

	OIA-071 SOP: Standard Operating Procedures				
	NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
	OIA-071	09/06/2023	B. Mooso	G. Firestein	1 of 1

1 PURPOSE

- 1.1 This procedure establishes the process to create and update standard operating procedures and associated checklists and worksheets.
- 1.2 The process begins when the Office of IRB Administration (OIA) director, institutional official 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 OIA director, OIA medical director, OIA assistant director, and/or institutional official carry out these procedures.

5 PROCEDURE

- 5.1 For a new standard operating procedure, assign a number.
- 5.2 Assign an author and approver.
 - 5.2.1 The approver will generally be the institutional official unless delegated to a designee.
- 5.3 The author creates or updates the standard operating procedure following the *OIA-505 TEMPLATE: SOP* or updates the associated checklist, worksheet, or equivalent.
- 5.4 The approver reviews and approves the document.
- 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 OIA website.
 - 5.5.4 File the old document, 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, OIA newsletter, or other appropriate means).

6 MATERIALS

- 6.1 *OIA-001 SOP: Definitions*
- 6.2 *OIA-505 TEMPLATE: SOP*

7 REFERENCES

- 7.1 [21 CFR 56.108\(a\)](#) and [21 CFR 56.108\(b\)](#)
- 7.2 [45 CFR 46.108\(a\)\(3\)](#) and [45 CFR 46.108\(a\)\(4\)](#)
- 7.3 [UCSD Policy and Procedure Manual \(PPM\) 100-5](#)