



## *Clinical Enterprise Compliance Program*

### **Introduction to Clinical Research Billing Requirements**

Welcome to clinical research at UCSF! The Clinical Research Billing Compliance team in the UCSF Clinical Enterprise Compliance Program would like to help you understand your obligations and resources to correctly oversee the billing activity on your clinical research studies.

Billing activity for the items and services provided to a patient as part of their participation in clinical research, whether “standard of care” or not, is subject to various laws, rules, regulations and policies that govern clinical research billing. When these services generate charges in the hospital and/or professional billing system(s), the charges require special review to ensure:

1. They are billed to the correct payor (study, patient/insurance) and not double-billed
2. Claims correctly report the NCT#, special codes/modifiers, and other study information on the claim as required by the insurance payor, in particular Medicare
3. Billing by both the hospital and professional billing offices is consistent with the approved study coverage analysis.

This billing complexity requires coordinated effort and communication across the enterprise to complete coverage analysis, include accurate cost language in the ICF, set up the study in the billing system, identify subjects and protocol visit activity in the billing system, and properly manage the related charges across the research revenue cycle to comport with the coverage analysis. APeX, (Advanced Patient-Centered Excellence), is UCSF’s EPIC-based Electronic Medical Record System (EMR) and electronic health record (EHR), which includes very specific functionality to achieve correct clinical research-related billing. You and your study staff will need to be fully trained in these clinical research functions. UCSF utilizes OnCore, our clinical trial management system, in use and available to the entire UCSF community.

For additional UCSF Research resources, please visit:

- **UCSF Clinical Enterprise Compliance Program:** <http://cecp.ucsf.edu/clinical-research-billing>
- **UCSF Office of Ethics and Compliance:** <http://compliance.ucsf.edu/>
- **UCSF Office of Research:** <http://officeofresearch.ucsf.edu/>

To help you understand the rules underlying the complexity of research billing and our need for your diligence in this area, we ask that you become familiar with the following:

1. **Medicare Clinical Trial Policy** <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&fromdb=true>
2. **Medicare Coverage of IDE Studies:** <https://www.cms.gov/Medicare/Coverage/IDE/index.html>
3. **Medicare Coverage with Evidence Development:** <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/>
4. **Mandatory NCT# Reporting:** <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8401.pdf>

Thank you for your attention and support to achieve UCSF’s mission of advancing health worldwide™

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