

Division of AIDS (DAIDS) Site Clinical Operations and Research Essentials (SCORE) Manual Appendix:

Clinical Research Site (CRS) Requirements for the CRS-specific Informed Consent Process Standard Operating Procedure

All CRSs must develop and implement an Informed Consent (IC) Process Standard Operating Procedure (SOP). CRSs must submit this SOP to the Office of Clinical Site Oversight (OCSO) Program Officer (PO) for review and approval before implementation.

CRSs must ensure their CRS-specific IC SOP includes the following, at minimum:

- Information about applicable local laws, regulations, guidance, and institutional policies pertaining to the IC process, including information on delegating the task/responsibility of obtaining and documenting IC to qualified CRS staff. CRSs must ensure that the IC process is consistent with all the applicable laws and regulations and apply the most stringent applicable laws and regulations when developing this process.
- Mandatory criteria for obtaining IC from a potential participant, and/or their legally authorized representative (LAR) (hereinafter referred to as participant/LAR) to participate in clinical trial (i.e., use Institutional Review Board-approved documents, administer IC in a private setting, provide participant/LAR ample time to read, resolve participant/LAR questions, personally sign and date the document).
- Information on obtaining and documenting IC when the CRS may enroll vulnerable populations in a clinical trial (e.g., minors; prisoners; wards; fetuses; neonates; decisional-impaired individuals; members of a group with a hierarchical structure; individuals with incurable diseases; individuals in nursing homes; refugees; individuals in emergency situations; lesbian, gay, bisexual populations; women in some global cultures such as with limited rights; and economically or educationally disadvantaged individuals, etc.).
- Information—per local laws, regulations, guidance, and institutional policies—about who may serve as an:
 - Impartial witness
 - LAR
 - Advocate for a participant
- Relevant information about the Principal Investigator (PI)/Investigator of Record (IoR) availability/involvement in the IC process and how the PI/IoR will supervise staff that they delegate trial-related duties to (e.g., obtaining IC per International Council on Harmonisation Good Clinical Practice [ICH E6] section 4.2.5).
- Procedures for documenting the IC process in participant research records which must include:
 - PI's /IoR's availability/involvement during the IC process (e.g., the PI/IoR was available to answer participant questions, as necessary).

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- Individuals involved in the IC discussion (e.g., impartial witness, interpreter, study coordinator, etc.).
- Confirmation that the IC process (including providing answers to participant/LAR questions) preceded clinical trial procedures.
- Tools used by the CRS staff to document the consent process and assess participant/LAR understanding (e.g., checklists, source document worksheets, etc.).
- Informed Consent Form (ICF) version and date.
- Confirmation that the participant/LAR received a copy of the signed ICF and if applicable, reasons the participant/LAR declined or did not receive a copy of the ICF.
- Re-consenting procedures and requirements.
- Description of alternative/remote informed consent processes when allowed.

Note: The PI/IoR maintains overall responsibility for clinical trial conduct at the CRS, including delegated tasks.

REVISION SUMMARY

Version/ Revision	Summary of Changes
1.0	Original Version and became effective on 1/19/2021.
01	DAIDS-OCS-A28-MAN-00020 rev 01 is the first revision of this manual in MasterControl. The document numbering and document format have been updated to reflect current requirements. Removed language to align language as required by current Executive Orders.