



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health
National Institutes of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

Delegation of DAIDS Primary Contact Responsibilities

Per DAIDS-OPC-A15-WI-00002 - DAIDS Primary Contact (PC) Oversight of TMF Documents, DAIDS Primary Contact (PC), \_\_\_\_\_ elects to transfer all or some of their PC Oversight responsibilities as outlined in the DAIDS-OPC-A15-SOP-00002 Management of DAIDS Trial Master Files Standard Operating Procedure (SOP), to Delegate(s),

\_\_\_\_\_
for protocol(s) \_\_\_\_\_.

The Delegate(s) will be responsible for the following responsibilities, please check all responsibilities that are being delegated:

- Ensuring that documents generated during the course of the study have been filed in the Sponsor TMF, in all applicable systems.
Following the DAIDS PC review requirements as outlined in DAIDS Work Instruction (WI) DAIDS-OPC-A15-WI-00002 and filing the completed DAIDS PC checklist in the TMF for that study.
Reviewing, verifying, and providing feedback on TMF fundamental documents (e.g., TMF Index, TMF Plan, Electronic Systems Mapping document).
Escalating any concerns to the DAIDS TMF Team.
Additional TMF responsibilities, specified here:

This delegation of DAIDS PC responsibilities will become effective on the latter of the signature dates shown below.

DAIDS PC:

X \_\_\_\_\_

Delegate:

X \_\_\_\_\_

X \_\_\_\_\_

X \_\_\_\_\_

X \_\_\_\_\_

X \_\_\_\_\_