CLINICAL TRIAL (CT)	An award given specifically for the controlled, clinical testing in human subjects of investigational new drugs, devices, treatments, or diagnostics, or comparisons of approved drugs, devices, treatments, or diagnostics, to assess their safety, efficacy, benefits, costs, adverse reactions, and/or outcomes. Such studies may be conducted under an industry-developed protocol or an investigator-developed protocol, cooperative group studies and correlative studies.
COVERAGE ANALYSIS (CA)	A focused review of all CT related documents to determine financial responsibility for all items and services provided to the research subject over the course of the study. Process aligns the CT protocol, CTA, ICF and budget. CA creates a reference document for subsequent billing and invoicing decisions by study team, post-award team and patient billing. UCSF Coverage Analysis mandate effective June 1, 2013.
ICD9 DX CODE V70.7	V70.7 diagnosis code is especially important when billing Medicare for research procedures. This code placed in different positions on a claim identifies a patient's participation in a clinical trial and fulfills the requirements for diagnosis reporting per Medicare rules. V70.7 diagnosis code does not route charges to insurance, this **code routes information.**
APeX SYSTEM	UCSF's electronic medical record system (EMR) and electronic health record (EHR) system. The APeX CT Study Request form must be submitted to ensure clinical trial visibility and subject accrual(s). A complete APeX build includes CT information *and* chargeable procedure(s) list. A skeletal APeX build includes minimal CT information for subject accrual and linkage.
OnCore SYSTEM	UCSF's clinical trial management system (CTMS) is the system of record for the completed coverage analysis and related document uploads.
Principal Investigator (PI)	The PI is ultimately responsible for ensuring the coverage analysis billing grid is accurate. PI sign-off to confirm agreement with final CA is required.
CLINICAL TRIAL **NIH Definition Eff. 1/25/2015**	A "research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes." *http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html*

CLINICAL TRIAL Innovation, Technology & Alliances (ITA) Definition Eff. 01/01/2013	The UCSF ITA definition of a clinical trial award has expanded to include the following: The controlled, clinical testing in human subjects of investigational new drugs, devices, treatments, or diagnostics, or comparisons of approved drugs, devices, treatments, or diagnostics, to assess their safety, efficacy, benefits, costs, adverse reactions, and/or outcomes. Such studies may be conducted under an industry-developed protocol or an investigator-developed protocol.
Cooperative Group Study (COOP)	A clinical trial involving more than one institution. The Food and Drug Administration (FDA) and Department of Health and Human Services (HHS) regulations permit institutions involved in multi-institutional studies to use reasonable methods of joint or cooperative IRB review. While the IRB assumes responsibility for oversight and continuing review, the clinical investigator and the research site retain the responsibility for the conduct of the study. ***http://www.fda.gov/RegulatoryInformation/Guidances/ucm126422.htm***
Consortium Trial	A clinical trial that is designed to enhance collaboration among the clinical research studies, to provide a forum for the exchange of research ideas, and to create a framework for collaborating on analyses that pool data from multiple studies.

COVERAGE ANALYSIS MATRIX

Clinical Trial Type (may apply to more than one category)	Clinical Trial Definition	System Requirements							
UCSF Coverage Analysis Reference Guide * *INTERNAL USE ONLY* *		OnCore	OnCore Calendar Build	OnCore Billing Grid	APeX	APeX Study Build	APeX Subject Accrual	APeX ICF Patient signed	
Therapeutic Clinical Trial	A clinical trial for the purpose of measuring the therapeutic effect, e.g., efficacy, of the test article. It excludes trial that measure off target effects, e.g., toxicity.	✓	Yes	Yes2	✓	Yes1	Yes2	Yes	
Non-therapeutic Clinical Trial	A clinical trial not designed for the purpose of measuring the therapeutic effect of the test article. The aim of a non-therapeutic trial is to obtain knowledge which may contribute towards the future development of new forms of treatment or procedure. A non-therapeutic trial is unlikely to produce any direct benefit to the participants involved.	✓	No	No	✓	Yes1	Yes2	Yes	*Example:* Non Qualifying Clinical Trial Principal Investigator Attestation Form i.e.: confirmation of trial "type' with upload into OnCore ***Draft form and process under development***
Observational Clinical Trial	A clinical trial where the trial design does not assign participants to specific interventions, tests, etc. Participants may receive interventions as part of their routine medical care, which can include medical products, such as drugs or devices, or procedures, and the investigators assess the outcomes.	✓	No	No	✓	Skeletal3	Yes2	Yes	Principal Investigator Attestation Form i.e.: confirmation of trial "type' with upload into OnCore ***Draft form and process under development***

COVERAGE ANALYSIS MATRIX

Clinical Trial Type (may apply to more than one category)	Clinical Trial Definition	System Requirements							
UCSF Coverage Analysis Reference Guide * *INTERNAL USE ONLY* *		OnCore	OnCore Calendar Build	OnCore Billing Grid	APeX	APeX Study Build	APeX Subject Accrual	APeX ICF Patient signed	
Biorepository/Tissue Block/BioBank	A clinical trial in which biological materials, e.g. patient tissue or fluids, are collected, processed, evaluated, and stored. In some cases, the materials also may be made available to support future research.	✓	Yes1	Yes2	✓	Yes1	Yes2	Yes	Principal Investigator Attestation Form i.e.: confirmation of trial "type' with upload into OnCore ***Draft form and process under development***
Diagnostic/Screening Clinical Trial	A clinical trial aimed at finding new ways to detect and diagnose medical conditions (e.g. a better test, a more effective procedure or a more sophisticated tool).	✓	Yes1	Yes2	✓	Yes1	Yes2	Yes	
Genetic Clinical Trial	A clinical trial that studies human DNA to find out what genes and environmental factors contribute to a disease.	✓	No	No	✓	Skeletal3	Yes2	Yes	Principal Investigator Attestation Form i.e.: confirmation of trial "type' with upload into OnCore ***Draft form and process under development***
Registry Clinical Trial	A clinical trial that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes.	✓	No	No	✓	Skeletal3	Yes2	Yes	Principal Investigator Attestation Form i.e.: confirmation of trial "type' with upload into OnCore ***Draft form and process under development***

COVERAGE ANALYSIS MATRIX

Clinical Trial Type (may apply to more than one category)	Clinical Trial Definition	System Requirements							
UCSF Coverage Analysis Reference Guide * *INTERNAL USE ONLY* *		OnCore	OnCore Calendar Build	OnCore Billing Grid	APeX	APeX Study Build	APeX Subject Accrual	APeX ICF Patient signed	
Survey Clinical Trial	A clinical trial that collects information or data as reported by individuals. Surveys are questionnaires (or a series of questions) that are administered to research participants who answer the questions themselves. Since the participants are providing the information, it is referred to as self-report data.	✓	No	No	✓	Skeletal3	Yes2	Yes	Principal Investigator Attestation Form i.e.: confirmation of trial "type' with upload into OnCore ***Draft form and process under development***

Footnotes:

1 Translational Informatics (TI). Research Team initiates calendar build request.

2 Accrued subjects must be identified in APeX (Responsible party: Study team/CRC)

3 Skeletal - Minimum clinical trial information entered into EMR (APeX), in order to link patients to a study

Document creation date: November 3, 2014