Purpose

The purpose of this standard operating procedure (SOP) is to establish a uniform procedure for developing, revising and approving Knight Cancer Institute Clinical Research SOPs. The Knight SOPs are intended to assist in ensuring compliance and consistency with OHSU, Knight, state, and federal regulations, policies and procedures.

Scope

This SOP applies to Knight Clinical Research SOPs that are applicable to all clinical research conducted within the Knight Cancer Institute.

References

Knight Cancer Institute Policy POL001: Policy on Standard Operating Procedures

Definitions

Policy – Principles used to guide good decision-making.

Standard Operating Procedure (SOP) – Detailed written instructions to achieve uniformity of the performance of a specific function.

Procedures

1. **SOP Format**: SOPs are written using the standard SOP Template (posted on the Knight Clinical Trials Office [KCTO] website) which includes the following information:
   a) **Purpose**: What is the purpose of the SOP?
   b) **Scope**: To whom does the SOP apply?
   c) **References**: List of resources that are useful to review and provide rational for development of the policy/procedure (reference to applicable regulations)
   d) **Definitions**: Definitions for any terms used in the SOP that need clarification to aid in understanding
   e) **Procedure**: Series of steps taken to accomplish a task
   f) **Header**: Includes number and title of SOP; adopted date; revision number; revision date. Clinical research SOP numbers will have a prefix of “CR” followed by a 3-digit number. For new SOPs, this number will be assigned in sequence by the KCTO auditor.
2. SOP Preparation:
   a) As new SOP needs are identified, an appropriate subject matter expert(s) will be identified to develop the SOP. The KCTO auditor will facilitate the development of the SOP document.
   b) As needs for revisions to SOPs are determined, an appropriate subject matter expert(s) will be identified to modify the document. The KCTO auditor will facilitate the revision of the document. SOP changes are documented in a tracked version with rationale documented and referenced under the change within the body of the document. Each revision is consecutively numbered and dated as revised by changing the version number and revision date in the “header” section of the SOP.
   c) SOPs should be written in a concise, step-by-step, easy-to-read format. The information presented should be unambiguous and not overly complicated. The active voice and present verb tense should be used. The term "you" should not be used, but implied. Though not required, the inclusion of a process flow chart to illustrate the process being described can be very helpful for the reader.

3. SOP Review & Approval:
   a) The Director of KCTO or designee, Knight Clinical Research Management Leadership Committee members and the Knight Executive Leadership Committee members review and approve new or modified SOPs. Though the entire committee must review and agree to the SOP, a single committee designee may sign/date approval on behalf of each of the two committees.
   b) The finalized SOP is posted in read-only format on the KCTO website. The posting date represents the adopted date (new SOP) or revision date (revised SOP).
   c) The KCTO will notify all Knight Clinical Research staff members of the posting of the new or revised SOP.

3. Frequency of Revisions & Reviews
   a) All SOPs are systematically reviewed by the Director of KCTO or designee on an annual basis to ensure continued accuracy and applicability. Annual review will be documented either through note indicating no update required or through the development of a revised SOP.
   b) SOPs are updated as changes that impact the SOP are identified.
4. **SOP Document Control, Tracking, & Archiving**

   a) The KCTO auditor maintains a master file of all current and historic SOPs with original approval signatures. Old versions are never discarded.
   
   The master file includes the following information:
   
   1. Revision Number (Version number increases by a whole number with any revision)
   2. Revision Date (last date SOP was signed off as approved for a revised SOP)
   3. Summary of Revision (i.e., New document, Policy revision)
   4. Adopted Date (Date SOP is posted on KCTO website)

5. **Training on New or Revised SOPs**

   a) As SOPs are newly developed or revised, the Director of KCTO or designee will assess whether formal training should be conducted or whether individuals can master the SOP on their own.

   b) If it is determined that there is a need for formal training, the KCTO auditor/education will facilitate training of the applicable staff on the SOPs.
SOP: CR001 Writing and Revising SOPs

X New SOP
☐ Revised SOP

Brief summary of changes:

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Approvals:

Print Name  Signature  Date
Director of Knight Clinical Trials Office or Designee

Print Name  Signature  Date
Knight Clinical Research Management Leadership Committee

Print Name  Signature  Date
Knight Executive Leadership Committee