	Document/Information to be Submitted	UC Health Process
❑	UC Health Research Administration Signature IPS Form (“IPS”)	Review for: • Consistency between informed consent form (“ICF”), protocol coded schedule of events, (“SOE”) and research billing worksheet (“RBW”) • Contact IDS if applicable • PI signature
❑	Coded Schedule of Events SOE	Review for consistency with ICF and protocol.
❑	Research Billing Worksheet	• Review for consistency with ICF and coded SOE • Obtain documentation of research agreement with price estimates • Obtain VP of Finance signature
❑	Facilities use agreement (as needed)	Verify that rental agreements for services or space are signed and have had legal review as necessary
❑	Immediate response lab (“IRL”) Accounts (as needed)	• Review IRL account lab tests for consistency with coded SOE and ICF • Verify that lab account is set up • Verify that researcher has appropriate requisitions with study specific account code
❑	Category B Device coverage approval and renewals (as needed)	• Receipt of copy of the application for Medicare coverage to be verified within 2 weeks • Verification of final approval • Verification of renewals • Documentation that purchase arrangement is in place (if applicable) • New technology committee has signed off (if applicable)
❑	Final protocol	Verify presence of copy
❑	Final approved ICF or waiver of consent	Verify presence of ICF with institutional review board (“IRB”) stamp or IRB waiver of consent or documentation from the UC IRB ICF waiver of consent or not human subjects research is ok
❑	Release of indemnification from the Clinical Trials Office	Verify documentation of UC Health indemnification
❑	Appropriate HIPAA approval or waiver	Verify presence of copy of IRB HIPAA approval or waiver
❑	IRB approval letter or letter of exemption	Verify presence of copy of IRB approval letter or IRB documentation that not human subjects research

Clinical research performed at UC Health entities requires that investigators and research personnel be credentialed by UC Health and appropriate approvals have been obtained. This includes hospital training, access to medical records, investigational pharmacy, site/service agreements, budgeted services, coding and billing, and device approval as applicable. Investigators must assure that UC Health staff have received the appropriate training for the study, drug or device, and have access to research staff for questions. This applies to all clinical research at UC Health facilities. Researchers should utilize available research categorization tools from the Research Committee to determine which documents, discussed in this SOP, are required for UC Health approval to proceed with their research study.

UC Health will review the completed research submission packet for completeness, compliance, and clarity. An approval letter will be issued by UC Health to the principal investigator ("PI") when:

- Review of all documents has been accomplished.
- All questions have been answered to the satisfaction of the hospital representative.
- The study documentation is determined to be in compliance with UC Health policies.

*The study should **not** commence until this approval letter has been received.*