Procedure Name:

Effective Date:

DOCUMENT CONTROL

Change Record:

EFFECTIVE DATE	AUTHOR	VERSION	CHANGE HISTORY LOG

DOCUMENT LOCATION:

Unified Site Coding Procedure
CTEP PROCEDURE DOCUMENT

CTEP Procedure: Document #
Title: Unified Site Coding Procedure

I. PURPOSE

The purpose of this unified procedure is to provide a common mechanism between 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, 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), Cancer Therapy Evaluation Program (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 (To be developed)

V. DEFINITIONS

Adult Brain Tumor Consortium (ABTC) – CTEP funded network.
AIDS Malignancy Consortium (AMC) – CTEP funded network.
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.

Associate – person that participates in research in a role other than that of a physician.
Audit Flag – Flags in the AIS and RSS that are set to indicate how a CCOP and CCOP component will be audited.
Audit Information System (AIS) – An application within the CTEP Enterprise system used to manage Group rosters and audit data.
Audited Site - An institution that is identified on the CTMB-AIS roster for auditing purposes.
Cancer Therapy Evaluation Program (CTEP) Enterprise – All integrated systems used to support CTEP processes.
Cancer Trials Support Unit (CTSU) 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 Branch (CTMB) – Clinical Trials Monitoring Branch is a branch within CTEP with direct oversight of all quality assurance programs and the audit process and results.
Code Management Committee (CODE) – 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 alicensed 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, maintenance, and dispensing of investigational agent received from the Pharmaceutical Management Branch.
Enterprise Core Module (ECM) – An application within the CTEP Enterprise system used to create and maintain institutional code information.
Enterprise Core Unit (ECU) – Contractor assigned to process and maintains site code related requests for the CTEP Enterprise system.
Grantees – CTEP-funded entities provided funds through a grant mechanism.
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.
Production Database Update form – form used to document production data updates to the Regulatory Support System.
Regulatory Support System (RSS) – An application 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.
Site Code Update Checklist (SCU) – checklist used to document site code updates.

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 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. 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), and the Clinical Data Management System (CDMS);
- 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 Enterprise Core Unit (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 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 workflow 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.
c. Validate information with the site contact and/or via on-line 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."

1. **Rostered institutions** meet one or more of the following criteria:
   - Direct receipt of agent from CTEP;
   - Holds an FWA or listed as a component of an FWA;
   - Contract with a Cooperative Group or other CTEP-supported network;
   - Enrollment of patients;
   - Direct receipt of federal funds; and/or
   - Responsible for submission of data to the study sponsor or their designee.

2. **Locations such as physician practices and satellite clinics** that are used solely for the convenience of patients 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. They must meet one of the following criteria to waive roster requirements.
   - Physician practices covered under an existing NIA or IIA, and are by extension covered under an institutional FWA and an IRB.
     - Example – Community Hospital contracts with a physician practice to provide medical services for the hospital owned community cancer center. Research is conducted under the hospital's FWA and hospital employed staff is responsible for the submission of data. The doctors associated with the physician practice may also see patients in their office for a component of the research process.
   - Satellite location legally owned by a rostered institution and covered by the organization's FWA and IRB.
     - Example – academic cancer center operates several convenience locations throughout a major metropolitan area.

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. (Please see appendix 1 for examples of locations requiring an institution code.)

3. Maintaining Rosters in RSS and AIS

The Cooperative Groups and P2C contractors will maintain their rosters in the Regulatory Support System (RSS) and the CTMB-AIS. Organizations maintaining their rosters in RSS may use multi-tiered rosters to define institutional relationships. The caveat for maintaining these relationships is that all sites that meet the definition of an institution must also be added to the CTMB-AIS roster and, therefore, must be able to be mapped to the standard two-tiered main member/affiliate or CCOP/CCOP Component structure supported by CTMB-AIS. Use of multi-tiered rosters will ensure that all locations meeting the definition of an institution are accurately reported for enrollment, auditing, data reporting, and drug shipment purposes.

Cooperative Groups are scheduled to integrate with RSS as their front end application for CTMB-AIS by the end of 2011. 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 workflow 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 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 < 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
   i. Research to check for duplicate codes within the CTEP Enterprise
   ii. Web site verification of institution address and name
   iii. Notification within 5 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 moves, 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 workflow 3)
   a. Address change due to institutional relocation or a simple address change must meet ALL of the following criteria (Example – G.W. Hospital):
      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.

b. Institution relocation under the same umbrella organization – criteria for the research component of a facility includes (Example –Moores University of California San Diego Cancer Center):
   i. The research component of an institution is relocating to a new physical address.
   ii. The original physical location will remain a health care facility.
   iii. Patients, staff, and records will be relocated to the new address.
   iv. Retention of previous relationships and all linkages to the old location is required.
   v. The institution will receive a new CTEP institution code, but data associated with the research facility including roster, regulatory, enrollment, and audit data will be mapped to the new site code. A history of the originating site code will be retained.

c. Institutional mergers – criteria for an institutional merger includes (Example: Huntington Hospital and Edwards Comprehensive Cancer Center):
   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 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 Federal Wide Assurance?
      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.

d. Institution split – criteria for an institutional split includes (Example – Kinston Medical Specialist/Lenoir Hospital):
    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, patients, and audit history will map to the new institution 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.

e. 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.

f. Duplicate institutions – criteria for duplicate institutions includes (Example – University of Chicago codes IL008 and IL057):
    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.

g. Coding discrepancy – incorrectly assigned institution code (example – St. Joseph's Hospital Benton Harbor vs. St. Joseph's Hospital Warren):
    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.

h. 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(s) 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. The requestor should complete the 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 5 business days of receipt. [day 6]
    a. Notifications will be sent to the stakeholder's identified membership coordinator, audit coordinator, and the CTSU. A listing is available on the CTSU organizational roster and in hard copy.
    b. Dates of notification and parties notified will be identified on the SCU checklist.
4. Impacted stakeholders will have 10 business days to respond with approval or with concerns regarding the proposed updates. [day 16]
    a. During this time the Cancer Trials Support Unit (CTSU) will prepare a Production Update form outlining the required changes to RSS including roster updates and updates to regulatory information.
    b. Cooperative Group, grantee, and contractor research and responses will be documented on the SCU checklist and shared with all stakeholders.
5. The ECU will inform the impacted Cooperative Groups, grantees, and contractors of the site code resolution within 5 business days of the end of the review period. [day 21]
    a. The date of notification will be documented on the SCU checklist.
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 5 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.
   a. Updates will be documented on the SCU checklist.
8. Cooperative Groups, grantees, and contractors are responsible for verifying that the appropriate data updates are complete and for making any needed manual updates. QC of the changes must be completed in 5 business days by all stakeholders. [day 19]
   a. QC completion will be documented on the SCU checklist.

G. Site Code Update – System Changes
1. The audit trail of the original institution/ site code will be maintained and a history of the original site code retained.
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 Operations Discrepancy (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.

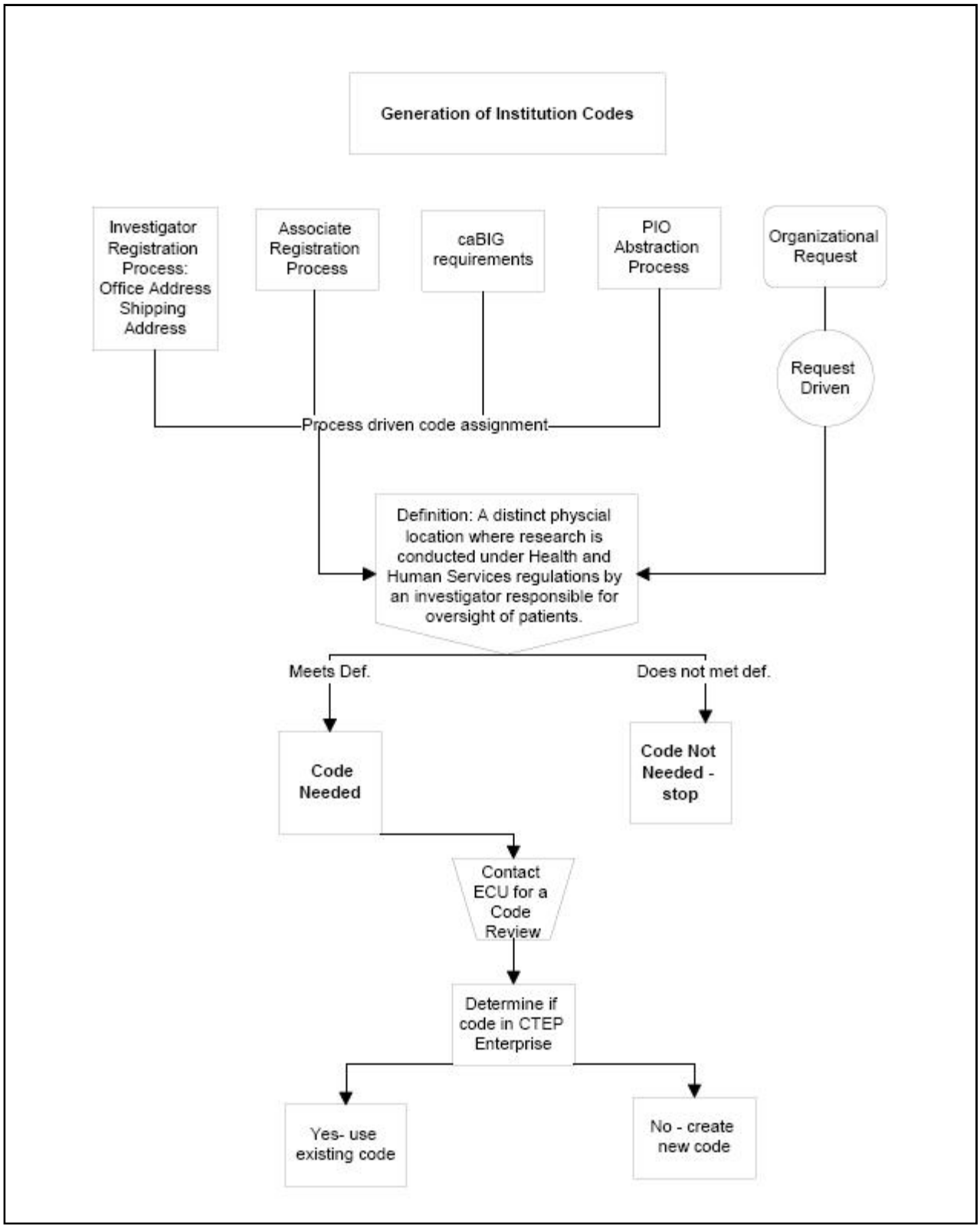
VIII. DOCUMENTATION REQUIREMENTS

Each stakeholder involved with an institution code change will file copies of the documentation per their institutional policies.
The type or reasoning behind the institution code change will be noted in CTMB-AIS under ECU comments by ECU when changes are made.

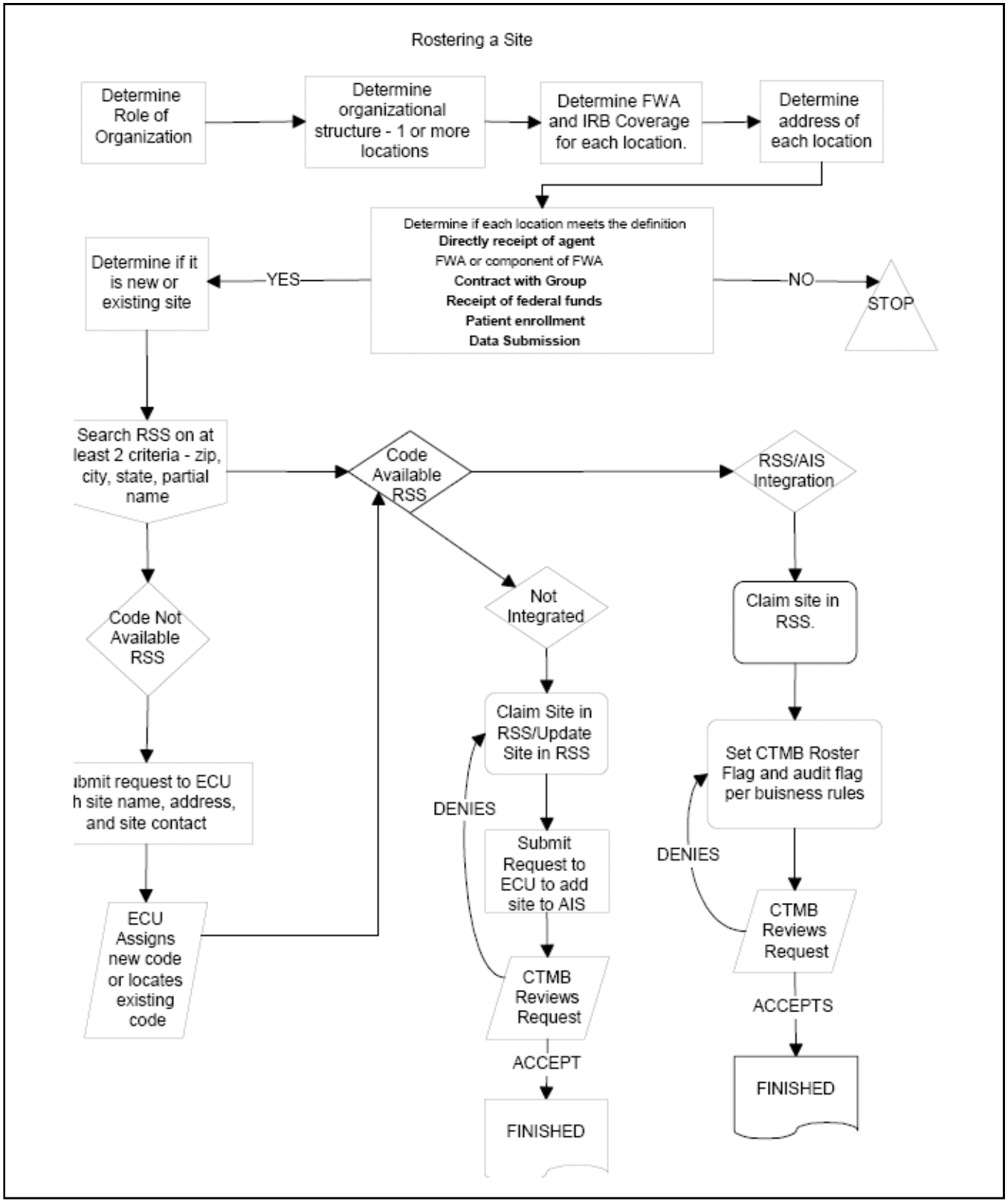
IX. REVIEW AND REVISION

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

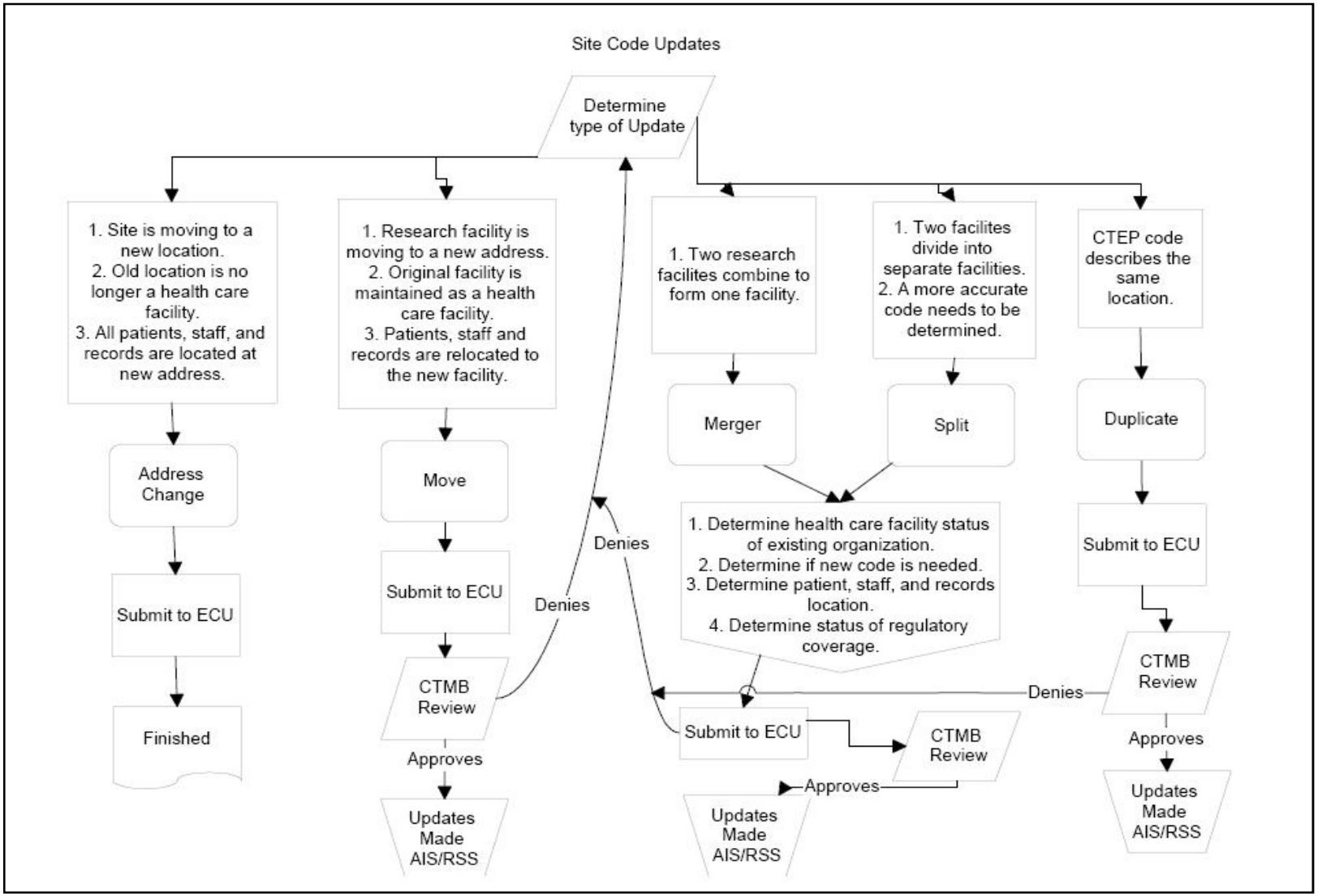
Workflow 1: Generation of Institution Code



Workflow 2: Rostering an Institution



Workflow 3: Site Code Updates



Appendix1: Site Code Update Checklist

Site Portion			
Date Reported:	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☐ Yes☐, *if yes an IRB approval for each study will need to be submitted to the CTSU Regulatory Office.*		
Did the site FWA change due to this code update?	No☐ Yes☐, 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.)			

Reporter Portion	
Date Reported to ECU	Click here to enter a date.
Comments (if applicable)	

ECU Portion		
Research Summary per organization:		
Organizations Notified: (check when response received)		R ☐ NR ☐
R ☐ NR ☐	R ☐ NR ☐	R ☐ NR ☐
R ☐ NR ☐	R ☐ NR ☐	R ☐ NR ☐
R ☐ NR ☐	R ☐ NR ☐	R ☐ NR ☐
R ☐ NR ☐	R ☐ NR ☐	R ☐ NR ☐
R ☐ NR ☐	R ☐ NR ☐	R ☐ NR ☐
Date of Notification Initial Notification	Click here to enter a date.	
Date of Resolution Notification or Notification of referral to CODE group	Click here to enter a date.	Referred to CODE: YES ☐ NO ☐
Resolution Summary:		
CTEP ESYS Mapping	YES☐ NO ☐ Date Complete (if app) Click here to enter a date.	
CDUS Mapping	YES☐ NO ☐ Date Complete (if app) Click here to enter a date.	
AIS Mapping	YES☐ NO ☐ Date Complete (if app) Click here to enter a date.	
RSS Mapping	YES☐ NO ☐ Date Complete (if app) Click here to enter a date.	

QC Confirmed per Organization	☐	☐
☐	☐	☐
☐	☐	☐
☐	☐	☐
☐	☐	☐
☐	☐	☐