

 <p>Senior Associate Vice Chancellor for Health Sciences</p> <p>Office of Clinical Research</p>	SOP Number	OCR:020 Page 1 of 1
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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 and associated documents.
- 1.2 The process begins when the Office of Clinical Research director or designee determines that a standard operating procedure needs to be created or modified.
- 1.3 The process ends when the new or revised standard operating procedure has been approved and filed.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 REQUIREMENTS

- 3.1 None.

4 RESPONSIBILITIES

- 4.1 The Office of Clinical Research Director or designee carries out these procedures.

5 PROCEDURE

- 5.1 For a new standard operating procedure, assign a number.
- 5.2 Assign and author and approver.
 - 5.2.1 The approver will generally be the Office of Clinical Research Director unless this responsibility is delegated to a designee.
- 5.3 The author creates or updates the standard operating procedure following the OCR-114 Template SOP, or updates the associated checklist or worksheet.
- 5.4 The approver reviews and approves the document(s).
- 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 standard operating procedure files.
 - 5.5.3 Post the approved procedure on the Office of Clinical Research website.
 - 5.5.4 File the previous document version, if any, in the standard operating procedure files.
 - 5.5.5 Communicate the change to relevant individuals, either via email or an alternative communication method (e.g., web update, group email, or other appropriate means).

6 MATERIALS

- 6.1 OCR-114 Template SOP

7 REFERENCES

- 7.1 None