

# TMF Oversight – DAIDS PC Checklist

Version 1.0, 12/1/2023

This is the checklist for Trial Master File (TMF) document-level review carried out by a DAIDS Primary Contact (PC) of documents they are responsible for, per the DAIDS Protocol Specific Index, contributing to Sponsor Oversight of documents in the TMF. The review should ensure that documents generated during a study have been filed in the TMF, per requirements as outlined in DAIDS Work Instruction DAIDS-OPC-A15-WI-00002.

|  |  |
| --- | --- |
| Checklist completed by: |  |
| QC Review Start Date: |  |
| Electronic System: |  |
| Protocol(s): |  |

For documents included in this review, were you also the Authoritative Source who uploaded the document(s)? [ ]  Yes [ ]  No

*If Yes, then below Steps of DAIDS PC QC would be N/A, as additional review is not needed. Documents you uploaded as AS and PC should be listed in table below. See DAIDS-OPC-A15-WI-00002.*

*If No, review criteria in steps of DAIDS PC QC below.*

## Steps of DAIDS PC QC:

By checking these boxes, I attest that I have checked and evaluated the following criteria for each document included in this review.

[ ]  Reviewed for each document and document version generated during the study to be filed within the TMF

[ ]  Reviewed that the document(s) are **final**

[ ]  Reviewed that the document(s) are **complete**

[ ]  Reviewed that the document(s) are **legible**

[ ]  Reviewed that the document(s) are associated with the appropriate **study/studies**

[ ]  Reviewed that the **Document Date** field(s) match the date found on the document(s)

[ ]  Reviewed that the **Document Version** field(s) match the version found on the document(s)

[ ]  Reviewed that the document(s) are filed in the **expected location** per the Index

If any issues are identified during the review, please add specific comments including corrective actions and resolution in the document list below.

## All Documents Reviewed during DAIDS PC QC:

|  |  |  |  |
| --- | --- | --- | --- |
| Protocol(s) | Artifact # / Artifact | Document ID / Unique Identifiers | Comments on Significant Findings(including resolution) |
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|  |  |  |  |
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*Please add or remove rows to the table above as needed.*

Signed:

The location to file oversight documentation is based on the protocol-specific Index for the TMF. A summary outlining where to file your PC Memo, Delegation Memo, and Checklist are below.

* **HPTN 083, HPTN 084, IMPAACT 2017**: RSC VV in Zone 09, Third Parties > General > Relevant Communication
* **MTN-034, MTN-042, MTN-043, IMPAACT 2019, IMPAACT 2032, HPTN 083-01, HPTN 084-01, PHOENIx, A5359, IMPAACT 2023, IMPAACT 2034, A5418, IMPAACT 2036:** RSC VV in Zone 09, Third Parties > Third Party Oversight > Ongoing Third Party Oversight
* **IMPAACT 2040:** Planned, NIAID eTMF Trial Interactive in Zone 09, Third Parties > Third Party Oversight > Ongoing Third Party Oversight

Any communication for resolution of issues should be documented and filed into Zone 09, Third Parties > General > Relevant Communication.

* **HPTN 083, HPTN 084, IMPAACT 2017**, **MTN-034, MTN-042, MTN-043, IMPAACT 2019, IMPAACT 2032, HPTN 083-01, HPTN 084-01, PHOENIx, A5359, IMPAACT 2023, IMPAACT 2034, A5418, IMPAACT 2036:** In RSC VV emails and documentation of resolution should be uploaded as Relevant Communication once finalized. A message should be sent to the RSC asking them to link that documentation to this Checklist using the Send as Link feature or via email to DAIDS\_TMF@tech-res.com.
* **IMPAACT 2040:** In NIAID eTMF – Trial Interactive: process pending