Job Aid

DAIDS PC Oversight Activities – Use of Risk Assessment Tool and Filling out the PC Checklist

Version 1.0

March 27, 2023

Purpose: This Job Aid serves to describe the requirements for completing PC Oversight Activities - to include the Use of the Risk Assessment Tool and filling out the PC Checklist.

DAIDS PC Oversight

DAIDS PC Oversight includes the use of the Risk Assessment Tool and filling out the DAIDS PC Checklist.

Risk Assessment Tool

The Risk Assessment Tool is required for a PC to conduct their document level QC. This tool is based on a risk-based approach to the quality assessment of the DAIDS Sponsor TMF. Applicable TMF documents within the DAIDS Index were reviewed and subsequently color-coded, based on a risk assessment that was performed by the DAIDS TMF Team and then reviewed by the PCs. There are three ratings that were applied: Critical (Red), Major (Orange) and Minor (Yellow). This assessment shows the overall impact on the TMF, if any of these documents, were missing, on the Safety, Rights, and Well-Being of Participants, as well as Data Integrity (See Example 1 – IMPAACT Network Risk Tool).

Example 1

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S
Core or Recommended per DIA	Status	Authoritative Source (Entity functioning as the Source	DAIDS Primary Contact (Entity functioning as the DAIDS F	Zone #	Zone Name	Section #	Section Name	Artifact #	Artifact name	Sub-Artifact/Examples	Definition / Purpose	Source Location (System) (Entity functioning as the Source of th	System Owner (Entity functioning as the Source	Risk	ICH Code	Start	Conduct	Close
Recommended	Required	International CRS	DAIDS PRT	03	Regulatory	03.01	Trial Approval	03.01.01	Regulatory Submission	Non US Regulatory Submission	A set of documents, along with required associated regulatory forms and correspondence, submitted to one or more regulatory agencies requesting approval to conduct the trial or for the purpose of notification, or requesting approval of changes to the trial documents or of any trial events that could adversely affect the safety of subjects, impact the conduct of the trial or alter the regulatory authority's	NCRMS - DPRS	DAIDS			X	Intentionally left blank	Intentionally left blank
Core	Required	RSC	DAIDS RAB SAR	03	Regulatory	03.01	Trial Approval	03.01.02	Regulatory Approval Notification	Regulatory Approval	A documented notification received from a regulatory authority stating that the Submission has been received and	TRI - Veeva Vault	TRI	Critical	8.2.9 8.3.4	X	Intentionally left blank	Intentionally left blank
Core	Required	FHI Clinical	DAIDS RAB SAR	03	Regulatory	03.01	Trial Approval	03.01.02	Regulatory Approval Notification	Regulatory Approval	A documented notification received from a regulatory	TRI - Veeva Vault	TRI	Critical	8.2.9 8.3.4	X	Intentionally left blank	Intentionally left blank
Core	Required	International CRS	DAIDS PRT	03	Regulatory	03.01	Trial Approval	03.01.02	Regulatory Approval Notification	Regulatory Approval	A documented notification received from a regulatory	NCRMS - DPRS	DAIDS	Critical	8.2.9 8.3.4	X	Intentionally left blank	Intentionally left blank
Core	Required	RSC	DAIDS RAB SAR	03	Regulatory	03.01	Trial Approval	03.01.03	Notification of Regulatory Identification Number	Notification of Regulatory Identification Number	Document identifying unique Identification (ID) number used to uniquely identify the trial or the trial level in that region, assigned	TRI - Veeva Vault	TRI	Major		X	Intentionally left blank	Intentionally left blank
Core	Required	CRSS	CRSS COR	03	Regulatory	03.01	Trial Approval	03.01.04	Public Registration	Initial Public Registration	Documentation related to registration of clinical trials in public registries such as	PPD - Veeva Vault	PPD	Major		X	Intentionally left blank	Intentionally left blank
Core	Required	SDAC	DAIDS Network PO	03	Regulatory	03.01	Trial Approval	03.01.04	Public Registration	Results Public Registration	Documentation related to registration of clinical trials in public registries such as	SDMC Veeva Vault	FSTRF	Major		X	Intentionally left blank	Intentionally left blank
Core	Required	CRS	DAIDS PAB	03	Regulatory	03.02	Investigational Medicinal	03.02.01	Import or Export License Application	Import/Export License	An application made to one or more regulatory agencies	CRS	NA	Minor		X	Intentionally left blank	Intentionally left blank
Core	Required	CRS	DAIDS PAB	03	Regulatory	03.02	Investigational Medicinal	03.02.02	Import or Export License	Import/Export License	A document issued by a national government authorizing the	CRS	NA	Critical		X	Intentionally left blank	Intentionally left blank

Process: The Risk Assessment Tool (Color coded Protocol - Specific Index) will be sent out to the PCs for their review after the protocol-specific Index has been finalized (i.e. Initial Index or an Updated Index). PCs will be given 2 weeks to review the tool. Once the tool is finalized the PCs will be notified, and their document level QC can begin as outlined in the PC Oversight Memo.

Location: A copy of the Risk Assessment tool can be found in the DAIDS TMF Resources Folder

DAIDS PC Checklist

The DAIDS PC Checklist serves to assist the PCs with performing their document level QC. The checklist provides documentation of the DAIDS PC's review of TMF documents, they are responsible for per the DAIDS Index for a given study, and notes which applicable DAIDS approved electronic system or systems a PC went into to carry out their review.

Each time a PC carries out a document level QC within an DAIDS-approved electronic system or systems for a protocol specific TMF, they will need to fill out a DAIDS PC Checklist. If a PC is doing their review in more than one system for a given TMF, the review can be documented within a single checklist.

Note: Before a PC initiates their review of documents for a protocol specific TMF, they will need to create a DAIDS PC Oversight Memo. Once the memo is created it can be linked to subsequent TMFs the PC has oversight for. The memo is a high-level document that provides a brief description of the DAIDS PC Oversight Process. For more information, refer to **DAIDS – OPC- A15-WI-00002**.

Location: the DAIDS PC Oversight Checklists are network specific. Copies can be found in the DAIDS TMF Resources Folder.

Completing and Utilizing the PC Checklist

Go to the *Details Tab*

1. Column B: Fill out Study Details (See Example 2)
    a. Identify the protocol
    b. Identify the DAIDS PC
    c. Identify the date QC began

Example 2

A	B
Study Details	
Protocol #:	HPTN 083
QC conducted by:	Mr. Example *Accept my typed name as my signature.*
QC review start date:	2/19/2023

2. Identify the applicable electronic systems involved in your review by using the drop-down options to select - yes or no (See Example 3)

Example 3

A	B
Study Details	
Protocol #:	HPTN 083
QC conducted by:	Mr. Example *Accept my typed name as my signature.*
QC review start date:	2/19/2023
Systems Name	Included in Review?
RSC Veeva Vault	Yes
SCHARP Veeva Vault	Yes
PPD Veeva Vault - NCSM	Yes
CRPMC Veeva Vault	No
Westat/NICHD Box GxP	No
Westat/NICHD MediData eTMF	No
FHI 360 Transperfect	No
HPTN LC Florence	No

Go to the applicable *Electronic System's Tab*

1. Use the Risk Assessment Tool to find the document(s) that will be QC'ed during your PC document level review.

2. Log in to the applicable electronic system you will do your review in.

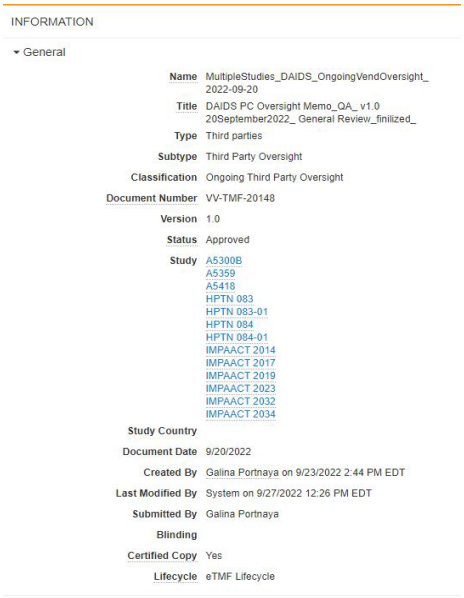
3. Navigate to the document of interest within that system.
    a. Steps 4a-c should be completed for each document that is reviewed within a given system.

4. Start your review and complete your document level QC within the applicable Electronic Systems Tab of the DAIDS PC Checklist. For the below example, the RSC Veeva Vault Tab is being filled out, since the review is being conducted on a document within that system.
    a. Fill out the Document ID (Column B).
        - This is the system generated number that has been provided as a way to identify the document within a given DAIDS approved electronic system.
        - As an example, this is the Document Number Field located within the metadata section for a document within the Veeva Vault eTMF system.
    b. Conduct your review against the criteria listed in Column A.
        - This includes assessing the following: Document Quality, Metadata Check, and Classification Review.
    c. Use the drop-down options (Column B) - Yes, No, or N/A for each criteria.
        - If No is selected, list your findings within the comment section (Column C) (See examples 4 & 5)

Note, if there are findings, the PC needs to work with the AS and the electronic system owner to resolve them.

Example 4 & 5

A	B	C
System Reviewed: **RSC Veeva Vault**		
	Document ID:VV-TMF-20148	
Document Quality Review	**Yes/No/NA**	**Comments (includes any findings)**
Document is *Final*– not a draft or in tracked changes	Yes	
Document is *Complete*–Signature(s), Dates, Version Numbering, if applicable, are present and no missing pages	Yes	
Page numbers are present and in sequential order	Yes	
Document is *Legible* -clean, not skewed, and text is 'readible'	Yes	
Expected Document is present	Yes	
Metadata Check (if available)		
Document is associated with the appropriate study	Yes	
Document Date Field - matches the date found on the document	Yes	
Document Version Field - matches the version found on the document	Yes	
Classification Review		
Document is filed correctly per the Index (correct Zone and system)	Yes	
Note: Some items above may be NA due to limitations of a given system.		



Filing the PC Checklist

Once completed, the PC Checklist will be filed in Zone 9, "Ongoing Third-Party Oversight" (See Example 6).

Example 6

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S
Core or Recommended per DIA	Status	Authoritative Source (Entity functioning as the Source of the document to review and verify. Adjust as needed.)	DAIDS Primary Contact (Entity functioning as the DAIDS PC for the document to review and verify. Adjust as needed.)	Zone #	Zone Name	Section #	Section Name	Artifact #	Artifact name	Sub-Artifact/Examples	Definition / Purpose	Source Location (System) (Entity functioning as the Source of the document to review and verify. Adjust as needed.)	System Owner (Entity functioning as the Source of the document to review and verify. Adj	Risk	ICH Code	Start	Conduct	Close
Recommended	Required	Relevant DAIDS Programs & Offices and Vendors	Relevant DAIDS Programs & Offices and Staff	09	Third parties	09.01	Third Party Oversight	09.01.03	Ongoing Third Party Oversight	Ongoing Vendor Oversight, Oversight Memo, Oversight Checklist, Oversight Reports, PPD Training Plan	To confirm throughout the duration of a study that a third party continues to meet all relevant criteria to fulfill a contractual obligation.	TRI - Veeva Vault	TRI			Intentionally left blank	X	Intentionally left blank

Appendix: DAIDS PC Checklist Flowchart