Background:
The University of California brings in billions of dollars from organizations such as the National Institutes of Health (NIH) for clinical research. However, clinical research billing (CRB) continues to present challenges to health care providers.

The interpretation of reimbursable clinical items and services is being challenged by requirements for enhanced documentation for claim payment and appeal processes. The key to compliant clinical research billing is the seamless exchange of information across distinct units of the research enterprise. Clear processes for managing study-related charges and the proper oversight of offices/individuals assigned to a function in the process are critical to mitigate risks of inaccurately billed services and non-compliance with clinical research billing rules. The challenge is to improve organizational communication on implementation questions related to the CRB policy procedures (coverage analyses, clinical trial modifiers), the clinical trial management system, study data management, and billing review tools.

Current Status:
- ECAS, with help from a national expert, has conducted reviews of the clinical research process at all the Academic Medical Centers.
- ECAS is coordinating two “boot camps” for CRB for staff involved in the full cycle of clinical research—from billing, status determination, grant review cycle, compliance, etc.
- ECAS established a Clinical Research Billing work group to review the clinical research billing processes and procedures and assess the extent that campus processes include:
  - Timely coverage analyses
  - Coordination with Institutional Review Boards (IRBs) and appropriate charges to third party payers.
  - The work group will identify systemwide areas for collaboration and ways to identify and mitigate risks.

Contact:
Sheryl Vacca, SVP and CCAO (Sheryl.Vacca@ucop.edu)
David Lane, Systemwide Deputy Compliance Officer (David.Lane@ucop.edu)