



Montreal Neurological Institute and Hospital
McGill University

CBIG-01-001

**ADMINISTRATION OF
STANDARD OPERATING PROCEDURES**

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1. REVISION HISTORY

Version	Summary of revisions	Effective Date
1.0	Initial	01-May-2020

2. SCOPE AND APPLICATION

This Standard Operating Procedure (SOP) describes the processes for the development, review, approval and maintenance of all C-BIG written SOPs. This document is to provide guidelines on the format of the SOP to be used within C-BIG.

3. REFERENCE TO OTHER SOP OR DOCUMENTS

Note: When adopting this SOP for local use please reference *C-BIG Repository*.

3.1. Reference to Other C-BIG SOPs or Documents

NA

3.2. Reference to External SOPs or Documents

1. CTRNet Standard Operating Procedure: SOP 01.005 Administration of Standard Operating Procedures
2. NIH Version Control Guidelines V2.0 (24Apr2013)
3. Experimental Therapeutics Program: ETP-G-0001 Management of Standard Operating Procedures

4. PERSONNEL QUALIFICATION AND RESPONSIBILITIES

This SOP applies to all C-BIG personnel involved in writing, revising, reviewing, approving and maintaining SOPs.

5. ABBREVIATIONS AND DEFINITIONS

Abbreviation	Definition
C-BIG	Clinical Biological Imaging and Genetics Repository
REB	Research Ethics Board
SOP	Standard Operating Procedure

6. MATERIALS AND EQUIPMENT

NA

7. PROCEDURES

SOPs are controlled documents designed to give instructions for performing routine and essential processes, to ensure that they are performed consistently and in a manner upholding to C-BIG quality and integrity. This document is designed to provide guidance in the preparation and review process of an SOP.

7.1. Developing New SOPs or Revising Previously Issued SOPs

1. Identify the need of a new SOP, or revision of existing SOP. The need can arise from the findings of a routine SOP review or from changes to regulations, guidelines, research practices, or institutional policies.
2. Individuals well versed with the procedures or methods being described should draft or assist in drafting a new or revised SOP.
3. The SOP should follow the standard format (see SOP template, Appendix A). The word 'draft' should be added to the header. See section 7.5 for version control. The first version of an SOP is always v1.0.
4. All revisions to a previously existing SOP should be tracked within the document.
5. Develop/revise associated attachments, as applicable, and revise the version date.
6. Update the SOP index (see Attachment B) as necessary.

7.2. Review and Approval of SOPs

1. Circulate draft SOP to applicable reviewers (SOP working committee, other qualified personnel, management – e.g. SOP users) for comments.
2. Incorporate the comments, revise the draft version date and circulate the revised draft SOP to C-BIG Director or designate.
3. Review the final draft SOP for accuracy and completeness and for compliance with regulations, guidelines and standard practices. In some circumstances, this may involve REB approval of amendment. Also, should note whether change in SOP will require amendment to other administrative documents.
4. For revisions to existing SOPs, include a summary of the revision in section 1 of SOP.
5. Add the effective date to the form page (the date that the final sign-off is scheduled to be implemented). Remove 'draft' from the header.
6. Obtain approval from the Director of the final SOP. Have necessary personnel sign-off the SOP.

7. The SOP takes effect on the day of final approval, with a 2-week grace period to allow for personnel training.

7.3. Frequency of Revisions and Review

1. When a procedure is modified, corresponding SOP must be revised and re-approved.
2. SOPs should be reviewed regularly (see Appendix B for suggested review schedule). The SOPs should be reviewed sooner if there are changes to regulations, guidelines, research practice, or institutional policies.
3. Existing SOPs should be reviewed no less than every two (2) years.
4. Once an SOP is reviewed, complete the SOP Review Record (Appendix C) to document the changes and comments.
5. If revisions to an SOP are required, follow the review and approval process (see Section 7.2).
6. If only revisions to an attachment are needed, modifications may be made without revising the SOP. Revise the attachment, update the version date, and file a copy.

7.4. SOP Identification and Format

1. Write the SOP using the formatting and font style (e.g. Arial) as shown in the standard SOP template (Appendix A).
2. Complete the heading information as shown in the SOP Template.
3. The effective date refers to the date that the approved SOP is to be implemented.
4. An SOP index should be created to list all the approved SOPs, separating them into logical categories (Appendix B). Combining the abbreviated SOP category with a series of numbers created the SOP number. The original list of SOPs may contain gaps in the numbering sequence in order to accommodate new SOPs in logical order.

Standard Operating Procedure Categories and Numbering System

SOP Category	Program-Category (xx)-SOP number (xxx)
General	CBIG-01-001
Procedural	CBIG-02-001
Equipment	CBIG-03-001
Material Handling and Documentation	CBIG-04-001
Materials Request and Release	CBIG-05-001

- For new SOPs, assign the next consecutive number in the appropriate category. The SOP version number for each original (new) SOP is v1.0.
- Divide the content into sections as shown in the Standard SOP Template (Appendix A).

7.5. SOP Version Control

7.5.1 Version Numbers

The author of the document will ensure the current version number is identified on the first page and is incorporated into the header of the document and appears on every succeeding page.

7.5.2 Draft Document Version Number

- The first draft of a document will be version 0.1 (v0.1).
- Subsequent drafts will have an increase of “0.1” in the version number (e.g. 0.2, 0.3, 0.4, [...], 0.9, 0.10).

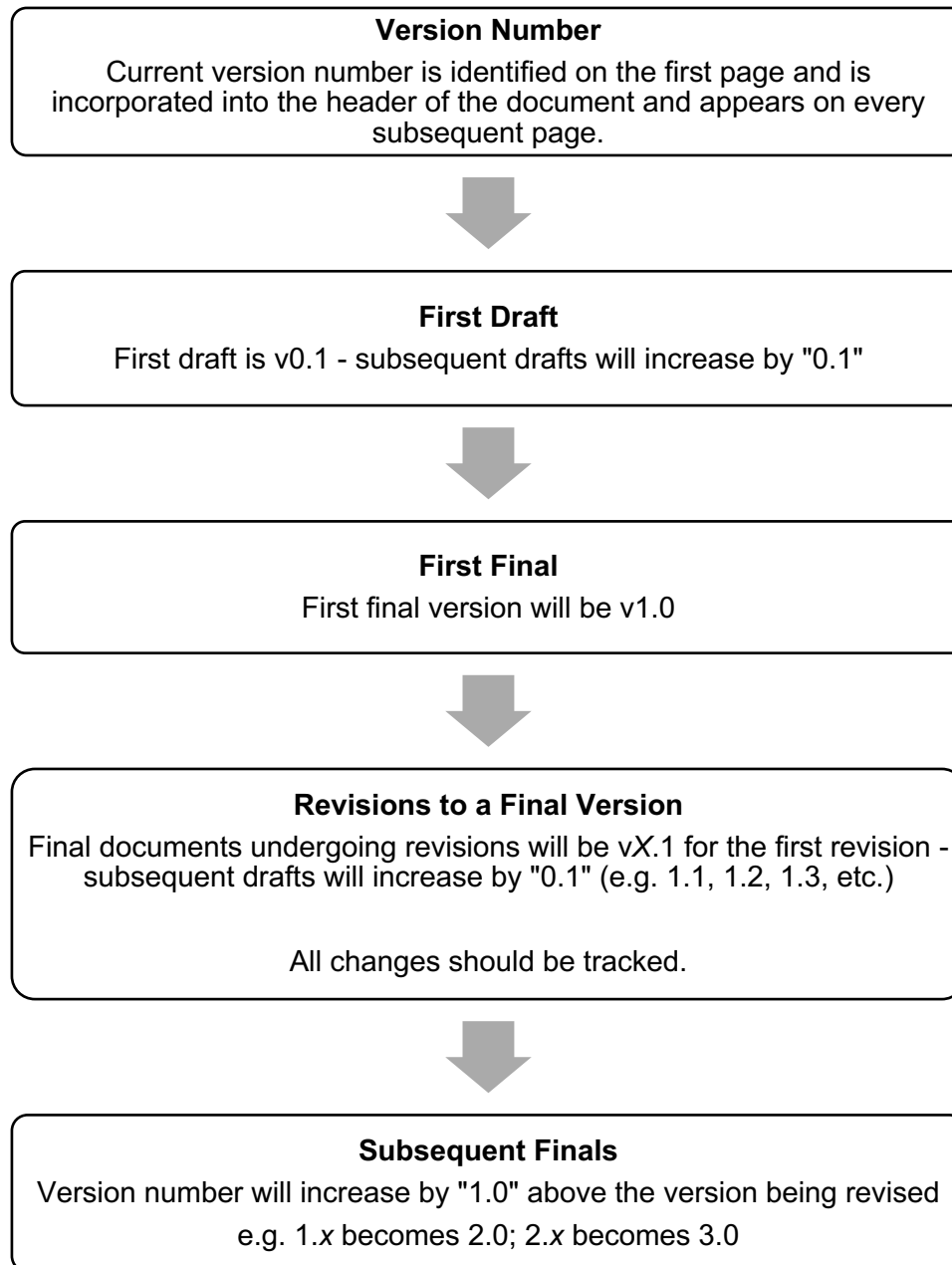
7.5.3 Final Document Version Number

1. The author (or Director) will deem an SOP or attachment final after all reviewers have provided final comments and the comments have been addressed.
2. The first final version of a document will be version 1.0 (v1.0). The effective date reflects the date of the final sign-off.
3. Subsequent final documents will have an increase of “1.0” in the version number (e.g. 2.0, 3.0., etc.).

7.5.4 Final Documents Undergoing Revisions

1. Final documents undergoing revisions will be version X.1 (vX.1) for the first version of the revisions.
2. While the document is under review, subsequent draft versions will increase by “0.1) (e.g. 1.1, 1.2, 1.3, etc.).
3. When the revised document is deemed final, the version will increase by “1.0” over the version being revised (e.g. the draft version 1.3 will become a final version 2.0).

7.6. Version Control Flow Chart



7.7. SOP Distribution and Communication

1. SOPs should be readily available to all personnel and other identified staff users.
2. Notify all personnel, management members, and other identified staff users of any new or revised SOPs. Direct users should be notified immediately of new/revised SOPs.
3. Provide training on new or revised SOPs. Document training as appropriate.
4. Retrieve outdated copies of SOPs and attachments and replace with updated versions.
5. Outdated SOPs, appendices and SOP indices should be archived.

7.8. SOP Storage

1. Designated individual responsible (SOP Administrator) for tracking and storage of SOPs should create and maintain a central SOP file.
 - a. Final, approved original and revised versions of each SOP.
 - b. One copy of the original and revised versions of each SOP appendix.
 - c. Original, signed SOP Review Records.
 - d. Copies of SOP training records
2. For electronic SOPs, final SOPs should be posted in a format that cannot be altered (e.g. .pdf format). Ensure that the electronic files are checked regularly and only current SOPs are referenced.

8. QUALITY CONTROL / QUALITY ASSURANCE

To promote quality of standards at C-BIG, existing SOPs are modified when a procedure has changed or are reviewed no less than every two (2) years. The SOPs should be



reviewed sooner if there are changes to regulations, guidelines, research practice, or institutional policies. See section 7.3 for 'Frequency of Revisions and Review'.

9. APPENDICES / FORMS

9.1. Appendix A – Standard SOP Template

9.2. Appendix B – Standard Operating Procedures Index

9.3. Appendix C – SOP Review Record



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