sufficient for F101.

Monitoring Resources

<https://dcu.musc.edu/campus/>

[DCU.musc.edu Home](#)

welcome to the
WebDCU™ Clinical Trial Data Management System *Training Center*

Project Independent Training

Modified Rankin Scale (mRS)

- [mRS Training Video](#)
- [mRS Certification Test](#)

Courtesy of Neurological Emergencies Treatment Trials (NETT) Network

NIH Stroke Scale (NIHSS)

- [NIH Stroke Scale Resource](#)

WebDCU™ CTMS Training

- Regulatory Management [MP4](#)
- Lab Kit Tracking [MP4](#)
- Editing Your DOA [MP4](#)
- Adding Study Team Members [MP4](#)
- Adding Screen Failures [MP4](#)
- Subject CRF Binder [MP4](#)
- Data Entry [MP4](#)
- F104 Adverse Event [MP4](#)
- Rule Violations [MP4](#)
- Data Clarification Requests [MP4](#)
- Finding Help [MP4](#)

Project Specific Training

StrokeNet

- [StrokeNet eConsent REDCap Training](#)
- Preparing for a Monitoring Visit [MP4](#)
- Expectations during a Monitoring Visit [MP4](#)

Monitoring Contacts

Always contact your NDMC Site Monitoring Manager with questions about monitoring visits or documentation!

ASPIRE- [Abigail Ault, ault@musc.edu](mailto:abigail.ault@musc.edu)

CAPTIVA- [Jama Olsen, olsen@musc.edu](mailto:jama.olsen@musc.edu)

FASTEST- [Katie Trosclair, trosclak@musc.edu](mailto:katie.trosclair@musc.edu)

FOCAS- [Caitlin Schaffner, schaffne@musc.edu](mailto:caitlin.schaffner@musc.edu)

I-ACQUIRE- [Abigail Ault, ault@musc.edu](mailto:abigail.ault@musc.edu)

SATURN- [Aaron Perlmutter, perlmutt@musc.edu](mailto:aaron.perlmutter@musc.edu)

SISTER- [Aaron Perlmutter, perlmutt@musc.edu](mailto:aaron.perlmutter@musc.edu)

Sleep SMART- [Katie Trosclair, trosclak@musc.edu](mailto:katie.trosclair@musc.edu)

STEP- [Caitlin Schaffner, schaffne@musc.edu](mailto:caitlin.schaffner@musc.edu)

TRANSPORT-2- [Katie Trosclair, trosclak@musc.edu](mailto:katie.trosclair@musc.edu)

VERIFY- [Abigail Ault, ault@musc.ed](mailto:abigail.ault@musc.edu)