SOP Number	*ADM-001-01*
SOP Name	*SOP on SOPs*
Effective Date	*01/MAR/2012*

1.0 SCOPE

1.1 This standard operating procedure (SOP) applies to any and all SOPs facilitating research involving UC Health, including SOPs governing any research activity involving an outpatient or inpatient setting for which the facility, resources or personnel are owned and operated, leased to or managed in part or in whole by UC Health. Covered SOPs may relate to research involving patients, persons who are not registered patients, staff, facilities or resources, human tissue or samples, and identified or de-identified data.

2.0 PURPOSE

2.1 The following describes the procedures required for producing, revising, and approving SOPs including the format, numbering and review methods for SOPs developed for UC Health.

3.0 DEFINITIONS

3.1 None

4.0 PROCEDURES

4.1 SOP Formatting

4.1.1 The header section of each page of the SOP contains the UC Health logo from UC Health's letter template and UC Health Office of Research Standard Operating Procedure, the SOP number, SOP name, and effective date.

4.1.2 The footer section of each page contains the page number, total number of pages, and UC Health Office of Research.

4.1.3 The font of the SOP will be Arial, 11 point.

4.1.4 Each SOP will contain at least the following sections. Additional sections can be added as necessary.

4.1.4.1 **Scope:** defines who the SOP applies to.

4.1.4.2 **Purpose:** defines the general area that the SOP addresses.

4.1.4.3 **Definitions:** defines words that are specific to each SOP.

4.1.4.4 **Procedures:** provides a detailed list of step-by-step instructions, including any additional notes that may assist in completion of the SOP.

4.1.4.5 **List of Attached Forms:** lists the forms and other documents related and that may be used in conjunction with each SOP.

4.1.4.6 **References:** lists references to other SOPs, policies or guidance documents and the specific source(s) from which the SOP was written. For example, a

Code of Federal Regulation reference would be listed as 21 CFR 312. An example of an internal reference would be "UC Health Research Policy XXX".

4.1.5   Each SOP contains a unique identification number which cannot be reassigned. These numbers are assigned by the UC Health Office of Research.

4.1.6   SOPs are organized into sections based on overall subject matter. Each section is consecutively numbered starting with 001. Each section will be categorized. The following are examples of categories: Administrative – ADM, Regulatory – REG, and Clinical – CLIN. Each section heading will end with the version number beginning with 01.

4.1.7   The text sections of each SOP are numbered using a standard outline format.

4.1.8   During development, all SOPs must be clearly marked DRAFT.

4.2 SOP Policies or Guidance Document References

4.2.1   Any reference to another document refers to the most recently approved version of that document.

4.3 List of Attached Forms

4.3.1   Forms may be used as a means of clarification and identification, or to document information obtained during the SOP execution. For example, the Quality Review Form is attached to the Quality Review SOP. It can be used for internal Quality Review.

4.3.2   Each form is associated with a specific SOP but may be referenced in multiple SOPs.

4.3.3   Every form is identified with the applicable SOP number, followed by an attachment number beginning with A1. For example, a form associated with this SOP would be numbered ADM-001-01 A1. Subsequent forms would be numbered ADM-001-01 A2.

4.3.3.1   The format and an example are located in section 5.0 of this SOP.

4.4 Effective Dates

4.4.1   The effective date is determined by the UC Health Office of Research after the SOP is reviewed. It is assigned based on the required need to implement and execute. The effective date will generally be the first day of the month following committee approval.

4.4.2   The effective date may also be referred to as the document version date.

4.5 Initiation of a new SOP for the Research Community

4.5.1   A new SOP can be requested by anyone within the research community.

4.5.2   The requester will consult with the UC Health Office of Research prior to initiating a new SOP process.

4.5.3 The UC Health Office of Research will consult with the members of the research community to determine if it is necessary.

4.5.4 If a new SOP is needed, the UC Health Office of Research will assign a SOP number.

4.5.5 The requester will submit the first draft of the new SOP to the UC Health Office of Research.

4.5.6 As needed, the UC Health Office of Research will review the proposed SOP. As appropriate, the UC Health Office of Research will include representation from the research community.

4.5.7 The UC Health Office of Research will approve new SOPs.

4.5.8 Once the SOP is approved, the UC Health Office of Research will maintain the new SOP in a centrally available electronic manner and ensure that the new SOP is communicated to the research community.

4.6 Revision to an Existing SOP

4.6.1 A request for revision to an existing SOP can be initiated by anyone in the research community.

4.6.2 The requester will contact the UC Health Office of Research to detail the changes requested in electronic format and include the rationale for the requested changes, including regulatory references as needed and a description of specific changes requested.

4.6.3 As needed, the UC Health Office of Research will review the requested changes. As appropriate, the UC Health Office of Research will include representation from the research community.

4.6.4 Once the revised SOP is approved, the UC Health Office of Research will maintain the revised SOP in a centrally available electronic manner and ensure that the SOP revisions are communicated to the research community.

4.7 SOP Review

4.7.1 All SOPs will be reviewed by the UC Health Office of Research at least once every 3 years to ensure compliance to applicable regulations and UC Health policies and procedures. These reviews will be maintained on the SOP Master Tracker.

4.7.2 If it is determined that revisions are needed the revisions will be completed per section 4.6 of this SOP.

4.8 Maintenance of SOPs

4.8.1 The UC Health Office of Research will maintain all current SOPs in an electronic format.

4.8.2   The UC Health Office of Research will archive all revised SOPs.

5.0 LIST OF ATTACHED FORMS

5.1 ADM-001-01 A1 SOP Format Template

5.2 ADM-001-01 A2 Form Template

6.0 REFERENCES

6.1 UC Health Corporate Policy – Research SOPs Policies and Procedures

7.0 APPROVAL

Signature on file	14/FEB/2012
VP of UC HEALTH RESEARCH OR DESIGNEE	DATE