1. Purpose

This standard operating procedure (SOP) describes the process for generating and finalizing a standard operating procedure (SOP) within the Office of Clinical Research (OCR). For the purposes of OCR, SOPs are considered externally facing guidance documents that incorporate applicable standards for the Perelman School of Medicine research community. Internal OCR processes are documented in Guide to Daily Operations (GDOs).

2. Scope

This procedure applies to all SOPs developed by the Office of Clinical Research (OCR).

3. Instructions and Procedures

a) **Format:** The current OCR SOP template is filed in the document repository system. All OCR units, when generating an SOP for review and distribution, are to use this template. Depending on the nature of the SOP, it may be developed by one unit within OCR, several units and/or outside collaborators. The OCR SOP template footer sets forth the following elements:

   - **SOP Number (Center Footer):**
     - Standard Operating Procedure (SOP) for Writing SOPs: 000
     - Sponsor SOPs: 001 to 099 Series
     - Manufacturing SOPs: 100 to 199 Series
     - Compliance and Site Operations SOPs: 200 to 299 Series
     - Finance SOPs: 300 to 399 Series
     - System and Training SOPs: 400 to 499 Series
   - **Effective Date/Revised Date:** Date of the SOP or Date of SOP revision.
   - **Version No.:** The version as displayed in the version control section.
   - **Pages:** Sequential numbering of pages and page totals
   - **Center Footer:** Perelman School of Medicine Office of Clinical Research
b) **New SOPs:** The Director of the functional unit identified on an SOP or designated by the Vice Dean for Clinical Research or Chief Operating Officer for Clinical and Translational Science as the Process Owner keeps the SOP current on an ongoing basis. Once generated or updated, the SOP is circulated to the other unit directors or their delegate for review and comment. The responsible director integrates input into a proposed final SOP, which is reviewed by the CTCU Director/Associate General Counsel. The Vice Dean of Clinical Research within the Perelman School of Medicine will conduct the final review, approval and signature for Sponsor, Manufacturing and Compliance SOPs. The Chief Operating Officer for Clinical and Translational Research will conduct the final review, approval and signature for Operations and Finance SOPs.

c) **Reviews and Revisions:** SOP reviews and revisions will undergo the same review process as new SOPs. The Process Owner, all other OCR Directors and other contributing parties, as necessary, review all SOPs by the biennial anniversary date of the SOP or as necessary dependent upon regulatory, institutional, system, or process changes. The biennial review of each SOP is documented in the revision history section of the SOP by the Process Owner. Revised SOPs are logged and stored on the OCR document repository as well as posted to the OCR website by the Operations Training Specialist.

The Operations Training Specialist or delegate, manages the biennial updating process, including sending a request to the OCR directors to review SOPs and sending appropriate follow-up messages, files the most current versions of all SOPs, maintains a separate file of prior versions, and keeps a log of all SOPs for version control and access purposes on the OCR document repository system.

d) **Termination:** Termination of an SOP will undergo the same review process as new SOPs. The reason for the termination of the SOP will be documented on the master list. Reasons for termination include:

1. Replacement by a new SOP.
2. SOP determined to be no longer necessary and/or outdated.

e) **Archiving:** All previous SOP versions and retired SOPs will be archived in accordance with University Policy 2132, Record Retention. These will be accounted for on the master SOP list.
4. Roles and Responsibilities

**Process Owner:** Generates new/updated SOPs; may designate an author of the SOP and remains responsible for the content and purpose of the SOP and management of the review and finalization process.

**OCR Directors:** Reviews drafts of all SOPs before they are sent to the Vice Dean for Clinical Research for final review.

**CTCU Director/Associate General Counsel:** Conducts final editorial review prior to Vice Dean and COO.

**Vice Dean for Clinical Research:** Conducts final review and serves as signatory official on all Sponsor, Manufacturing and Compliance SOPs.

**Chief Operating Officer for Clinical and Translational Science:** Conducts final review and serves as the signatory official on all Finance, System and Training SOPs.

**Operations Training Specialist:** Responsible for administration of the generation, updating, logging and filing of all OCR SOPs.

<table>
<thead>
<tr>
<th>Version No.</th>
<th>Description of Revision</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>Release of SOP</td>
<td>12/1/19</td>
</tr>
</tbody>
</table>