

## STANDARD OPERATING PROCEDURE PROCESS

### Introduction and Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the process for the development, format, review, revision, approval, maintenance, retirement of obsolete SOPs, and training of the SOPs utilized cross-departmentally in clinical research conducted at the University of Utah.

Human subject protection and reliability of trial results are essential to the mission of the University of Utah. SOPs are used to help ensure consistency and compliance in the conduct of clinical research. Establishing SOPs can help ensure implementation of best research practices and compliance to Good Clinical Practice guidelines and applicable federal regulations and guidelines, or other applicable regulations and guidelines.

Guidance Documents/Work Practice Documents specific to the individual departments or divisions may be created and maintained outlining their individual processes.

### Definitions and Acronyms

**Clinical Research:** Clinical research includes all research involving human participants. It does not include secondary studies using existing biological specimens or data collected without identifiers or data that are publicly available.

**Clinical Trial:** Clinical trials are clinical research studies involving human participants assigned to an intervention in which the study is designed to evaluate the effect(s) of the intervention on the participant and the effect being evaluated is a health-related biomedical or behavioral outcome.

<b>CRC:</b>	Clinical Research Committee (consists of the Associate Dean of Clinical Research, Vice President for Research Integrity, Co-Director of the CCTS, and other University Research leadership)
<b>GCP:</b>	Good Clinical Practices
<b>HCI:</b>	Huntsman Cancer Institute
<b>IRB:</b>	Institutional Review Board
<b>PI:</b>	Principal Investigator
<b>U of U:</b>	University of Utah
<b>Standardization:</b>	The process of developing and implementing procedures to maximize uniformity, consistency, repeatability, compatibility,

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**SOP:** interoperability, safety, and quality.  
Standard Operating Procedure: An SOP is the principal document, which describes **what** is to be done, **who** is responsible for doing it, and **when** it is to be performed. If the instructions on **how** a procedure is to be performed are relatively simple, this may be incorporated into the SOP; otherwise, a separate Guidance Document/Work Practice Document should be created.

### **Guidance**

**Document/WPD:** A Guidance Document or Work Practice Document is a supportive document, which describes in detail how a specific procedure is to be performed or operational processes, workflow, etc.

## Procedure

### 1. SOP Format

1.1. A standardized template for SOPs will be used. The following elements are contained in the template:

- Document Header, including:
  - SOP Number: a unique identification number consisting of UUSOP followed by a sequential number.
  - Version Date: Date of the current version of the procedure. This is the date of the last/final review and this date is not necessarily the same as the date accompanying the approvers' signature.
    - The date should be designated as "DRAFT" until the document is ready for approval.
  - Title: a concise, yet descriptive document title.
  - University of Utah approved logo.
- SOP content sections: the procedure should include the following sections:
  - Introduction and purpose – a brief statement explaining the background/context, description of the procedure to be performed, specific aims to be accomplished, and/or rationale for the SOP.
  - Definitions and Acronyms – definitions of technical terms and abbreviations or acronyms utilized in the SOP.
  - Procedure – instructions sufficiently detailed to enable a staff member

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not routinely involved in the task to perform it in a manner that is safe, effective, and in compliance with related policies and regulations. The procedure section should provide clear systematic instructions of how the procedure will be accomplished. However, if the steps are especially detailed or change depending on the individual department practices then a separate department specific Guidance Document/WPD should be created to describe the full details.

- Materials Required – lists those resources and materials needed to perform specific tasks described in the SOP. This includes access needed or a description of where the materials are located.
- References – lists any documents or sources used as a reference for developing or following the SOP (e.g. federal regulations, guidance documents, operation manuals, university policies, etc.).
- Documentation of SOP approval – includes a line for signature and date for each person approving the document as well as their full name and title.
- Revision History – records each version date and revision summary from the current SOP version back to the original document.
- Specific sections should not be deleted and N/A should be entered if there is no applicable content for a specified section.
- Additional sections may be added as appropriate for the individual SOP.
- Document footer, including:
  - University of Utah – Standard Operating Procedures and page number (page numbers will be in the format: Page # of ##)

## 2. SOP Development Process

### 2.1. Prioritization

- New SOPs will be identified and prioritized by the SOP Collaboration Group (comprised of Compliance and Quality Assurance leaders from various departments across the university).

### 2.2. Author Assignment/Writing of the Procedure

- Once a new SOP is identified, the SOP Collaboration Group will assign an SOP author with extensive knowledge of the procedure.

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- While drafting an SOP, the author should keep in mind the following:
  - The SOP should clearly describe **what** is to be done, **who** is responsible for doing it, **when** it is to be performed, and a general overview of **how** the procedure is performed.
  - An SOP should be written with sufficient clarity and detail so that different people can carry out the work consistently and so that the document can be used to train new employees unfamiliar with that practice.
    - If specific, detailed, departmental **how-to** instructions are needed, this is best as a supplemental and separate Guidance Document/WPD.
  - The extent of detail in a procedure depends upon the complexity of the task, the experience and training of the users, the frequency of performance, and the significance of the consequences of error.
  - Use of details such as individual's names, room/building numbers, phone numbers, and specific pieces of equipment should be avoided as it may require revision of the SOP each time these details change.

### 2.3. Review and Approval of an SOP

- Once an SOP draft is complete, the SOP Collaboration Group will collectively review to ensure accurate content.
- Reviewers should provide their comments/corrections and return the draft document to the author in a timely manner.
- Any comments or changes that cannot be resolved via email may be discussed during the SOP Collaboration Group meetings.
- Any conflicts that arise over procedural text will be resolved during the meeting.
- The final SOP draft will be sent to the CRC for review and approval.
- The SOP will be discussed at the next CRC meeting and CRC members will have a recommended ten (10) business days to submit comments or changes.
- When there are no additional comments from the approvers, a final copy will be printed and routed to the Vice President for Research to sign.
- The date in the signature line of the Document Approval section is the effective date of the SOP.

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### 3. Distribution and Maintenance of SOPs

3.1. When an SOP has been approved a scanned copy of the SOP will be uploaded to the Clinical Research SOP website for cross-departmental access by coordinators, investigators, and all other applicable clinical research personnel.

<https://qualitycompliance.research.utah.edu/clinical-research-sops.php>

3.2. Department/division managers will be responsible to inform their applicable staff and ensure that they have access to the document.

3.3. Original signed SOP documents will be maintained by the Office of Quality Compliance. The official SOP is the original hand-signed document and the scanned electronic copy on the Clinical Research SOP website. Printed copies of SOPs are unofficial working copies and should be verified by same-day comparison with the current approved document to ensure the current version is used.

### 4. SOP Training

4.1. Training for cross-departmental SOPs will be the responsibility of department managers and trainers following their outlined procedures.

- SOP training may be conducted through individual reading and comprehension of the procedure. Alternatively, training may take place in organized group training sessions led by the SOP author, department managers/trainers, or in other settings.

4.2. All SOP training should be documented following each departments' / divisions' established process. If needed, training certificates are available on the Clinical Research SOP website

<https://qualitycompliance.research.utah.edu/clinical-research-sops.php>

### 5. Periodic Review of Approved Procedures

5.1. The SOP Collaboration Group will conduct review of each approved SOP. This review will occur approximately 2 years after initial approval and every 2 years thereafter. An SOP revision can be triggered earlier if there is a business or regulatory driven need to do so.

5.2. During the periodic review, the SOP Collaboration Group should assess whether the procedure is current clinical research practice and continues to meet applicable regulations and guidelines, GCP guidelines, University of Utah department/division policies, etc.

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5.3. If changes to the procedure are deemed necessary, the SOP Collaboration Group will assign an author to begin the process of revising the SOP.

### 6. Revisions and Retirement

- 6.1. To initiate an SOP revision the author should first confirm that they are working with the currently approved version of the document.
- 6.2. The author will solicit and compile all of the suggestions from each department utilizing the SOP.
- 6.3. The process of developing an SOP revision should follow the same process for review and approval as described above for new SOPs. Distribution, maintenance, and training on SOP revisions will also follow the process outlined above.
  - The outdated SOP will be removed from the Clinical Research SOP website and maintained in archives in the Office of Quality Compliance.
- 6.4. Any SOP that is determined to be obsolete will be retired.
  - Retired SOP documents will be removed from the Clinical Research SOP website and will be maintained in archives along with documentation of the reason for retirement.

### Materials Required

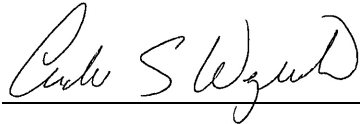
- Cross-Departmental SOP Template

### References

- 21 CFR 11            Electronic Records, Electronic Signatures
- ICH E6(R2), 1.55    Glossary
- ICH E6(R2), 2.13    The Principles of ICH GCP
- ICH E6(R2), 5.1.1    Quality Assurance and Quality Control
- ICH E6(R2), 5.5     Trial Management, Data Handling and Recordkeeping

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### Document Approval



10/1/2021

Andrew Weyrich, Ph.D.  
Vice President for Research, University of Utah

Date

### Revision History

Version Date	Change Summary
24Jun2020	Original Version
29Sep2021	Adding Guidance Document to the term WPD as they are used synonymously

**Printed or photocopied versions are considered unofficial copies unless it is the original signed document.**