The Office of Sponsor and Regulatory Oversight (OSRO) requires the use of F01-203-S01 Clinical Site Delegation of Authority Log for all clinical trials conducted under a Center for Cancer Research (CCR) held Investigational New Drug application (IND), Investigational Device Exemption (IDE) or Non-Significant Risk (NSR) Device Study.

The following Frequently Asked Questions (FAQs) address common questions that have been raised around the use of the OSRO Delegation of Authority Log (OSRO DOA Log).

Questions

Answers

1. What changes have been made to F01-203-S01 Clinical Site Delegation of Authority and Staff Signature Log?

Effective July 2023, F01-203-S01 Clinical Site Delegation of Authority and Staff Signature Log has undergone a significant change.

Revision 3 of the log no longer documents Staff handwritten (wet) signatures and initials for those individuals assigned a task requiring a handwritten signature or initials. Consequently, the log's name has been shortened to Clinical Site Delegation of Authority Log.

The OSRO DOA Log Revision 3 must be completed electronically; a paper version of Revision 3 using handwritten (wet) signatures will not be accepted.

PI confirmation of staff assignments via initials and date has changed to a digital signature so that authentication of the signature is possible.

Page numbering must be completed manually.

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2. My site is using Revision 2 of F01-203-S01 Clinical Site Delegation of Authority and Staff Signature Log. Do we have to change to Revision 3?

For active studies, Revision 2 will be accepted until the end of 2025 Quarter 1 however early adoption is encouraged. On June 1, 2025, Revision 2 will no longer be accepted; all studies still open on or after June 1, 2025, must use the current effective revision of the OSRO DOA Log.

Revision 3 is required for all new studies started after July 2023.

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3. Is there guidance on how to complete the OSRO Delegation of Authority Log?

Guidance for use and end-of-study completion instructions are included on pages 1 and 2 of the OSRO DOA Log.

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4. Are Staff Training Records required for everyone listed on the OSRO Delegation of Authority Log?

Yes. For the time period that Staff are active and delegated study responsibilities, the current Protocol, HSP, GCP and other specialized training records must be maintained and available for review by SROS clinical site monitors. **Important note -** Staff may not carry out protocol-related activities or functions if training records are not available for the following:

- Protocol
- HSP
- GCP
- As applicable:
    - Dangerous Goods Handling or International Air Transport Association (IATA)
    - Electronic Data Capture (EDC) system for non-NIH PI and Staff responsible for the use of the EDC system. Note: due before site activation.
    - Other specialized procedures, e.g., study product preparation.

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5. How can I get a copy of the OSRO Delegation of Authority Log?

A copy of the OSRO DOA Log can be obtained on the CCR Wiki site under OSRO Forms and Instructions. The form is titled Clinical Site Delegation of Authority. Here is the link.

The OSRO DOA Log is a PDF fillable form designed to be completed electronically in Adobe Acrobat DC. You must **download and save the file to your computer** to maintain the form functionality. Do **not** use "print to PDF" to obtain a copy of the Log; doing so will remove all form functionality. After opening the file, you must see red marks in the signature fields to confirm that the form is active.

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6. Can the same PDF fillable form be used as a paper Log for handwritten signatures?

It depends. Effective July 2023 with Revision 3, the OSRO DOA Log must be completed electronically; it cannot be used as a paper log for handwritten signatures or initials. For information on the new procedure for handling handwritten signatures and initials see Question 22.

Revision 2 of the Log may be used as a paper-based log for collection of handwritten (wet ink) signatures and initials. To create a paper-based log, just print-off the pages of the Log. Note – if printed, all of the form's electronic signature functionality is removed, and scanning back into PDF will not change it back to an electronic fillable form.

No studies activated after July 2023 will be allowed to use Revision 2.

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7. How should the Log pages be numbered?

OSRO DOA Log Revision 3. The Log will require that "Page ___ of ___" be typed in the footer of each page. Insert the consecutive page number in the first blank and at the end of the study, insert the total number of pages in the second blank.

OSRO DOA Log Revision 2. The Log is programmed to automatically number the pages. If paper pages of the Log are created and used, the page numbering will require manual correction. Cross out the preprinted number and write the correct number. Write your initials and the date nearby.

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8. How should the DOA Log be closed at the end of the study?

End of study requirements for the electronic DOA Log:

- Unused rows must be marked as not applicable with 'NA' or 'N/A' in the Name, Role, and Task Code cells.
- All pages of the Log must be numbered correctly.
- The PI must sign off on the Log using a digital signature (i.e., PIV card authenticated).

End of study requirements for the paper DOA Log:

- Unused rows must be marked as not applicable by drawing a single diagonal line across all rows, writing either 'NA' or 'N/A', and initialing and dating the entry.
- All pages must be numbered correctly.
- The PI must sign off on the paper DOA Log.
- The finalized paper DOA Log must be scanned into a PDF document. The paper DOA Log is kept by the site.
- At study closeout, if paper and electronic Logs were maintained then both Logs are submitted to the Sponsor eTMF along with a note to file stating that per Sponsor instructions, the site maintained two DOA Logs.

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9. Are external non-NIH sites required to use the OSRO Delegation of Authority Log?

Use of the OSRO DOA Log is not required if the non-NIH site's standard log and/or process is adequate. A different delegation of authority log format confirmed by the SROS Monitor to include elements similar to the F01-203-S01 Log may be used by non-NIH sites.

Before the SIV, the SROS Monitor will review the external site's log for adequacy, confer with OSRO and notify the site if it may continue to use its log or is required to use the OSRO DOA Log.

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10. What should I do with an old (previous) Delegation Log?

All old task delegation logs must be kept/filed as part of your site's regulatory document file. The old delegation log will no longer be used; you must complete a new OSRO DOA Log.

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11. If the study status is Data Analysis only, will my site need to implement the OSRO Delegation of Authority Log?

No. The OSRO DOA Log isn't necessary, but a Closeout Monitoring Visit (COV) is required in this case.

A COV includes confirmation that eCRF data entry is complete, no programmed and/or manual queries or action items are outstanding, and, as warranted, study product and study specimens are accounted for, and disposition is appropriate. After the closeout visit, the SROS Essential Documents Group will track the site's IRB Continuing Review status to ensure it remains in compliance until the data analysis is complete and the IRB formally closes the protocol.

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12. Are we required to list staff that have left the study?

No, only current staff should be captured on the OSRO DOA Log. All previous versions of the delegation log should be kept in your site's regulatory document file and include the end date for each staff member no longer on the research team.

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13. Should an End Date be entered when staff are on a personal short-term leave?

An End Date should not be entered when a staff member is on a temporary absence/short-term leave. The End Date is completed when a staff member leaves the research team.

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14. What Start Date should the staff use on the OSRO Delegation of Authority Log?

The staff start date from the **original delegation log** should be used for ongoing studies.

For new studies, the research team member's Start Date on the OSRO DOA Log should be consistent with the start of their delegated responsibilities, meaning the date can vary with each team member.

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15. What tasks should the Principal Investigator (PI) and the research staff be assigned on the OSRO Delegation of Authority Log?

The duties and task assignments must be within the scope of the PI and research staff depending on training, licensure, and per-protocol requirements. Assignments are listed on page 2 of the OSRO DOA Log.

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16. Why isn't the task of 'database changes' an option on the OSRO DOA Log?

Review of 'database changes' falls under the pre-printed task #24, "Conduct quality assurance/quality control procedures." A new 'database change review' task is unnecessary unless the team wants to add a more specific database change review task.

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17. Must the Principal Investigator (PI) sign after each staff entry?

The research staff task assignment is not considered complete without the PI's electronic signature after each staff entry. A valid PIV card is required to authenticate the signature. This is done to verify and confirm the 'Start Date' and the 'End Date' of each staff member listed on the OSRO DOA Log.

In Revision 2 of the OSRO DOA Log, the PI's typed initials and date are allowed if the electronic format is used or handwritten (using indelible ink) initials and date are allowed if a paper printout is used. A PIV card is not needed to enter initials. However, because the person typing or writing these entries cannot be authenticated, this practice has been phased out in Revision 3.

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18. The Log had a place for the staff member to initial. What happened to it?

The staff initials column was removed in Revision 3 of the OSRO DOA Log. For those staff members who need to document their initials refer to Question 22 for information on the new procedure for handling handwritten initials.

For those sites still using Revision 2 of the Log, the staff member may simply type their initials on the electronic form or write their initials using indelible ink on the paper form.

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19. When a page is complete but not all rows have been used, I should line out the unused lines of the form. How is that done electronically?

In the electronic PDF form, 'NA' or 'N/A' should be typed into each unused Name, Role, and Task Codes cell/space. The signature and date cells will remain empty because text entry is not permitted.

If using a paper printout, then draw a single line diagonally across the blank rows/spaces, type 'NA' or 'N/A' and write your initials and date next to the line.

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20. Is a cursor-drawn signature acceptable on the electronic OSRO DOA Log in PDF format?

No, the signature must be an electronic 'certificate-based' digital signature on the PDF form such as that using an active PIV card. The Adobe signature pen function (like on iMED consents) is NOT permitted.

Certificate signatures, also known as digital signatures, are authenticated and provide a high level of assurance in identifying a signer. The certificate-based digital signature requires using a PIV card to confirm the identity of the person who signed the document.

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21. Is a signature created with the Adobe Signature function instead of a PIV card acceptable?

No, the signature must be a certificate-based digital signature. Certificate signatures, also known as digital signatures, are authenticated and provide a high level of assurance in identifying a signer. The certificate-based digital signature requires using a PIV card to confirm the identity of the person who signed the document.

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22. I am responsible for a study task on which I complete a paper form. How can I authenticate my handwritten signature and/or initials?

Starting July 2023, CCR issued a new form, Signature Sheet on which an individual documents their legal signature and initials using indelible ink. This form must be on file in the OSRO eTMF prior to the SIV for those staff members completing handwritten records. A copy of the Signature Sheet can be obtained on the CCR Wiki (cancer.gov) site under CCR Policies/Standard Operating Procedures (SOPs), SOP# PM-1.

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23. What is the difference between an electronic and digital signature in Adobe Sign?

An electronic signature is a broad term for any electronic process for signing a record or document.

A digital signature refers to an authenticated electronic signature that is generated using a digital certificate and cryptographically bound to the document using public key infrastructure (PKI).

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