

Altman Clinical and Translational Research Institute Center for Clinical Research	SOP Number	CCR:011 Page 1 of 1
	Date:	10/06/2025
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SOP TITLE: STANDARD OPERATING PROCEDURES		

1 PURPOSE

- 1.1 This procedure establishes the process to create and update standard operating procedures (SOPs) and associated materials as applicable to clinical research conducted at the Altman Clinical and Translational Research Institute (ACTRI) Center for Clinical Research (CCR).
- 1.2 The process begins when the CCR director, CCR assistant clinical director, ACTRI leadership, or their designees, determine that a standard operating procedure needs to be created or modified.
- 1.3 The process ends when the new or revised SOP has been approved and filed.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 REQUIREMENTS

- 1) Compliance with published SOPs of the ACTRI and CCR is a condition of personnel employment in the CCR.
- 2) Compliance with published SOPs of the ACTRI and CCR is a condition of use of the CCR for non-ACTRI principal investigators and their staff.

4 RESPONSIBILITIES

- 4.1 The CCR director, CCR assistant clinical director, ACTRI leadership, or their designee carry out these procedures.

5 PROCEDURE

- 5.1 For a new SOP, assign the SOP number.
- 5.2 Assign an author and approver.
 - 5.2.1 The approver will usually be the CCR director unless this authority is delegated to a designee.
- 5.3 The author creates or updates the SOP using the CCR-105 TEMPLATE: SOP.
- 5.4 The approver reviews and approves the document.
 - 5.4.1 If edits are required, the approver returns the document to the author for revision.
- 5.5 Once approved by the approver:
 - 5.5.1 Update the approval date.
 - 5.5.2 File the approved new or revised document in the SOP files.
 - 5.5.3 Post the approved procedure in the published SOPs location.
 - 5.5.4 File the prior document, if any, in the SOP procedure files.
 - 5.5.5 Communicate the change in the SOP to the relevant stakeholders via email or an appropriate alternative method.

6 MATERIALS

- 6.1 CCR-001 SOP: Definitions
- 6.2 CCR-105 TEMPLATE SOP

7 REFERENCES

- 7.1 [The Belmont Report](#)
- 7.2 [Declaration of Helsinki](#)
- 7.3 [The International Council for Harmonisation \(ICH\) E-6 - Good Clinical Practice](#)