

DAIDS Bethesda, MD USA	Office of Clinical Site Oversight Standard Operating Procedure (SOP) Addition of Satellite Sites	No.: OCS-04
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## 1.0 PURPOSE

To define the process that will be used in the consideration to add a satellite site to an existing/approved Clinical Research Site (CRS).

## 2.0 SCOPE

This SOP applies to the Division of AIDS (DAIDS) HIV/AIDS Clinical Trial Networks (hereafter referred to as Networks), Clinical Trials Units (CTUs), and Clinical Research Sites (CRSs).

Clinical Research Sites working in communities that are highly impacted by HIV/AIDS may under certain circumstances need to utilize satellite sites. With justification from the CTU Principal Investigator(PI) and support from the Network Leadership Group(s), the DAIDS will consider requests for the addition of a satellite site if it; (1) does not compromise the safety of the study subjects and the integrity of the study and (2) is cost-effective when considering transportation, staff travel time, equipment and supplies. Sufficient resources (personnel, supplies, and fiscal resources) must be available from the CTU to both the CRS and satellite site for the appropriate conduct of any study related procedures performed at the satellite site.

NOTE: No additional funds from DAIDS will be available to set-up, initiate and /or maintain a stationary, mobile, or Prevention of Mother-to-Child Transmission (PMTCT) satellite site.

## 3.0 DEFINITIONS

The definitions of Satellite Sites are provided below. If the PI through his/her Network is proposing the addition of a site that does not conform to one of the below definitions, the Office of Clinical Site Oversight (OCSO) Program Officer (PO) should consult the DAIDS SOPs for CTU Award Modification-within scope and expanded scope at: <http://daidsportal.niaid.nih.gov/C6/C4/Site%20Oversight/default.aspx>

There are three types of satellite sites: stationary clinics, mobile and prevention of mother-to-child transmission (PMTCT). Satellite sites should be appropriately equipped based on study needs.

**Stationary Satellite Site:** A new, stationary clinical research location affiliated with a domestic or international Clinical Research Site (CRS) planning to screen, enroll, and/or follow-up under-represented or other specific populations impacted by HIV/AIDS who might not otherwise be accessible to the CRS or when enrollment of such subjects at the CRS might negatively impact the operations of the CRS(i.e. might

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be a separate clinic location to avoid risk of transmissible airborne infections). The satellite site must be staffed with qualified clinical personnel affiliated with the CRS to conduct protocol visits and address any medical emergencies that may arise.

Mobile Satellite Site: A motorized vehicle that is affiliated with a domestic or international Clinical Research Site (CRS) and is used as a research location to conduct study visits for research protocol participants. The mobile site must be staffed with qualified clinical personnel affiliated with the CRS to conduct recruitment/screening visits, protocol follow-up visits and address any medical emergencies that may arise.

PMTCT Satellite Site: A labor and delivery facility and/or obstetric service that is affiliated with a domestic or international Clinical Research Site (CRS), is new to the DAIDS Network, and would be utilized to optimize participation of mothers and infants in a network-supported study for the prevention of mother-to-child transmission (PMTCT) of HIV. The PMTCT site must be staffed with qualified clinical personnel to conduct protocol visits and address any medical emergencies that may arise.

#### 4.0 RESPONSIBILITIES

The CTU Principal Investigator (PI) is responsible for justifying the need and securing appropriate approvals through his/her Network per the Network's SOPs. The CTU PI will submit a proposal, with the endorsement of the parent network to the CTU OCSO Program Officer (PO) for satellite site consideration.

The OCSO PO will review and obtain input from other appropriate DAIDS staff (i.e. Program, Pharmaceutical Affairs Branch (PAB), and the DAIDS Clinical Laboratory Oversight Team (DCLOT). After consultation with the PAB, the CRS Pharmacist of Record (PoR) may be asked to submit a revised pharmacy plan to the PAB.

The OCSO Director is responsible for approving the request based on PO recommendation and will communicate the decision to DAIDS Management.

The OCSO PO will notify by e-mail appropriate CTU/CRS, Network Leadership and Network/Operations Center, Data Management Center, NIAID Grants Management Specialist, DAIDS Regulatory Compliance Center (RCC), DAIDS-ES Support, and appropriate DAIDS staff {Pharmacy Affairs Branch (PAB), Regulatory Affairs Branch (RAB), Protocol Registration Team (PRT), DAIDS Clinical Laboratory Oversight Team (DCLOT), Office of Program Operations and Scientific Information (OPOSI/SCIB)} of approval of a satellite site.

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## 5.0 POLICY

### 5.1 General Policies for Adding Satellite Sites

- 5.1.1 The CRS in collaboration with the CTU identifies a need to add a satellite site (stationary, mobile and/or PMTCT) in order to meet the needs of potential subjects in a DAIDS' approved research agenda area for that CTU/CRS.
- 5.1.2 The CTU PI will submit a proposal to the CTU OCSO Program Officer (PO) for satellite site consideration. (For a guide to possible PMTCT satellite site scenarios, see Appendix I.)

The proposal should include:

- 5.1.2.1 A description of the satellite site including location of facilities, available personnel, equipment, laboratory services and /or description of plan for transport of specimens, and general plan for storage and dispensation of study product. Proposal should include information as to whether the satellite site is being requested for protocol-specific activity or for all Network studies (as appropriate to the site). For specific requirements for the laboratory, refer to DAIDS Policies and Procedures Laboratory section at:  
<http://www3.niaid.nih.gov/research/resources/DAIDSCLinRsrch/Laboratories.htm>
- 5.1.2.2 Amended quality management plan that incorporates QA/QC for the satellite site
- 5.1.2.3 Letter of support for request from appropriate Network
- NOTE: Networks will have the right to allow or disallow the use of satellite facilities based on study requirements.
- 5.1.2.4 Documentation of Institutional Review Board (IRB)/Ethics Committee (EC) approval of the addition of satellite sites and related activities
- 5.1.3 The OCSO PO will review the proposal and obtain input and approval for plans from Program, Pharmaceutical Affairs Branch (PAB) and DAIDS Clinical Laboratory Oversight Team (DCLOT). PAB will review the

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proposed revisions to the pharmacy plan and provide comments. DCLOT will be asked to comment on all aspects of proposed laboratory related activities to include the performance of proposed tests, specimen management, laboratory data management, and laboratory quality management.

- 5.1.4 Once a new satellite site is endorsed and approved by the Network, a visual inspection by DAIDS or DAIDS contractor may be required before the protocol is activated and a site identifier is assigned to assure Regulatory, PAB and DCLOT compliance.
- 5.1.5 The OCSO PO will make a recommendation through the OCSO Team Leader to the OCSO Director to approve or disapprove the request to add a satellite site.
- 5.1.6 Stationary and mobile satellite sites will not receive an additional number. Stationary and mobile sites will be tracked on the OCSO Portal. For new PMTCT satellite sites, the OCSO PO will obtain a site number.
- 5.1.7 For international satellite sites the OCSO PO will ensure that the required information has been entered into the Foreign Tracking System (FTS).
- 5.1.8 The OCSO PO will ensure that an updated FDA Form 1572 and/or Investigator of Record Agreement (IoR) incorporating the satellite site are received by DAIDS.
- 5.1.9 The OCSO PO will notify by e-mail appropriate CTU/CRS, Network Leadership and Network/Operations Center, Data Management Center, NIAID Grants Management Specialist, DAIDS Regulatory Compliance Center (RCC), DAIDS-ES Support, and appropriate DAIDS staff (PAB, RAB, PRT, DCLOT, OPOSI/SCIB) of approval of a satellite site. This approval does not signal that a satellite site(stationary, mobile, or PMTCT) may start enrollment into a specific Network trial/protocol. A separate protocol-specific activation is required prior to trial/protocol start. (See OCSO Policy: Responsibilities for Protocol Activation for Network Sites).

## 5.2 Essential Elements of a Satellite Site Proposal

- 5.2.1 Description of how a satellite site would enhance participation in network protocols. Description should include if possible, regional HIV epidemiological and demographic information of the geographic area to be served by the satellite site.

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- 5.2.2 Description of the study specific activities and types of procedures for which the satellite site will be utilized (i.e. phase of study, investigational study agents, laboratory/diagnostic tests required etc.). For specific requirements for the laboratory, refer to DAIDS Policies and Procedures Laboratory section at:  
<http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/Laboratories.htm>
- 5.2.3 Description of barriers the local population may face in traveling to a main clinical research site and how the satellite unit would facilitate protocol participation.
- 5.2.4 List of equipment available at the satellite site and proposed quality control procedures to ensure equipment is in working order (i.e. phones, faxes, computer equipment, temperature monitoring for study specimens, appropriate storage and temperature monitoring equipment for study medications during the limited time they are at the site, and emergency response equipment such as a defibrillator, etc).
- 5.2.5 Procedures for securing study medications (included in the proposed revision to the pharmacy plan), specimens and patient medical information within the satellite site while the site is in use (i.e. storage and lock-up of study medications, etc). Routine storage of research records is not permissible at satellite sites. An exception at PMTCT sites may include storage of the labor and delivery and postpartum records/source documents.
- 5.2.6 Procedures for maintaining the integrity of pharmaceutical and laboratory specimens during the transportation of study product and/or specimens back and forth between the main clinical research site and the satellite site to maintain integrity of materials, subject confidentiality, and chain of custody.
- 5.2.7 Proposed revision to the pharmacy plan prepared by the CRS PoR to include transportation of study products, procedures for ensuring that appropriate storage conditions are maintained, procedures for ensuring the security of study products and processes for documenting chain of custody.

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- 5.2.8 Proposed staffing plan for clinical, administrative and other staff who will see participants at the satellite site. In addition, a detailed plan should be included as to how the PI or another responsible physician can be contacted by staff at the satellite site at any time when patients are being seen (or presenting for labor and delivery at the PMTCT satellite site).
- 5.2.9 For stationary satellite sites only, include a proposed schedule of satellite site usage, the institutional affiliation of the site to be used and how access to the site will be obtained.
- 5.2.10 For stationary and PMTCT satellite sites only, indicate travel times between sites, approximate distance from the CRS and photographs of facilities (if possible).
- 5.2.11 For mobile satellite sites only, provide floor plans/diagram of the mobile satellite and the proposed work areas and waiting spaces for the patients. Indicate the approximate distance from established parked locations to the CRS as well as plans for dealing with the need for hospitalizations that may arise. Provide photographs if possible.

## 6.0 REFERENCES

Not applicable

## 7.0 INQUIRIES

Questions and comments regarding this policy may be directed to the OCSO Policy Group at [OCSOPolicyGroup@niaid.nih.gov](mailto:OCSOPolicyGroup@niaid.nih.gov).

## 8.0 AVAILABILITY

This policy is available electronically at the following URL:  
<http://daidsportal.niaid.nih.gov/C6/C4/Site%20Oversight/default.aspx>

The signed original is maintained in the OCSO Director's Office.

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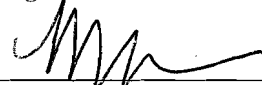
## 9.0 CHANGE SUMMARY

Version #	Date	Replaces	Date of Revision	Rationale for Revision/Retirement

## 10.0 APPENDICES

Appendix I: Guidance for OCSO POs for the Determination of PMTCT Satellite Site Eligibility

## 11.0 APPROVAL

Authorized By:	<i>Signature</i> 	<i>Program/Branch</i>	<i>Date</i> 10/9/2008
	Manizhe Payton Director	Office for Clinical Site Oversight (OCSO)	

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**Appendix I: Guidance for OCSOPs for the Determination of Prevention of Mother-to-Child Transmission (PMTCT) Satellite Site Eligibility**

**PMTCT Satellite Scenario**

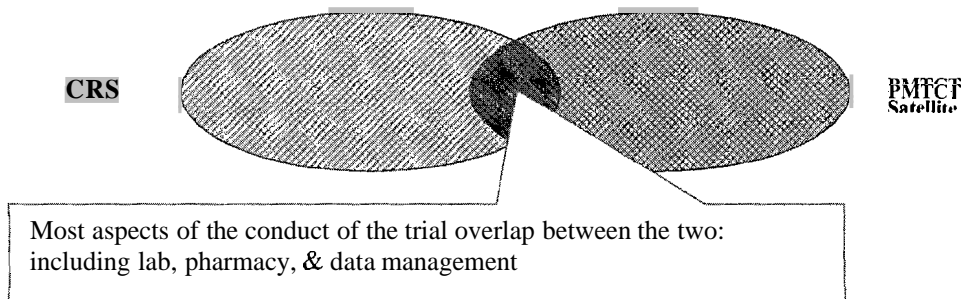
A DAIDS clinical research site is deemed eligible by a Network to participate in a perinatal trial, but the site has no obstetric (OB) service or labor and delivery facility within the CRS structure to accommodate the trial; or their current service is suboptimal for adequate access and participation of pregnant women and their infants in the trial.

**Option A**

The CRS has an OB unit within its institution that will accommodate the trial.

Conditions of the PMTCT Satellite Site

- The OB unit falls within the same IRB or, the separate IRB will coordinate with the primary IRB (of the CRS).
- Study laboratory evaluations will be performed by the DAIDS-approved laboratory of the CRS. Safety laboratory evaluations may be conducted at the PMTCT satellite provided the laboratory meets DAIDS DCLOT requirements.
- The OB service will obtain participant's study drug from the DAIDS-approved CRS pharmacy.
- Research records will not be stored at the PMTCT satellite location.
- Relevant OB personnel will collaborate closely and will receive training on the protocol by CRS staff.
- Randomization and data management activities will remain within the CRS.
- Proposed funding plans for PMTCT satellite site conforms to NIH grants policy regarding consortium and consulting arrangements.
- Scientific or Network credit will be directed to the CRS.



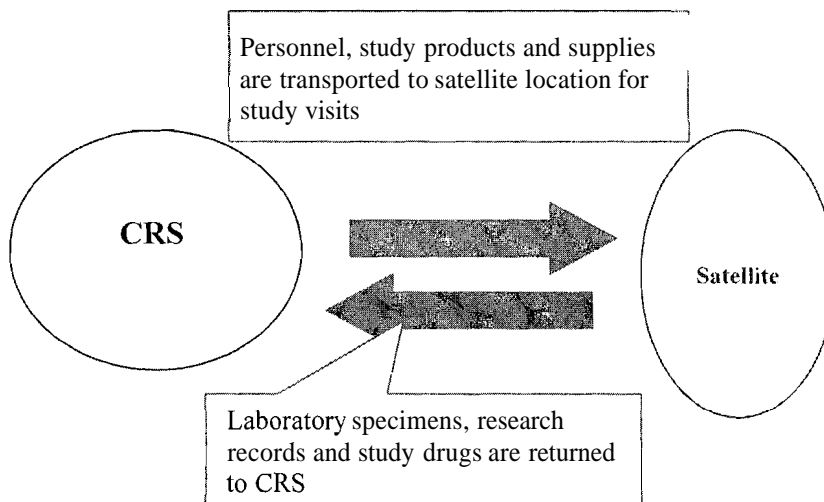
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## Option B

The CRS team and necessary supplies are mobile and can be transported to a local OB unit or facility to conduct study visits.

### Conditions of the PMTCT Satellite Site

- The OB unit falls within the same IRB or, the separate IRB will coordinate with the primary IRB (of the CRS).
- Study laboratory evaluations will be performed by the DAIDS-approved laboratory of the CRS. Safety laboratory evaluations may be conducted at the PMTCT satellite provided the laboratory meets DAIDS DCLOT requirements.
- Study products will not be stored at the PMTCT satellite site, but will be dispensed or administered to participants there by CRS staff.
- Research records will not be stored at the PMTCT satellite site location.
- CRS staff will conduct the visits; however, relevant OB personnel will collaborate and receive protocol training from the CRS staff.
- Randomization and data management activities will remain within CRS.
- Proposed funding plans for PMTCT satellite site conforms to NIH grants policy regarding consortium and consulting arrangements.
- Scientific or Network credit will be directed to the CRS.



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**Option C**

The CRS and CTU have an existing partnership with a community clinic or district hospital that will collaborate closely in the conduct of the trial.

Conditions of the PMTCT Satellite Site

- The OB unit falls within the same IRB or, the separate IRB will coordinate with the primary IRB (of the CRS).
- Study laboratory evaluations will be performed by a DAIDS-approved laboratory. Safety laboratory evaluations may be conducted by the satellite site provided the laboratory meets DAIDS DCLOT requirements.
- Research records will be secured and stored on location.
- Study products will be stored on location per PAB requirements.
- OB personnel will receive protocol training and closely collaborate with the CRS staff to conduct study visits.
- Randomization and data management activities will be performed at PMTCT satellite site; however, data management will be coordinated between the two locations.
- Proposed funding plans for PMTCT satellite site conforms to NIH grants policy regarding consortium and consulting arrangements.
- Scientific or Network credit will be directed to the CRS.

