Background
The University of California utilizes Protected Health Information (PHI) for research in a manner that respects human subjects’ privacy in accordance with the privacy regulations (the Privacy Rule) promulgated under the Health Insurance Portability and Accountability Act (HIPAA) and other applicable laws. In 2010, UC revised the systemwide HIPAA Privacy Rule Implementation Guidelines of 2005 to reflect technical changes to the law and to provide additional clarity. At that time, revisions to the HIPAA Research Policy were delayed purposefully so that appropriate stakeholders may be consulted on a few critical open issues about how UC currently approaches HIPAA in the clinical research context. After robust discussion about these issues among systemwide privacy, IRB and research administrators the decision was made to retain the approach to HIPAA and research as outlined in the 2005 Guidelines.

Development and Vetting
In CY 2012 a workgroup was formed, led by UCLA Chief Compliance Officer and systemwide Health Sciences Privacy Liaison Marti Arvin and comprised of a few OGC members, Institutional Review Board (IRB) Directors, Health Sciences Compliance/Privacy Officers and research compliance administrators, to create a HIPAA Research Policy that was more accurate and clear than the 2005 Guidelines.

Once the draft policy was finalized by the workgroup, the HIPAA Research Policy was vetted widely with key stakeholders including all IRB Directors, Health Sciences Compliance Officers and Chief Privacy Officers across the system. The proposed key revisions are outlined below.

Next Steps
- Review by Academic Senate and Academic Personnel
- Submission through Presidential Policy Approval Process

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Proposed Key Revisions

1. Added new definitions for ‘Utilize’ and ‘Electronic Signature’
2. Individual Subjects’ Authorization:
   a. Modified language to allow campuses, with appropriate approval, to create their own HIPAA authorization forms
   b. Specified that campuses may elect to combine the informed consent document and the HIPAA authorization if they choose, with appropriate approval
3. Waiver of Authorization – clarified the requirements for a Privacy Board
4. De-identified Data – provided emphasis on the fact that all the identifiers for not only the individual but the family and household members must be removed to use the safe harbor approach
5. Activities Preparatory to Research:
   a. Provided additional comments on the need to assure that activities preparatory to research would not allow the researcher to received PHI from the covered component
   b. Removed any reference to the use of the preparatory to research exception for recruitment
6. Accounting for Disclosures for Research Purposes:
   a. Modified to clarify the researcher’s responsibility to work with the covered component to assure that an accounting can be provided should a patient request one
7. Research Databases:
   a. Provided clarification around obtaining PHI to create a database for research and using an existing clinical database to obtain information for a particular research project
8. The Patient’s Right to Access PHI Created in a Research Study:
   a. Clarified patient’s right to access information maintained in the covered component’s designated record set even if the data was obtained solely for the research project
9. Compliance and Oversight Activities:
   a. Clarified that an authorization is not required for the covered component to