# Site Code Assignment
# Frequently Asked Questions and Rostering Scenarios

**Question:** Does my physician's office need to be added to the Cooperative Group roster?

It is dependent on how the physician office functions. Physician practices are not required to be rostered under the following conditions:

- The practice is covered under an existing NIA or IIA, and by extension covered under an institutional FWA and an IRB.

Physician practices must be rostered if any of the following criteria are met:

- Direct receipt of CTEP agent
- Directly contracted with the rostering organization
- Direct receipt of federal funds
- Responsible for submission of data to the study sponsor or their designee
- Enrollment or consent of patients/research participants

*Refer to scenarios 1, 2, and 3 for examples.*

**Question:** My institution maintains several satellite clinics in the area for patient convenience. Do they all need to be rostered?

It is dependent on how the satellite clinic functions. Satellite offices are required to be rostered if they meet any of the following conditions.

- Direct receipt of CTEP agent
- Directly contracted with the rostering organization
- Direct receipt of federal funds
- Responsible for submission of data to the study sponsor or their designee
- Enrollment or consent of patients

Satellite clinics that do not meet any of the above criteria, are legally owned by the rostering institution, and are covered under the rostering institution's FWA and IRB do not need to be added to the rosters.
*Refer to scenario 1 for an example.*

**Question:** Can we use our membership code (CCOP or Main member institution code) to register all our patients?

No, patients should be registered under the institution code that is responsible for their treatment. The CCOP or Main Member codes should only be used when they function as the treating institution.

**Question:** Does my CCOP administrative office need to have an NCI institution code?

Yes, assignment of a CTEP institution code is required for CCOP Administrative Offices for reporting and auditing purposes.

**Question:** Can standard of care be given at a location other than the clinical site?

Yes, OHRP guidance's allow for routine care and testing to be completed at locations other than the clinical trials site, but the study investigator must retain responsibility for the study agent and reporting. The investigator must also ensure that these locations are appropriately qualified.

**Question:** What if I have already rostered my physician practices and/or satellite locations and now find it was not required?

The sites should remain on the rosters. The long-term goal is that all locations "engaged" in research under the OHRP definition[1] are accounted for on the appropriate rosters. Some allowances are made in the current version of the policy until audit and reporting requirements are reviewed and updated.

**Question:** Will all institutions in my network need to be audited and can we consolidate audits for multiple locations?

Per CTMB guidelines, any institution that enrolls a patient, must be on the Group's roster and will be subject to an audit.

Consolidation of audits: depending on the Cooperative Group audit method, affiliates or CCOP components may be audited individually at their locations or at their Main Member or CCOP when the Main Member or CCOP is being audited. Each affiliate and/or main member will have a separate site-specific audit report.

[1] Guidance on Engagement of Institutions in Human Subjects Research Oct. 23, 2008

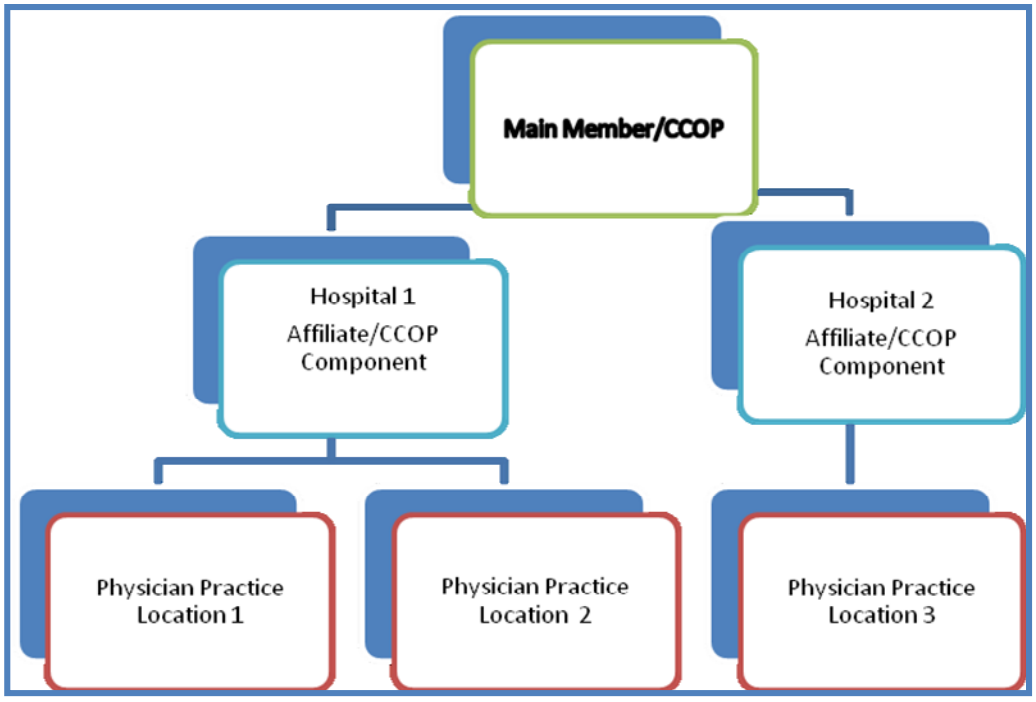
Scenarios 1 to 4 provide examples to help guide organizations in determining if a site needs a CTEP Institution code and should be added to the organization's roster.

Questions and clarifications should be submitted to the ECU Helpdesk. The ECU Helpdesk can be reached by phone at 703-738-9166 or by email at ecuhelpdesk@mail.nih.gov.

**Scenario 1 - Physician Practice Site**

Under this scenario, the physician practices are solely for the convenience of the patients and do not need to be added to the Cooperative Group rosters nor assigned a site code.

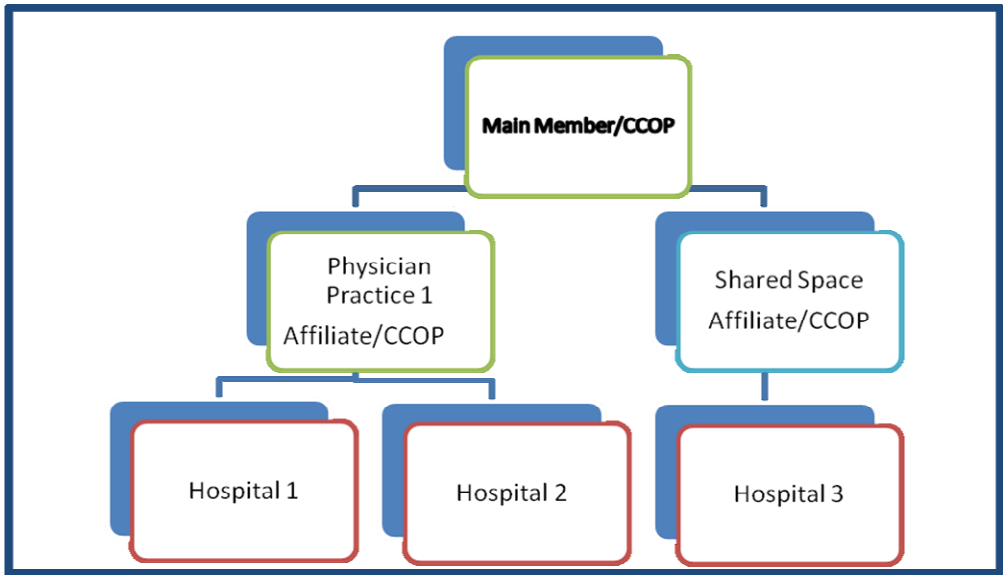
1. Physicians are salaried or contracted employees of the hospital.
2. Drug is shipped from PMB to the hospital(s). The hospital pharmacy is the control pharmacy and the transport of agents is on a per-patient/per dose basis when patients are seen in the physician practice location.
3. The IRB is at the hospital level and the physician practices are covered under an NIA or IIA.
4. Rules:
   - If drug is stored greater than 24 hrs a satellite dispensing log is required
   - Cannot store drug for greater than one cycle at a convenience site
   - Cannot consent patients, enroll patients, or long-term data storage
   - Patients cannot be enrolled or consented at the location



**Scenario 2 - Virtual Organization**

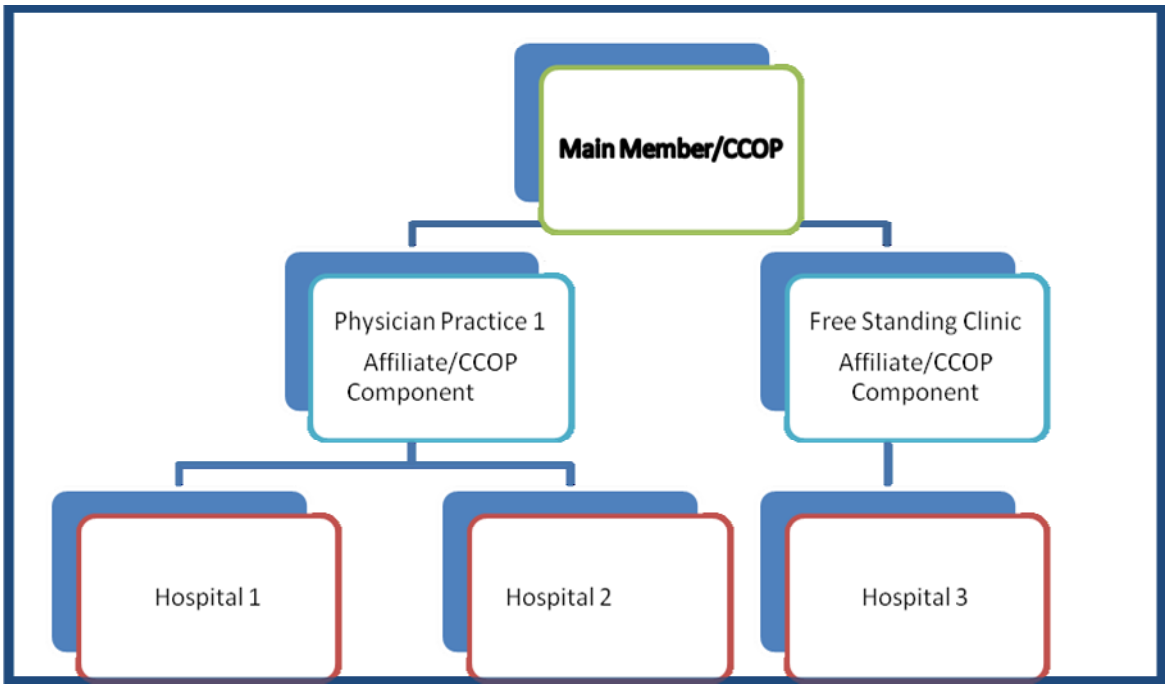
In this scenario, the physician practice has primary oversight of research but works in cooperation with local hospital(s). Dependent on the relationship the hospital may function as a separate entity on the roster as an affiliate/CCOP component, or at the third level as a participant but with no oversight or patient enrollment privileges.

1. Investigators are private practice physicians.
2. Investigators have practicing privileges at least one local hospital.
3. Drug shipment
    a. Drug is shipped from PMB to the hospital(s). The hospital pharmacy is the control pharmacy and transports agent on a per-patient per dose basis when patients are seen in the physician(s) practice or in a leased space shared by the hospital and physician practice.
    b. Drug may also be shipped directly to the physician practice.
4. The hospital may operate an infusion center. Patients are routinely seen at the physician practice locations for protocol related care and follow-up. Patients on protocols requiring intravenous infusions of study agents are treated in the hospital's infusion center.
5. The IRB covers the physician practices and hospital, and the physician practice is covered under their own or the hospital's FWA.
6. Rules
    a. Hospital must be captured at the third level in RSS as a participant, but cannot directly enroll patients; and
    b. If the hospital and physician practice share a leased space for research, the physician practice and hospital are captured at the third level and cannot consent or enroll patients.



**Scenario 3 - Physician-Based Research Practice**

1. Investigators are private practice physicians.
2. Investigators have practicing privileges at several local hospitals.
3. Drug is shipped from PMB to the investigator practice.
4. The physician practice may use the hospital or a commercial IRB and is covered under their own FWA or the hospitals FWA.
5. The hospital may operate an infusion center, and patients only receive their study- related infusions at the hospital. Patients may receive care at the hospital due to unplanned hospitalizations or standard of care surgical procedures.
6. Rules
    a. Rostering of the hospitals as a participant is optional.



**Scenario 4 - Network as an Affiliate or CCOP component**

1. Affiliate/CCOP component level is a network of sites.
2. Investigators have practicing privileges at one or more hospitals.
3. Drug is shipped from PMB to the primary network site or individual clinic sites.
4. The network is covered by an FWA and the IRB at the network level covers all clinics, and as applicable, associated hospitals.
5. Rules
    a. Clinic sites may be added as participant sites if they do not directly enroll patients, receive drug, or are responsible for data.
    b. Clinic sites that directly receive drug must be rostered as affiliates/ CCOP Components
    c. If the Network main is an administrative site it must be listed as an affiliate/CCOP component if it acts as the central pharmacy, but can be listed as a satellite if it is only administrative.
    d. If the Network main is administrative all treating clinical sites must be rostered as affiliates/CCOP components to register patients.