



Procedure Name: Unified Site Coding Procedure

Effective Date: October 8, 2012

DOCUMENT CONTROL

Change Record:

EFFECTIVE DATE	AUTHOR	VERSION	CHANGE HISTORY LOG
Feb. 8, 2012	Site Code Working Group	1.0	Initial release of policy
Feb. 29, 2012	Site Code Working Group	1.1	Minor editorial update to section E.1.vi numbering and wording, and to appendix 2.
Oct. 8, 2012	Site Code Working Group	1.2	Revised wording to definition of a rostered site per Cooperative Group feedback and minor editorial and formatting corrections.

Document Location: CTSU and CTEP websites.

CTEP PROCEDURE DOCUMENT

Unified Site Coding Procedure

I. PURPOSE

The purpose of this unified procedure is to provide a common mechanism between Cancer Therapy Evaluation Program (CTEP) and CTEP-supported Cooperative Groups, grantees, and contractors to assign, maintain, and utilize CTEP institution code assignments.

II. SCOPE

This procedure applies to all activities associated with the creation, maintenance, and utilization of CTEP institution codes including, but not limited to, maintenance of rosters, protocol abstraction, Institutional Review Board (IRB) approval collection, patient registration, accrual crediting, drug shipment, adverse event reporting, CDUS reporting, auditing, and investigator and associate registration.

III. RESPONSIBILITY

This procedure applies to all CTEP staff, CTEP-supported Cooperative Groups, grantees, and contractors who maintain institution rosters for the purposes of patient enrollment, drug shipment, compliance reporting, and compliance auditing, funding, and funding reports. The Enterprise Core Unit (ECU) is responsible for the coordination of code assignment, maintenance, and utilization activities under the supervision of the Pharmaceutical Management Branch (PMB), CTEP. All CTEP institutional code changes, deletions, and/or additions shall be approved by the CTEP Branch Chief, or their designee, impacted by the change.

IV. REFERENCES

ICH 5.6 – Investigator selection
21CFR50.3 – Institution definition
21CFR312.53 – Selecting investigators and monitors
CTMB Guidelines
Glossary

V. DEFINITIONS

For full definitions please refer to the companion glossary document (appendix 5).

Adult Brain Tumor Consortium (ABTC)
AIDS Malignancy Consortium (AMC)
Audit Information System (AIS)
Cancer Therapy Evaluation Program (CTEP)
Cancer Trials Support Unit (CTSU)
Clinical Data Update System (CDUS)
Clinical Trials Monitoring Branch (CTMB)

Code Management Committee (CODE)
Enterprise Core Module (ECM)
Enterprise Core Unit (ECU)
Regulatory Support System (RSS)
Site Code Update Checklist (SCU)

VI. BACKGROUND

The creation and maintenance of CTEP Institution codes is necessary to provide a common set of institutional identifiers across CTEP-funded and sponsored activities. The creation and maintenance of common institutional identifiers allows for the ready exchange of data across all aspects of clinical trials for administrative, research and reporting purposes. Historically there have been multiple mechanisms to add, delete, or change a CTEP institution code. This procedure outlines requirements for when an institution code is created and assigned to address local activities at the institution. In addition, procedures are provided for claiming an institution for a multi-institution roster (e.g., Cooperative Group). The purpose of these procedures is to provide a common mechanism for creating and maintaining institution codes.

VII. PROCEDURE

A. Definition of an Institution:

An institution is defined in 45 CFR 46.102 (b) as “any public or private entity or agency (including federal, state or other agencies)”. Additionally, for the purpose of this procedure it must also be a distinct physical location where research is conducted under Health and Human Services regulations by an investigator responsible for the oversight of patients/research participants. Section C of this document outlines requirements for adding an institution to a roster.

B. Creation of an institution code and requesting of institution codes:

CTEP institution codes are created and assigned for a number of purposes in the CTEP Enterprise System including, but not limited to the following:

- Identification of an investigator’s office address and shipping address during the CTEP investigator registration process;
- Location where CTEP-sponsored clinical research trials are conducted;
- Identification of an associate’s office address during the associate registration process;
- Abstraction of participating institutions during the protocol abstraction process for non-Cooperative Group studies;
- CBITT / caBIG related tasks including the Clinical Trials Reporting Program (CTRP);
- Request of the Cooperative Groups; and
- Request of CTEP-supported grantees and contractors.

For many of the tasks above, such as investigator and associate registration, institution codes are generated as part of the application processing. For others, a request must be submitted to the ECU to generate an institution code. The ECU is responsible for the generation of all new institution codes under the supervision and following the procedures of CTEP branch chiefs or their designees. All institutions meeting the institution code definition and/or as outlined in CTEP procedures will be assigned an

institution code. It is important to note that CTEP institution codes for extramural institutions are assigned at the institutional level as opposed to the department or program level. While it is recognized that large institutions may internally “departmentalize” many of their programs, at this time CTEP codes can ONLY be assigned at the institutional level and not per department. Request for assignment of a new institution code can be sent to the ECU Core Unit at ecuhelpdesk@mail.nih.gov.

1. Standard Code Creation Procedure by ECU (*see appendix 1*)

Institution codes are created and assigned by the ECU. Detailed information regarding the creation of codes is available in the SOP for Creating New Institution Codes. To determine if a new code is needed, the **ECU staff** complete the following checks.

- a. Verify an appropriate institution code does not already exist in the ECM Module;
- b. Obtain complete institution name and address; and
- c. Validate information with the site contact and/or via online search.

C. Roster Requirements

It is important that the Cooperative Groups, contractors, and grantees are familiar with the basic criteria for adding a site to their rosters. Per the institution code definition in section A, “An institution is defined in 45 CFR 46.102 (b) as any public or private entity or agency (including federal, state or other agencies). Additionally, for the purpose of this procedure it must also be a distinct physical location where research is conducted under Health and Human Services regulations by an investigator responsible for the oversight of patients/research participants.”

1. Rostered institutions meet one or more of the following criteria*:

- Direct receipt of agent from CTEP;
- Enrollment of patients/research participants;
- Institutions whose employees, representatives, and/or agents are authorized to obtain informed consent from patients consistent with their institutional review board policies;
- Direct receipt of federal funds; and/or
- Directly responsible for submission of data to the study sponsor or their designee.

**Individual organizations may have additional criteria for rostering member sites.*

2. Non-Rostered institutions (Satellite Clinics) are defined as health care facilities used solely for the convenience of patients and do not need to be added to the Cooperative Group, grantee, or contractor rosters for reporting or auditing. These locations may be used to administer research related treatment as allowed by protocol, research related exams and test, or for follow up and consulting purposes. These locations may not directly receive CTEP agents, hold the agents for greater than one cycle of treatment (defined as treatment for one patient for one visit), or enroll patients. For example a physician office that is primarily used for patient followup visits. The Frequently Asked Questions document includes diagrams with scenarios under which a health care location can be defined as a satellite clinic.

It is recognized that large institutions may have several pharmacies that receive research agents. In the event that an investigator is receiving agent at an address, and provides evidence to ECU that the address is part of a larger already recognized institution, then a second institution code will not be assigned. For example, an investigator receives agent at the inpatient pharmacy versus the outpatient pharmacy of the same institution.

3. Maintaining Rosters in RSS and AIS

The Cooperative Groups, Phase Two Contractors (P2C) contractors and most other funded networks and consortiums will maintain their rosters in the Regulatory Support System (RSS). In RSS, an organization may maintain a three-tiered organizational hierarchy of parent (main member/ Community Clinical Oncology Program [CCOP]), child (affiliate/CCOP component), and grandchild (satellite clinic) institutions. The third-tier (grandchild) institutions are optional to maintain with the exception of a hospital or health care facility that acts as a receiving location for agent, but is not responsible for the conduct of research.

Institutional roster data in RSS will be electronically passed to the Clinical Trials Monitoring Branch - Audit Information System (CTMB-AIS) to support monitoring activities at CTMB. Institutions maintained at the parent and child levels must be made available to the CTMB-AIS and must map to the standard two-tiered main member/affiliate or CCOP/CCOP component structure supported by the CTMB-AIS. Institutions defined as satellite clinics do not need to map to the CTMB-AIS and with the exception noted above are optional to maintain on the RSS rosters.

Cooperative Groups are scheduled to integrate with RSS as their front end application for CTMB-AIS by the middle of 2012. Other contractors and grantees must maintain rosters in RSS and, if applicable, in CTMB-AIS under a separate request process. Until integration is complete, users should complete the following steps to determine if an institution code is already available prior to adding a new site to their roster.

- a. Determine if an institution code is required (*see appendix 2*)
- b. What is the role of each location in the research process?
 - i. Does each location meet the definition of an institution for enrollment and auditing purposes?
 - ii. Determine the structure of the institution
 - a. Is this a single location or multiple locations?
 - b. Is each location covered under a Federal Wide Assurance (FWA) and by an IRB?
 - iii. Determine if an institution code exists in RSS/AIS
 - a. Query the institution search screen using two separate searches with different search criteria. For example, a first search by partial zip code and a second by partial name (%mary%) and partial CTEP institution code (VT%).
 - iv. Cooperative Groups that have completed the AIS/RSS integration process must complete the following steps:
 - a. Claim the institution in RSS. Please note roster terminology is defined by each Group, but all treatment/prevention rosters must map to standard CTMB institution role types of CCOP/CCOP component or main member/affiliate.
 - b. Set the CTMB flag to “yes” if the institution meets the institution code definition.
 - c. Set the [Audit flag] to “yes” for all institutions meeting the institution code definition and mapped to main member/affiliate role. The flag may be set to “yes” or “no” for the role of CCOP/CCOP component, based on CTMB business rules. (see D.6.c-d).

- v. Questions and concerns from stakeholders regarding institution code assignment should be addressed to CTMB.
- vi. Cooperative Groups that have not completed AIS/RSS integration, must complete the following steps to add an existing institution code to the Group roster:
 - a. Claim the institution in RSS. Please note roster terminology is defined by each Group, contractor or grantee. Grantees and contractors are instructed to use the standard roster terms of main member/affiliate for their rosters.
 - b. Submit a separate request in the CTMB-AIS to add the institution to CTMB-AIS. The request will be reviewed by CTMB, and if approved, submitted to ECU for review.
- vii. If the institution code cannot be located in RSS, a request for a new institution code should be submitted to the ECU at ecuhelpdesk@mail.nih.gov. The request should include the following:
 - a. Complete Site Name
 - b. Complete Site Address
 - c. Site Contact information (for verification)

D. ECU/CTMB Communication Process

1. CTMB is responsible for approving all requests to add or modify institution codes on the CTMB-AIS roster.
2. ECU and CTMB will follow internal procedures to verify the requested code
 - a. Research to check for duplicate codes within the CTEP Enterprise;
 - b. Web site verification of institution address and name; and
 - c. Notification within five business days to requestor regarding status of their coding request.
3. For Cooperative Groups that have completed AIS/RSS integration, confirmation will be made via automated e-mail from AIS that is passed through RSS.
4. For Cooperative Groups that have not completed AIS/RSS integration, grantees, and contractors, ECU will submit a confirmation e-mail to the requestor and CTMB.
5. E-mail notifications will be sent to the requestor, Group, grantee, and contracting staff designated as audit and membership contacts in the RSS.
6. The Cooperative Group designee will set the CTMB-AIS flags in RSS. The flags will be set based on the following rules:
 - a. The CTMB” flag will be set to “yes” for all institutions added to the CTMB-AIS roster.
 - b. The “audit” flag will be set to “yes” for all main member and affiliate institutions.
 - c. The “audit” flag may be set to “yes” or “no” for a CCOP, but if set to “no” all CCOP components must have the “audit” flag set to “yes.”
 - d. For CCOP components, the “audit” flag may be set to “yes”, or “no” when the CCOP “audit” flag is set to “yes.”

E. Institution Code Updates

Institution code updates may occur for a variety of reasons including local business mergers, sale of all or part of an institution, institutional relocations, and closures. To accommodate any request to update institutional code information, the Cooperative Group, grantee, or contractor notified of the change should initiate the process outlined below. Critical to the institution code update process is

identification of the responsible party for any legacy data associated with prior activities at a site (e.g., patient registration, drug shipments, auditing).

1. Determine the type of code update (*see appendix 3*)
 - a. Address change due to institutional relocation or a simple address change must meet ALL of the following criteria:
 - i. The institution is moving to a new location.
 - ii. The old physical location will no longer be used as a health care facility.
 - iii. Patients, staff, and records will now be located at the new address.
 - iv. There is no change in institution structure.
 - v. The institution will retain its CTEP institution code and the address will be updated in the CTEP database with the exception of institutions that move across state lines.
 - vi. Institution relocation under the same umbrella organization –the research component of an institution is relocating to a new physical address.
 - a. The original physical location will remain a health care facility.
 - b. Patients, staff, and records will be relocated to the new address.
 - c. In RSS an audit trail is maintained to retain linkages to the original institution code.
 - d. The institution will receive a new CTEP institution code, but data associated with the research facility including roster, regulatory, and enrollment, data will be mapped to the new site code.
 - e. In CTMB-AIS the original roster record will be withdrawn and a new roster record created under the newly assigned institution code. Audit data cannot be mapped to the newly created site code; therefore organizations must track the audit history locally, and correspond with CTMB regarding the audit status.
 - b. Institutional mergers – criteria for an institutional merger includes:
 - i. Determine if the merged research facility is located at a new location or at one or both of the existing institutions.
 - a. If at a new location, a new CTEP institution code will need to be assigned. If the institution remains at the original location, that location's code can be retained.
 - ii. Determine if the original institutions will remain as health care facilities.
 - a. If yes, they will need to retain their CTEP institution codes.
 - b. If no, the new location may inherit one of the institution codes with no loss of CTMB history.
 - iii. Determine if each institution in the merger will retain all or part of the patient/research data.
 - a. If yes, a review of the data must be completed to document which patients will be retained under the originating code.
 - b. If no, all data may be migrated to the new code though a history will be retained.
 - iv. Determine the impact of regulatory coverage. For example, will one of the merging institutions need to change their IRB of record or be added as a component under the FWA?

- a. If yes, documentation from the site, signed by the IRB signatory, that clearly indicates which studies will be retained under the originating IRB must be submitted.
 - b. If a new IRB is used, IRB approval for all studies supported by that IRB must be submitted to the CTSU Regulatory Office.
 - v. Determine if all or part of the institution(s)' staff will move to the merged institution's facility.
 - a. If staff is split, documentation stating which location each investigator and associate is affiliated with must be submitted to the affiliated Cooperative Groups with a copy to the ECU and the CTSU.
 - vi. Determine if the merger will impact institutional agreements with the Cooperative Groups, grantees, or contractors.
- c. Institution split – criteria for an institutional split includes:
 - i. Determining if the original institution will remain a health care facility.
 - a. If yes, the site code must be retained and the newly formed institution will need to receive a separate CTEP site code, however linkages must be in place if some patient records are retained at the original participating site.
 - b. If no, the scenario can be handled as institution relocation (refer to E.1.b.).
 - ii. Determining the extent of the institution split. Are all or part of the research staff, patients, and records going to the new institution?
 - a. If all research related functions, patients, and staff are relocating, the original institution will retain its code, but all regulatory information, research staff rosters, and patients will map to the new institution code. Audit history will be retained with the original code. Note that regulatory may only be mapped upon verification that the IRB covering the original institution is also covering the newly created institution for all open studies.
 - b. If only part of the research related functions will move to the new facility, a careful review of enrollments, regulatory records, and facility staff will need to be completed and the appropriate records mapped. Audit history will be retained at the original site. Patients using the new facility will be transferred.
- d. Change of association
 - i. On occasion, institution splits will not result in any changes to the CTEP institution codes but are split due to changes in Cooperative Group, grantee, or contractor relationships or funding (e.g., a hospital leaving a CCOP and becoming an affiliate). A careful assessment must be undertaken of which patients, staff, and regulatory information will be retained at the facility leaving the arrangement. The audit history for the institution will be retained under the original association.
- e. Duplicate institutions – criteria for duplicate institutions includes:
 - i. Verification that the facility address is the same or, if different, the difference is limited to variations in facility offices (e.g., one code reflects a business office but the second code reflects the treatment facility location).

- ii. Determination, by ECU in consultation with the stakeholders, that the code is to be retained; and communication of this to all stakeholders.
- iii. Mapping all rosters, regulatory information, enrollments, and audit history to the retained code.
- f. Coding discrepancy – incorrectly assigned institution code includes:
 - i. Provide evidence that the institution code was incorrectly assigned or that a more accurate institution code exists based upon address.
 - ii. Determine if the assigned institution code designates an actual institutional location.
 - iii. Determine if a more accurate institution code is available for all or part of the data associated with the assigned code. If a code does not already exist, ECU will create a new code.
 - iv. All roster, site registration, and accrual data linked to the incorrect site code will be mapped to the new code.
 - v. The audit history related to the incorrectly assigned code will be mapped to the new site code; however in some instances audit history will be retained at both institution codes.
- g. Facility Closure – when an institution closes to research and/or general health care services the disposition of patients and records must be determined:
 - i. Determine if the research activities are closing or if the institution is closing.
 - ii. Determine status of patients in active treatment and follow up.
 - iii. Determine if continued IRB coverage is required and date of transition of IRB responsibilities if applicable.
 - iv. Determine status of persons at the organization.

F. Institution Code Processing

1. Cooperative Groups, grantees, and contractors should assign a staff person or central e-mail address to act as a liaison with ECU and CTMB on institution site coding issues. Persons assigned should have a working knowledge of the guidelines for assignment of institution codes, Group, contractor or grantee membership policies, and CTMB policies.
2. A request to update institution code information must be made to the ECU Help Desk by the Cooperative Group, grantee, or contractor. For complex roster updates it is helpful to use the optional Site Code Update Checklist (SCU) and submit it to the ECU at ecuhelpdesk@mail.nih.gov. [day 1]
3. The ECU will review the request and notify all impacted stakeholders regarding the requested update within five business days of receipt. [day 6]
4. Notifications will be sent to the stakeholder's identified site code contact and the CTSU. Impacted stakeholders will have 10 business days to respond with approval or with concerns regarding the proposed updates. [day 16]
 - a. All stakeholders must respond to the ECU notification with their approval or concerns. Non-responses will be considered as agreement with the proposed changes.
 - b. During this time the CTSU will prepare a Production Update form outlining the required changes to RSS including roster updates and updates to regulatory information.
5. The ECU will inform the impacted Cooperative Groups, grantees, and contractors of the site code resolution within five business days of the end of the review period. [day 21]

6. In the event that all stakeholders cannot agree on a resolution, the ECU will complete the following steps:
 - a. Notify all stakeholders that the code resolution has been referred to the Code Management Committee (CODE) for review and resolution within five business days of the end of the review period.
 - b. Provide in the notification a summary of all research from ECU and the stakeholders that has occurred on the coding issue to date.
7. Requests will be processed as received.
8. Cooperative Groups, grantees, and contractors are responsible for verifying that the appropriate data updates are complete and for making any needed manual updates. Quality control checks of the changes must be completed in five business days by all stakeholders.

G. Site Code Update – System Changes

1. The audit trail of the original institution/ site code will be maintained.
2. In RSS, with the exception of duplicate site codes and incorrect roster entries, rosters and regulatory data copied to a new site code will also be retained under the originating site code with a status of “withdrawn”.
3. In CTMB-AIS, the original institution code will be retained with a record status of “inactive”.
4. Patient records in RSS will be moved to the new site code and an audit trail will be kept of the originating site. These will not be processed as patient transfers.

H. CODE group

1. A committee will be formed to review procedures and review site coding disputes.
2. The committee will meet no less than quarterly, but more frequently if needed.
3. The committee will develop procedures for review and resolution of site code disputes.
4. The committee will consist of representatives from at least two CTEP-branches and stakeholders from the organizations impacted by the coding changes being reviewed.

I. Future Enhancements

It is recognized that there are limitations to the current system and that updates to the system will be required.

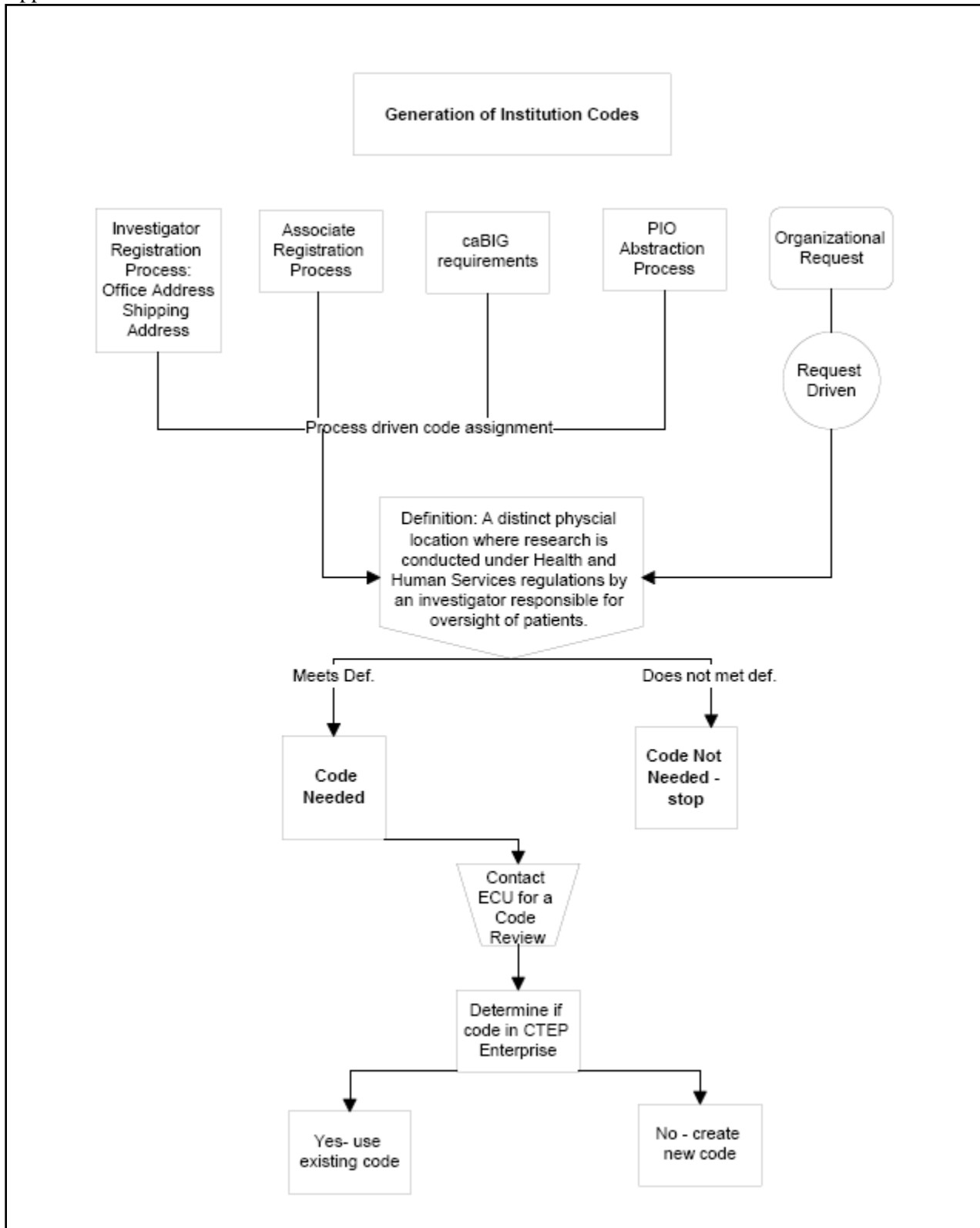
VIII. DOCUMENTATION REQUIREMENTS

Each stakeholder involved with an institution code change will file copies of the documentation per their institutional policies.

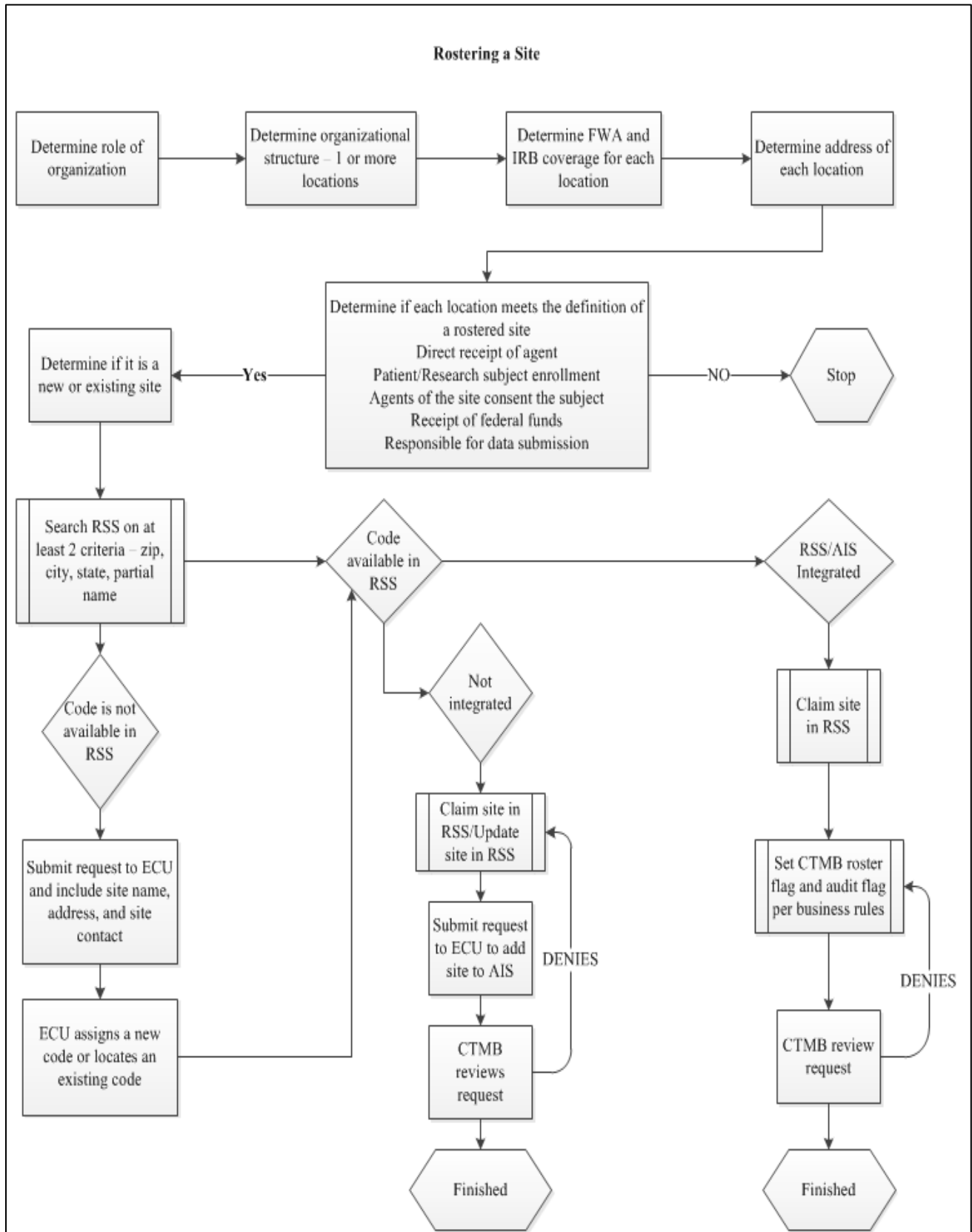
IX. REVIEW AND REVISION

This document will be reviewed by the Site Code Working Group annually.

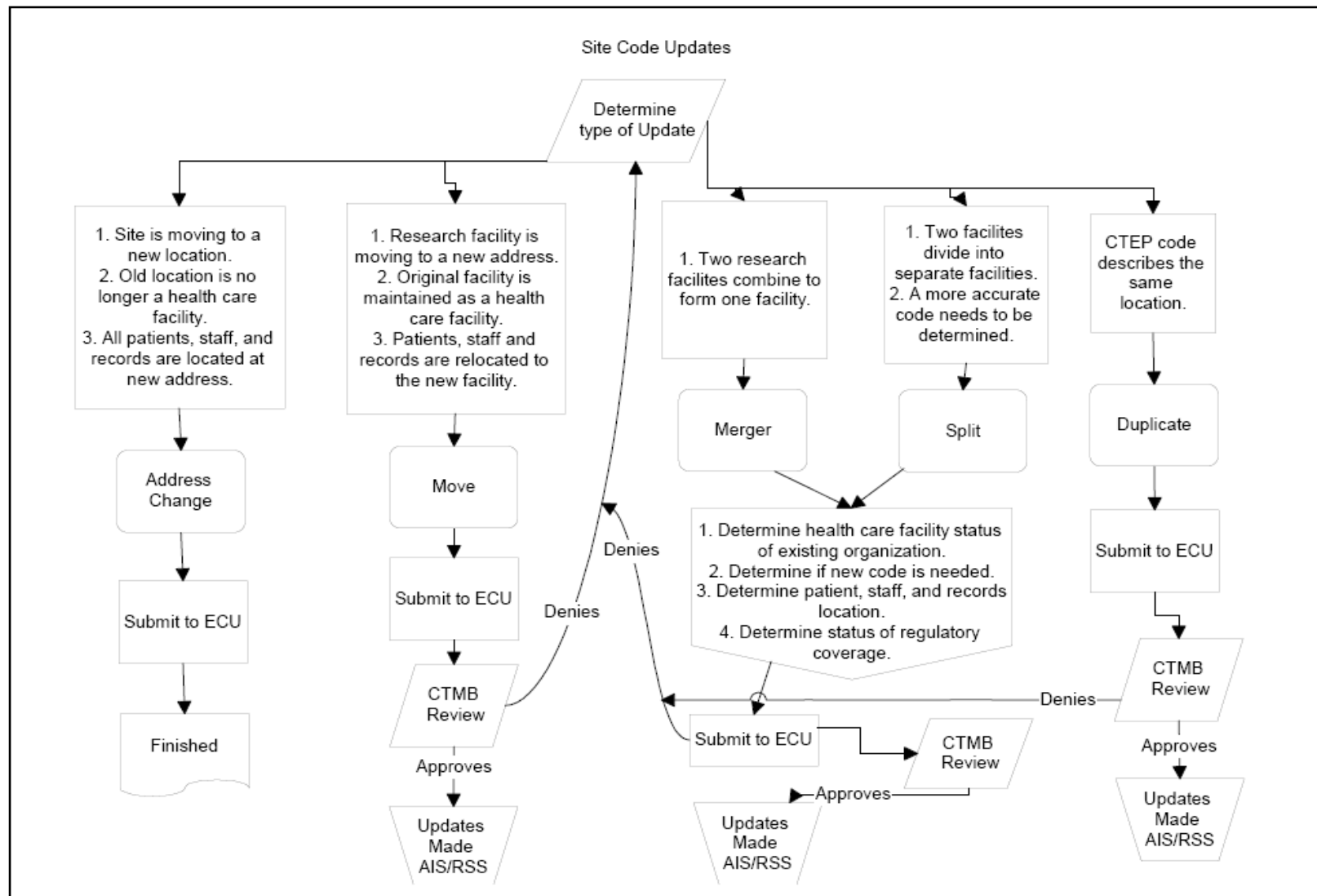
Appendix 1: Generation of Institution Code



Appendix 2: Rostering a Site



Appendix 3: Site Code Updates



Appendix 4: Optional Site Code Update Checklist

Site Portion			
Date Reported to ECU:	Click here to enter a date.	Reported To:	
Name of Site Contact for inquiries:		Phone:	
		E-mail:	
Select Code Update Type	Select One		
Briefly describe the code issues and if multiple updates are required.			
Do all Cooperative Group affiliations need to change due to the code update? State all or list Cooperative Group and other organizations that need to be updated.			
Will IRB coverage change due to this code update?	No <input type="checkbox"/> Yes <input type="checkbox"/> , <i>if yes an IRB approval for each study will need to be submitted to the CTSU Regulatory Office.</i>		
Did the site FWA change due to this code update?	No <input type="checkbox"/> Yes <input type="checkbox"/> , Please indicate new FWA		
Do all site registrations need to change? List "all" or list specific protocol lead Group study numbers? (Please note you may attach an Excel report.)			
Do all person rosters need to be updated due to this code change? If yes, indicate "all" or list the rosters or individuals that need to be updated? (Please note you may attach an Excel report.)			
Do CTSU and enrollments through OPEN need to be updated for site code due to this code update? If yes, list "all" or individual patient ID and study number as assigned by the lead protocol group. (Please note you may attach an Excel report.)			
Date of Resolution Notification or Notification of referral to CODE group	Click here to enter a date.	Referred to CODE: YES <input type="checkbox"/> NO <input type="checkbox"/>	
Resolution Summary:			

Glossary

Cancer Therapy Evaluation Program Branches:

Clinical Grants and Contracts Branch (CGCB) - The point-of-contact for the extramural community who are engaged in investigator-initiated clinical research.

Clinical Investigations Branch (CIB) - Responsible for scientific oversight and coordination of large, multicenter clinical trials exploring innovative disease therapeutics and biomarkers; partners with public and private entities to expand clinical trial participation to all populations.

Clinical Trials Monitoring Branch (CTMB) - Clinical Trials Monitoring Branch has direct oversight of all CTEP quality assurance programs and the audit process and results.

Investigational Drug Branch (IDB) - Implements and oversees an innovative investigational experimental therapeutics program. IDB collaborates with academia and industry through a unique contract and grant NCI funded program to carry out the clinical evaluation of novel anti-cancer agents.

Operations and Informatics Branch (OIB) - Provides support of protocol development and conduct through the Protocol and Information Office, PIO, as the operations hub, processes all submissions, and liaisons with all clinical sites. OIB also developed and maintains the CTEP Enterprise System, in use by the NCI as well as the extramural community, to collect, analyze and report a wide variety of protocol, accrual, adverse event and agent information.

Pharmaceutical Management Branch (PMB) - Provides pharmaceutical support for clinical trials sponsored by CTEP. Collects and maintains registration documentation for all investigators participating in CTEP clinical trials.

Regulatory Affairs Branch (RAB) - Provides IND support and acts as liaison to the FDA for CTEP, DCTD. RAB also fosters pharmaceutical collaboration in evaluating new anti-cancer agents, through the implementation of appropriate agreements.

Networks:

Adult Brain Tumor Consortium (ABTC) - A multi-institutional consortium created from the consolidation of two previous, separate NCI-funded consortia: the New Approaches to Brain Tumor Therapy (NABTT) and the North American Brain Tumor Consortium (NABTC). The ABTC permits NABTT and NABTC investigators to continue their research, but focuses management of their clinical program into a single entity.

Aids Malignancy Consortium (AMC) - The AIDS Malignancy Consortium (AMC) is a National Cancer Institute-supported clinical trials group founded in 1995 to support innovative trials for AIDS-associated malignancies.

Cancer Immunotherapy Trials Network (CITN) - The CITN is a multi-institutional consortium created founded in 2008 to support innovative trials in cancer immunotherapy.

Organ Dysfunction Group (ODG) - A CTEP Initiative designed to carry out trials to determine appropriate doses of investigational agents in patients with compromised hepatic and renal function.

Pediatric Brain Tumor Consortium (PBTC) - A multidisciplinary cooperative research organization formed by the NCI in 1999 as a clinical trials organization devoted to the study of correlative tumor biology and new therapies for primary CNS tumors of childhood.

Phase II Consortia (P2C) - CTEP funded contract holders that conduct phase 2 investigational drug studies.

Programs:

Cancer Trials Support Unit (CTSU) - A project sponsored by the NCI for the support of a national network of physicians to participate in NCI-sponsored cancer treatment trials.

Central Institutional Review Board (CIRB) - An NCI-sponsored initiative in consultation with the Office of Human Research Protections (OHRP) that provides an innovative approach to human subject protection through a “facilitated review” process that streamlines local IRB review of adult and pediatric national multi-center cancer treatment trials.

Clinical Trials Reporting Program (CTRP) - An NCI program to establish a comprehensive database containing regularly updated information on all NCI-funded clinical trials. The NCI initiated a phased launch of CTRP, which started January 2009 with a focus on registering interventional trials only. The registration of observational, ancillary and correlative studies will begin at a later date.

Systems:

Adverse Events Expedited Reporting System (AdeERS) - NCI’s web-based system for submitting expedited reports for serious and/or unexpected events forwarded to designated recipients and the NCI for all trials using an NCI-sponsored investigational agent/intervention.

Audit Information System (AIS) - An application within the CTEP Enterprise system used to manage Group rosters and audit data.

cancer Adverse Events Reporting System (caAERS) - open source software tool that is used to collect, process, and report adverse events that occur during clinical trials. This tool supports regulatory and protocol compliance for adverse event reporting and allows local collection, management, and querying of adverse event data, whether routine or serious. This tool also supports service based integration of data from other clinical trials management systems. (See <https://cabig.nci.nih.gov/tools/caAERS>). On a case-by-case basis this system may be used in place of AdeERS.

Cancer Therapy Evaluation Program Enterprise System (CTEPESYS) - All integrated systems used to support CTEP processes.

Cancer Trials Support Unit Enterprise - All integrated systems used to support the CTSU process.

Clinical Data Update System (CDUS) - Clinical Data Update System is the CTEP reporting system for demographic and clinical data.

Clinical Trials Monitoring Service (CTMS) - A service administered by a non-governmental organization under contract with NCI to receive, review, and perform data management and monitoring activities for early phase clinical trials (Phase 0, Phase 1 and select Phase 2 as determined by the Protocol Review Committee, CTEP), conduct Cooperative Group co-site visits, perform monitoring visits to Cancer Centers and other institutions conducting clinical trials involving NCI-supplied investigational agents, and provide audit support to International collaborators.

CTEP Enterprise Services (CES) - CES is a J2EE application under CTEP which facilitates message exchange between CBIIT's COPPA (Correlation of Organizations, People, Protocol Abstraction) Person and Organization (PO) and CTEP's Enterprise Core Module (ECM). The primary objective of CES is to synchronize data between PO and ECM using JMS technology. CES does not have any database of its own, however has exposed several public APIs and exchanges a small subset of COPPA objects over the wire using web services.

Drug Authorization and Review Tracking System (DARTS) - The PMB application within the CTEP Enterprise system used to track investigational agents.

Enterprise Core Module (ECM) - An application within the CTEP Enterprise system (CTEP ESYS) used to create and maintain institutional code information.

Enterprise Maintenance System (EMS) - A system within the Enterprise application that allows for the owners of applications the ability to update data and run reports based on certain criteria.

Enterprise Query Wizard (EQW) - A data analysis tool within the Enterprise application that provides real-time access to the data stored in the CTEP Enterprise database, conducts queries based on several different criteria i.e. document type, agent, disease, organization, etc., return results as a list of documents and can be exported to Excel or PDF, generates standard reports i.e., Accrual, Adverse Event, Response, etc., generates Protocol Complete Sheets, and integrates with other CTEP apps i.e., PATS, CDUS, DARTS, IR, etc.

Integrated Platform for Agents and Diseases (IPAD) - A newer data analysis tool that is replacing EQW and providing more extensive analysis tools in a more user-friendly environment.

JIRA™ - tracking software used by Westat to track development tasks in the CTSU Enterprise services.

NCI Enterprise Services (NES) - An application to collect data that researchers commonly reference in clinical trials applications includes organizations (research institutions), people (investigators and patients), and protocols (treatments), and the relationships between and among those entities. The resulting web services began with the name COPPA and evolved to NCI Enterprise Services (NES). It involves numerous internal and external stakeholders, including systems requiring or providing information, to the NCI cancer Biomedical Informatics Grid (caBIG).

Oncology Patient Enrollment Network (OPEN) - The web-based registration system for patient enrollments onto NCI-sponsored Cooperative Group clinical trials. The system is integrated with the CTSU Enterprise System for regulatory and roster data, and with each of the Cooperative Groups' registration/randomization systems for patient registration/ randomization. OPEN provides the ability to enroll patients on a 24/7 basis.

Protocol Abstraction and Tracking System (PATS) - A database module of the CTEP ESYS into which PIO abstracts key data elements from Letters of Intent (LOIs), Concepts, and Protocols, in order to track the progress of solicited and unsolicited proposals from the LOI through the Protocol approval process.

Regulatory Affairs Branch Information Tracking System (RABITS) - An application within the CTEP Enterprise system to track CTEP investigational applications and regulatory information.

Regulatory Support System (RSS) - An application created within the CTSU Enterprise system to create and manage institution, person, and regulatory data for CTEP-supported Cooperative Groups, contractors, and grantees. It is also used to manage CTSU-specific enrollment and delinquency tracking data.

Terminology:

Accrual Credited Site - A site identified within RSS or another organization's enrollment database that will receive credit for a patient enrollment. In CDUS, this site is not anticipated to be updated.

Affiliate - May be hospitals or community based clinics or offices which have lower accrual rates. Affiliates administratively function and interact with the Cooperative Groups through the Main Member.

Associate - Person integral to the conduct of research that is not a physician. Persons must be registered with CTEP through the CTEP-IAM process.

Auditable Flag - The auditable flag indicates how the CCOP and CCOP components will be audited. The flag applies only to CCOP and CCOP components and can be changed by the Cooperative Groups.

Audited Site - An institution that is identified on the CTMB-AIS roster for auditing purposes.

Common Terminology Criteria for Adverse Events (CTCAE) - Provides a descriptive terminology that is to be utilized for AE reporting. A grading (severity) scale is provided for each AE term.

Community Clinical Oncology Program (CCOP) - A community based administrative and financial unit, designated by the Division of Cancer Prevention (DCP), funded by a peer-reviewed cooperative agreement to participate in NCI sponsored cancer treatment, prevention, and controlled clinical trials. It usually consists of community hospitals, clinics, HMOs or private physician practices. A CCOP and its components must accrue at least 50 participants to treatment trials and 50 participants to cancer prevention and control trials annually. The CCOP may actively accrue participants or may be a “storefront” that only enrolls participants for its components.

Community Clinical Oncology Program Components (CCOP Components) - Groups of community hospitals, university hospitals, clinics, HMOs or group of physicians and private practice belonging to a specific CCOP, they actively enroll participants onto NCI sponsored cancer Treatment, Prevention, and cancer control trials. These hospitals, clinics, HMOs and physician practices are all considered CCOP components within the AIS. Components must be included in the Cooperative Group roster and are held to the same standards as other clinical participants.

Center for Biomedical Informatics and Information Technology (CBIT) - NCI program that provides interoperable biomedical informatics infrastructure tools, applications and activities to support research initiatives.

Certification & Accreditation (C&A) - a process that ensures that systems and applications adhere to formal and established security requirements that are documented. It is required by the Federal Information Security Management Act (FISMA).

Code Management Committee - committee developed to discuss difficult site code issues and resolve coding disputes.

CTEP Institution (Site) Code - A unique ID assigned at the time an institution is initially created and used to identify that institution across all CTEP and CTSU applications.

CTEP Investigator - must be licensed medical doctor whom has registered with CTEP to conduct CTEP-supported treatment protocols, or other research personnel leading prevention or ancillary protocols.

CTMB Roster Flag - A flag in the Regulatory Support System on the institution roster screens that is set by the Cooperative Group designee to request an institution be added to the CTMB roster.

Drug Shipment Site - A site identified by an NCI-registered investigator on their Supplemental Investigator Data Form, which will be responsible for the receipt, management, and dispensing of investigational agent received from the Pharmaceutical Management Branch.

Enrollment – the process of registering a subject to a study that for purposes of this procedure is inclusive of receiving a patient identifier.

Enterprise Core Unit (ECU) - Contractor assigned to process and maintains site code related requests for the CTEP Enterprise system.

Grantees - CTEP or DCP-funded entities provided funds through a grant mechanism.

Institution - A distinct physical location where research is conducted under Health and Human Services regulations by an investigator responsible for the oversight of patients. The term institution is synonymous with site.

Investigator Registration (IR) - CTEP process to register investigators; collect mandatory regulatory information, and supplemental information for agent shipping.

Institutional Review Board (IRB) - Any board committee, or other group formally designated by an institution to review biomedical research involving human subjects, to approve the initiation of, and conduct periodic review of such research. The term is synonymous with *institutional review committee* (FDA 21 CFR 50, ICH 6A).

Main Member - Academic or medical center that makes significant contributions to Group activities and provide significant accrual to Group protocols. If the main member has affiliates, they shall contribute, oversee and hold responsibility for mentoring and monitoring them.

Membership Type - term that describes the institution's role on a roster. Terms may vary from dependent on the roster owner. Terms used within the CTMB AIS include: Main Member, Affiliate, CCOP, or CCOP Component.

Membership Status - term used to define an institution's status on a roster. Terms may vary dependent on roster owner. Terms used within the CTMB AIS include Active, Withdrawn, or Terminated.

Membership Status Date - Date status (active, withdrawn, or terminated) and/or other changes to the membership, such as change of membership role, change of Main Member/CCOP, name, address, or audit flag. The roster owner determines when the change is effective.

Membership Start Date - Date first joined Group. The audit history indicates changes regarding participation in the Group; therefore the original start date is a firm date.

Membership Study Type - Designation of a specific roster type based on a study category such as Treatment, Prevention, UCOP, STAR, SELECT, CICRS, etc.

Privacy Impact Assessment (PIA) - a decision-making tool used to identify and mitigate privacy risks at the beginning of and throughout the development life cycle of a program or system.

Plan Of Action and Milestone (POA&M) - federal system reporting requirements outlined by the Department of Health and Human Services to ensure initial and ongoing compliance of federal systems with FISMA and Office of Management and Budget requirements.

Protocol Submission Worksheet (PSW) - worksheet used at the time a protocol is submitted to CTEP for review.

Record - entry into a database; can reflect an institution, person, protocol, etc.

Record Status - Roster entry status

- Active – current roster entry
- Inactive – past roster entries

Roster History - A list of all changes made to a record in a database.

Satellite Location - A health care facility that provides a component of the research process under agreement with a rostered institution.

Site Code Update (SCU) - changes to CTEP assigned institution code.

Service Oriented Architecture (SOA) - a flexible set of design principles used during systems development.

Special Member - Non-member, participant has specific limitations set by the Group regarding their function within that Group. Examples include provisional status, restrictions related to Group activities, protocol participation, atypical auditing situations, etc.