National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Site Code Assignment
Frequently Asked Questions

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
- Hold an FWA or are listed as a component under an FWA
- Directly contract with the rostering organization
- Direct receipt of federal funds
- Responsible for submission of data to the study sponsor or their designee
- Enrollment of patients

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

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

- Direct receipt of CTEP agent
- Hold an FWA or are listed as a component under an FWA
- Directly contract with the rostering organization
- Direct receipt of federal funds
- Responsible for submission of data to the study sponsor or their designee

- Enrollment of patients

Satellite facilities 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.

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.

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

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

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.

Consolidate 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.

The ECU Helpdesk can be reached by phone at < 703-738-9166 > or by email at < ecuhelpdesk@mail.nih.gov >.