SOP Number	*ADM-013-01*
SOP Name	*UC Health Research Administration Approval Process*
Effective Date	*01/APR/2013*

1.0 SCOPE

1.1 All Clinical/Investigational research, including clinical trials, involving human subjects conducted within UC Health facilities and all human subjects research using UC Health services or records will be approved by UC Health Research Administration prior to commencement.

2.0 PURPOSE

2.1 To provide a structure for identifying, approving and tracking clinical research studies conducted at UC Health that will ensure compliance with all applicable regulations, will manage risk associated with clinical research, and will ensure appropriate billing and reimbursement for all parties involved.

3.0 DEFINITIONS

3.1 **Clinical Research Study:** any research performed for advancement of scientific knowledge involving human subjects in a clinical setting. Clinical research studies include:

3.1.1 Chart reviews through which an investigator reviews medical records for a defined group of patients

3.1.2 A study in which an investigator asks a patient to undergo additional testing or procedures, including investigational procedures, not part of their normal course of treatment, to be performed during a clinically required visit to a UC Health facility

3.1.3 A study in which an investigator asks a patient to visit UC Health on an inpatient or outpatient basis solely for the purpose of the research study

3.1.4 The administration, distribution or dispensing of investigational drugs or devices

3.1.5 Studies performed using space or equipment rented from UC Health for clinical research activities

3.2 **Principal Investigator:** the person who is responsible for all aspects of the research project and obtains approval from the IRB for a clinical research study.

3.3 **Institutional Review Board ("IRB"):** the University of Cincinnati IRB serves as the IRB for UC Health. UC Health operates under the Federal-wide Assurance for ethical conduct of human subjects research held by the University of Cincinnati. UC Health also recognizes external IRBs.

3.4 **Master Agreement for Clinical Research Services:** the agreement between a University of Cincinnati College of Medicine clinical department (including its affiliated practice corporation) or other separate entity and UC Health that defines researcher obligations and financial and other terms for conducting research within UC Health facilities and using UC Health services.

4.0 PROCEDURES

4.1 Principal Investigator or designee conducting research will perform the following prior to commencing a research study at UC Health. Some steps will be performed concurrently.

4.1.1 Obtain approval from an approved IRB. For information regarding approved IRBs please contact Research Administration at research-finance@uchealth.com and/or the University of Cincinnati IRB at http://researchcompliance.uc.edu/HSR/IRB/Overview.aspx.

4.1.1.1 Questions regarding the IRB policies and procedures should be directed to the IRB.

4.1.1.2 Approval by the IRB does not automatically translate into approval by UC Health administration because there may be issues unique to UC Health as the site for research that need to be addressed. Items 4.1.2 through 4.1.5 below address further requirements for study approval at UC Health.

4.1.2 Prior to requesting IRB approval the Principal Investigator or designee must contact UC Health at research-finance@uchealth.com for Price Estimates for study related services provided by UC Health.

4.1.3 If the study involves an investigational drug to be dispensed, distributed or administered by UC Health, the Principal Investigator or designee must contact the UC Health Pharmacy Investigational Drug Service in accordance with the ADM-012-01 Investigational Drug Services SOP.

4.1.4 Release of indemnification must be verified.

4.1.5 The following documents must be provided, as applicable, to UC Health:

4.1.5.1 UC Health Research Signature IPS Form is an attachment to the Master Agreement for Clinical Research Services that explains the nature of a research study, identifies the unit(s) within UC Health in which research patients will be seen and lists all services, procedures, tests and facility or equipment rentals, if any, to be involved at UC Health. All studies to be conducted at UC Health must submit a UC Health Research Signature IPS Form which includes the schedule of events (SOE).

4.1.5.2 Epic Research Forms is an attachment in the ADM-011-01 Epic Research SOP that serves as a financial agreement between UC Health and the non-UC Health entity for the purpose of defining the costs of research-related procedures and tests at UC Health and for defining the terms for payment. All studies in which services or materials will be provided by UC Health must submit the Epic Research Forms. The Epic Research Forms contains the following:

4.1.5.2.1 UC Health Cost Estimate sheet on which UC Health will provide a price estimate for services, procedures, tests, facility fees and rentals needed at UC Health. (Costs of some procedures may vary depending on the individual experiences of the patient.)

4.1.5.2.2 Research Billing Worksheet (RBW) showing the agreed upon list of services, procedures and tests the study requests from UC Health for the prices estimated. The RBW is reviewed by both parties before a study can begin; the RBW must be resubmitted and signed by both parties annually.

4.1.5.2.3 Research Encounter Form to be used for appropriately identifying patients in the study each time they receive study-related procedures or tests at UC Health.

4.1.5.2.4 Discount and payment terms ("Billing Terms") for services provided by UC Health

4.1.5.3 Copy of the final protocol and informed consent document(s)

4.1.5.4 Copy of the IRB approval letter

4.1.5.4.1 If an IRB approval is not applicable a written statement explaining why IRB approval is not necessary must be submitted.

4.1.5.5 Evidence of release of indemnification when needed.

4.2 Upon receipt of applicable documents as described above, UC Health will notify the requesting Principal Investigator or designee of approval within 10 business days.

4.3 The Principal Investigator or designee bears the following responsibilities:

4.3.1 Obtaining approval from the IRB for the study prior to commencing a research study;

4.3.2 Obtaining Price Estimates by providing a complete and specific list of procedures and tests, including CPT codes when applicable, to UC Health;

4.3.2.1 The responsibility for charges incurred secondary to the research study, as indicated by the SOE and clinical trial agreement.

4.3.3 Obtaining approval from UC Health administration prior to commencing a research study;

4.3.3.1 Approval by UC Health administration shall consist of all of the following that apply. Some studies may require more than one level of approval. All applicable forms/signatures must be obtained prior to commencing the research study.

4.3.3.1.1 Signature of the Vice President for Finance or designee on the RBW.

4.3.3.1.2 Signature of the Administrative Director or designee on any contract with a third party when required by the study sponsor or by UC Health, such as for the purposes of indemnification for UC Health.

4.3.3.1.3 For all studies, an approval letter signed by the Administrative Director or designee when all requirements for approval are met.

4.3.4 Providing contractual indemnification of UC Health and insurance protection from the Sponsor relating to UC Health participation in any study;

4.3.5 Providing UC Health Administration with a copy of any contract to which UC Health is a party with sufficient time to allow for legal counsel review;

4.3.6 Providing the study Protocol and ensuring that each study is conducted in accordance with the Protocol;

4.3.7 Submitting to UC Health all information and documentation UC Health may reasonably need to evaluate the study and be made aware of its progress;

4.3.8 Ensuring that each study is conducted in accordance with all UC Health policies and procedures, in addition to this policy, related to clinical research, use of investigational articles, patient rights and medical records;

4.3.9 Ensuring that each study is conducted in accordance with all applicable federal, state and local laws, regulations and guidelines;

4.3.10 Adhering to all aspects of the “Master Agreement for Clinical Research Services,” including making timely payments to UC Health for services.

4.4 UC Health bears the following responsibilities:

4.4.1 Responding in a timely manner to all requests related to clinical research;

4.4.2 Providing up-to-date Price Estimates within 10 business days of initial request;

4.4.3 Providing feedback to the Principal Investigator or designee within 15 business days on all contracts reviewed by legal counsel;

4.4.4 Providing instructions, support and assistance to Principal Investigators or designees for completion of forms and contracts required by UC Health (e.g., IPS, RBW and Patient Registration Card);

4.4.5 Returning signed copies of applicable contracts and RBW to Principal Investigator or designee within 10 business days;

4.4.6 Providing such equipment, supplies, services, space and records as agreed as reasonably necessary to conduct the approved study;

4.4.7 UC Health or designee will be responsible for billing the research study in accordance with the RBW in a timely manner;

4.4.8 Maintaining the following related to each study:

4.4.8.1 UC Health Research Administration Signature IPS Form

4.4.8.2 RBW completed by the Principal Investigator or designee and signed by the Vice President of Finance or designee

4.4.8.3 If not IRB approved, documentation as to why IRB approval was not applicable

4.4.8.4 Study Protocol and informed consent documents and all updates received from the Principal Investigator or designee

4.4.8.5 Documentation received from the Principal Investigator or designee regarding indemnification of UC Health

4.4.8.6 Study specific contracts signed by UC Health

4.5 Adhering to all aspects of the “Master Agreement for Clinical Research Services.”

5.0 LIST OF ATTACHED FORMS

5.1 ADM-013-01 A1 UC Health Research Administration Approval Checklist

5.2 ADM-013-01 A2 UC Health Research Administration Signature IPS Form

6.0 REFERENCES

6.1 None

7.0 APPROVAL

Signature on File	3/18/2013
VP of UC HEALTH RESEARCH OR DESIGNEE	DATE