FREQUENTLY ASKED QUESTIONS ON DCP ESSENTIAL RECORDS

1. **Our site has an SOP on Essential (or Regulatory) Records, and we have our own DTL template. Can we use our site DTL template for DCP studies?**

   Per SOP-01-01 *Essential Records Submission for Sponsor's Trial Master File*, the DCP DTL template must be used by sites participating in the DCP studies. Usually, the site DTL templates lack key information that is required to be maintained by the sponsor, therefore, they cannot be accepted.

   Sites can use their choice of platform to obtain eSignatures or a digital signature on DTL. All signatures obtained electronically must be 21 CFR Part 11 compliant. When providing a copy of these electronically completed records to the DCP Regulatory Contractor, all pages of the audit trail must be shared.

2. **Our site uses an eDTL program (e.g., eFlorence, Veeva Vault). Can we use it for DCP studies?**

   Sites can choose to use an eDTL of their choice, provided all fields and tasks as provided in the DCP DTL template can be added to the eDTL. The eDTL platform used must be 21 CFR part 11 compliant.

3. **The study is conducted at more than one research location at my site. How can this information be provided to DCP?**

   All locations where the research will be conducted should be entered as separate rows under the 'Site Information' section of the Site Information Form (SIF).

4. **Our site will be using more than one lab for this research study. How should the labs be provided to DCP?**

   All lab locations must be entered as separate rows under the 'Lab Information' section of the SIF.

5. **What process should we follow to add a new task and/or change the role of a staff member already on DTL?**

   Enter 'End date' for the staff's current task(s) and/or role. Re-enter staff as a new entry with their current role; add all the old task(s) and the new task(s) applicable for the new role. The start date should concur with the start date of the new task(s) and/or role. The new entry should be signed by the staff; and initialed and dated by the site PI. Initials can be entered electronically or by wet ink. All signatures obtained electronically must be 21 CFR Part 11 compliant.

   Example: When Dr. Doe was a sub-I, the tasks were assigned as 2 and 3. Add the end date to the line where the sub-I role is listed. After transitioning to PI, enter Dr. Doe as PI in the new line, with the tasks he will be performing as PI for instance, 1, 2, 3, 4, and 5.

6. **How do I make corrections to the DTL?**

   Any corrections to the DTL must be done by using a single line through the error so that the original entry is legible and then initialed and dated (either in wet ink or electronically- all signatures obtained electronically must be 21 CFR Part 11 compliant.) by the person correcting the error. As needed, provide a memo/Note-To-File (NTF) explaining the corrections.

7. **Can a site send the FDA 1572, Professional license (e.g., Medical License), Bio/CV, GCP Training, and Financial Disclosure Forms (FDF) electronically to the DCP regulatory contractor?**

   It is mandatory for all the staff participating in DCP studies to register and upload all required documents in the NCI Registration and Credential Repository (RCR) system. The DCP regulatory contractor will access RCR and download all staff level records except for staff who register as an 'Associate.' Refer to SOP-01-01 *Essential Records Submission for Sponsor's Trial Master File* for further information on the review process and records collected from RCR.

8. **A site staff added to the DTL has an RCR person registration type of 'Associate'. What records are required to be submitted?**

   While the RCR does not have document upload requirements for the 'Associate' person registration type, DCP requires a GCP certificate for 'Associates.' The GCP certificate should be sent electronically to the DCP regulatory contractor at regulatory@ccsainc.com. An 'Associate' added to DTL must register in and maintain an active RCR status.

9. **Staff will be performing the tasks listed for 'NPIVR' in DTL, however, the staff is registered as 'AP' in RCR. How should we address this?**

   The RCR CTEP ID must always match the tasks staff perform in a study. Please change the registration type in RCR to match the tasks staff will be performing in the study.

10. **An investigator at an international site is unable to sign the FDA 1572 form in RCR due to local regulations. What should be done?**

    Please inform the DCP Regulatory Contractor when the site staff cannot complete the form FDA 1572. A waiver to waive the collection of the form from the staff may need to be submitted to the FDA. RCR may allow site staff to complete an 'International Investigator Statement' for the staff to complete in lieu of the form FDA 1572.

11. **Does a staff with an IVR role need to submit the Agent Shipping Form in RCR?**

    For DCP CP-CTNet studies, submission of the Agent Shipping Form by the staff is **not** required in RCR. Staff registered in RCR as NPIVR or IVR can prescribe medications as permitted by the institution's policy, and local, state, and/or country laws and regulations. For studies using MRI Global, agent shipment can be requested by submitting the Investigational Agent Request form found on the [DCP website](#) to request the agent from MRI Global.

12. **The Principal Investigator at our site is changing. What records are required to be submitted to the DCP Regulatory Contractor?**

    The following steps should be completed:

    a. Site Information Form must be completed and signed by new PI

    b. 'End Date' must be added for the PI who is leaving the study on the DTL.

    c. The name of the new PI should be added in a new row of the DTL log with the tasks and start date. If the PI was a sub-I on the study, 'End Date' must be added for the sub-I role.

    d. PI must maintain active RCR account.

    e. Provide a copy of the most recent local consent form with the new PI listed.

    f. CIRB Approval of the Annual Principal Investigator worksheet for the new PI.

    g. CIRB Approval of Change of Signatory Institution Principal Investigator.

    h. IB or Package Insert acknowledgement form signed by new PI.

13. **We have a new staff member participating in the study. What records are required to be submitted?**

    The staff should maintain an active RCR account and be added to the DTL. The completed DTL should be provided to the DCP Regulatory Contractor.

14. **Should we add the study statistician/investigator listed on the protocol cover letter to the DTL?**

    It is not required to add the statistician/investigator listed on the protocol cover page to the DTL. They must maintain an active RCR account during the tenure of the study. The DCP regulatory contractor will download the staff documents (FDA 1572, Bio, and GCP) for them from RCR, review, and save them for the sponsor's TMF.

15. **Why are the CLIA and/or CAP certificate(s) provided not acceptable?**

    It is highly recommended to match the lab information as on the CLIA certification for US sites. The CLIA# on the CAP certification must match the CLIA certificate.

16. **Why is the Lab Normal Values (LNV) record provided not acceptable?**

    The LNV provided for the sponsor's TMF must have information to be able to identify the lab, such as the lab name and full address, CLIA number, or the lab's unique license number. This can be added by the site staff on the first page of the LNV document with the initial and date, or an NTF can be provided.

17. **How do we indicate that the LNV record provided is applicable to more than one lab participating in the study?**

    Either an NTF stating the list of labs with the name and address to which the LNV is applicable, or all the lab names and addresses can be added to the first page of the LNV to which it is applicable.

18. **What IRB documents are required to be provided to the DCP Regulatory Contractor?**

    All IRB letters (acknowledgements, approvals, notifications, etc.) must be provided to the DCP Regulatory Contractor. If the site staff has information on the type of submissions the local IRB issues a letter, they should provide the details to the DCP Regulatory Contractor.

19. **What is a Note to File?**

    A Note to File NTF is a document written by any member of the study team to provide additional information or clarification when other documentation is unavailable or inadequate elsewhere in the study records. This would include any study memos created by the LAO to distribute to AOs; these will be accepted in NTF format only.

20. **What should be included in an NTF?**

    An NTF is not valuable if it simply states the error. An NTF should be printed on institutional letterhead and should be initiated and authored by the individual or organization responsible for its content; the NTF should document the issue or discrepancy, the site action or inaction, the root cause, and any corrective actions taken, and the plan for preventive action, if applicable.

21. **When is it appropriate to use an NTF?**

    It is appropriate to use an NTF to provide additional information or clarification. An NTF may not be used to modify or change the conduct of the study in any way. Any change to a protocol and/or study procedures requires a protocol amendment and must be reviewed and approved by the CIRB/IEC before implementing the change. An NTF should also not be created if it is

redundant and already explained in other documentation. An NTF should not be created in lieu of a protocol deviation. A Protocol Deviation form must be used to report deviations to DCP and to CIRB, per CIRB policy.

If an NTF meets CIRB requirements for review, approval from DCP and CIRB must be obtained prior to distribution by protocol or LAO PI to all sites participating in the study. Refer to the CIRB SOPs, Section 5.9.4, for more information.

22. **Where should I save any NTFs?**

NTFs should be filed with the site's essential study records A copy should be provided to the LAO for submission to the DCP Regulatory Contractor for placement in the TMF. Any NTF that contains PHI should be filed only in the LAO/AO regulatory binder and not be provided to the DCP Regulatory Contractor.

23. **Do NTFs need to be submitted to DCP for review?**

An NTF generated by the Study PI or LAO that pertains to the logistics of a study should be submitted to the DCP study group overseeing the trial for review/approval before dissemination to the organizations participating in the study (AOs). NTFs generated at an accruing LAO or AO that pertain to site-specific clarifications only need to be provided to the LAO for submission to the DCP Regulatory Contractor for placement in the TMF

If you have any additional questions, please contact regulatory@ccsainc.com