



ISO 9001:2008  
Certificate No. TUV 100 05 1782

# Bicol University College of Medicine - IRB

## 5. Writing and Revising Standard Operating Procedures

VERSION NO: 2  
EFFECTIVE DATE:  
July 4, 2014

### 5. Writing and Revising SOPs

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- Writing SOPs
- Revising SOPs

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| Supersedes:     |  |
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| Effective Date: | July 4, 2014                                   |
| Approved by:    | Jesson V. Butcon, RN., PhD, Chair of the Board |
| Approved by:    | Ruben Caragay, MD, PHD, Dean                   |
| Approval Date:  | July 4, 2014                                   |

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### 5.1. Purpose

To define the process for writing and revising SOPs used by the Bicol University College of Medicine Institution Review Board (IRB).

### 5.2. Scope

This SOP provides instructions on how the Bicol University College of Medicine IRB Standard Operation Procedures are prepared, approved and distributed.

### 5.3. Responsibility

It is the responsibility of the Chair of Bicol University College of Medicine IRB to appoint an SOP Team to formulate or revise the SOPs of the Bicol University College of Medicine IRB. The Chair designates the members of the team, initiate approval processing of final version of SOPs, and submit the SOP to the Bicol University College of Medicine IRB Chairman for final approval.

The SOP Team is an ad hoc committee composed of appointed IRB members with invited resource persons. The team is responsible for proposing and formulating new SOPs, and reviewing and revising existing SOPs when necessary. The team must follow existing procedures, format, and coding system of the hospital when drafting or editing any SOP's of the hospital, and consults the Secretariat and Chair about the need for new or revised versions of SOPs. The team submits SOP drafts to the Chair for approval processing.

The Secretariat is responsible for coordinating the writing and revising of SOPs, maintains current SOPs with a complete SOP list, ensures that all Bicol University College of Medicine IRB members have access to the SOPs and are working according to the current version of the SOPs.

Bicol University College of Medicine IRB members are responsible for reviewing and approving the drafts of new or revised SOPs in a full board meeting, keep a copy of complete SOPs, and perform their functions according to current SOPs.

The Bicol University College of Medicine Dean is responsible for final approval of all SOPs.

### 5.4. Writing SOPs

#### 5.4.1. Process Flow/Steps for New SOP

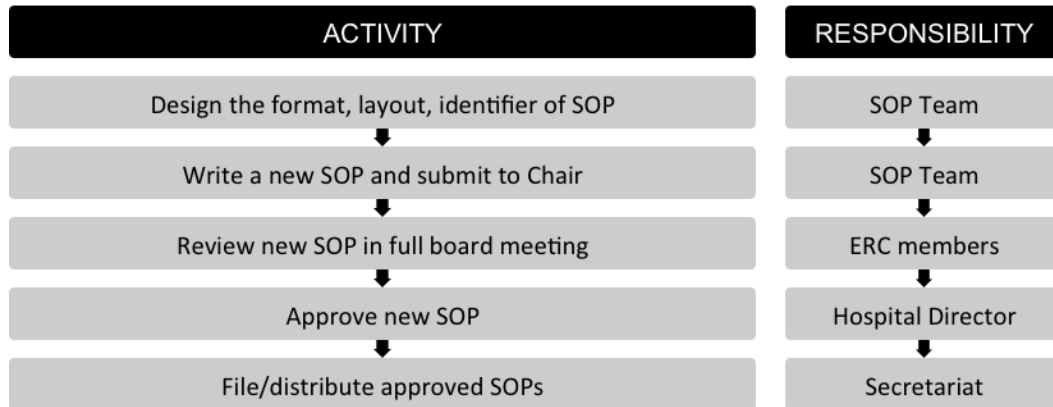


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### Detailed Instructions

#### 5.5. The Chair designates an SOP team

- 5.5.1. The Chair assigns members and non-members, as needed, to be part of the SOP Team
- 5.5.2. The SOP Team receives an orientation from the Chair regarding duties and responsibilities
- 5.5.3. The Chair can organize SOP Team workshops to facilitate the drafting of SOPs.

#### 5.6. The design the format and layout of an SOP is based on the following guidelines:

- 5.6.1. An SOP is written according to the following format:
  - Number and version
  - Title
  - Objectives of the SOP
  - Scope which includes description and purpose of the SOP
  - A flowchart when necessary
  - Detailed instructions
  - Glossary
  - References
- 5.6.2. Assign an identifier to the SOP  
Each SOP should be given a number and a title that is self-explanatory and is easily understood. For the Bicol University College of Medicine IRB SOPs, the following format is used: Bicol University College of Medicine IRB SOP XX/YY-ZZZZ where XX is a two-digit number corresponding to the chapter/section in the manual where the SOP is found. The YY is a two-digit number identifying the version of the SOP and ZZZZ is a four-digit number identifying the year of SOP was drafted or revised.

Thus, the SOP on writing of SOPs is identified as SOP 05.1/01-0-2012 meaning that this SOP can be seen in Chapter 5 of the SOP

## Bicol University College of Medicine - IRB

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manual (01), it is section 1 of Chapter 1 (01.1), it is the first version (01.1/01), and has no changes, (01.1/01-0) as of 2012 when it was drafted.

5.6.3. The layout of a typical SOP uses a header with the following elements:

- Institutional seal or logo
- Name of institution
- SOP identifier
- SOP title
- Effective date
- Page number

5.6.4. The SOP is introduced by a cover laid out as a typical SOP page with the following additional items included:

- Summary content after the title
- Institutional contact details (address, telephone numbers, facsimile number, email address)
- Date of the previous version; if not applicable, the date of previous issue is indicated by "N/A" (not applicable)
- Name of the authors/editors
- Approval information such as approving authorities and offices

**5.7. The SOP Team makes a draft of the SOP based on the design and format detailed above.**

5.7.1. The SOP Team submits completed draft to the Chair.

5.7.2. The Chair submits the draft to full board review where IRB members deliberate on the draft

5.7.3. Upon full board approval, the Chair submits the approved draft to the Dean for final approval.

5.7.4. The Bicol University College of Medicine Dean approves the SOP by signing in the appropriate section in the cover page.

5.7.5. The approved SOPs will be implemented from the date of approval by the Dean.

**5.8. File and distribute the SOP.**

5.8.1. Upon approval of Bicol University College of Medicine Chairman, the Secretariat distributes SOP to Bicol University College of Medicine IRB members, and publishes the SOP through the Hospital website.

5.8.2. The Secretariat distributes the printed copy of the approved SOPs to the Bicol University College of Medicine IRB members and staff; with an electronic copy published through the University website.

5.8.3. The Secretariat retains one complete originally signed SOPs copy.

**5.9. Revising SOPs**



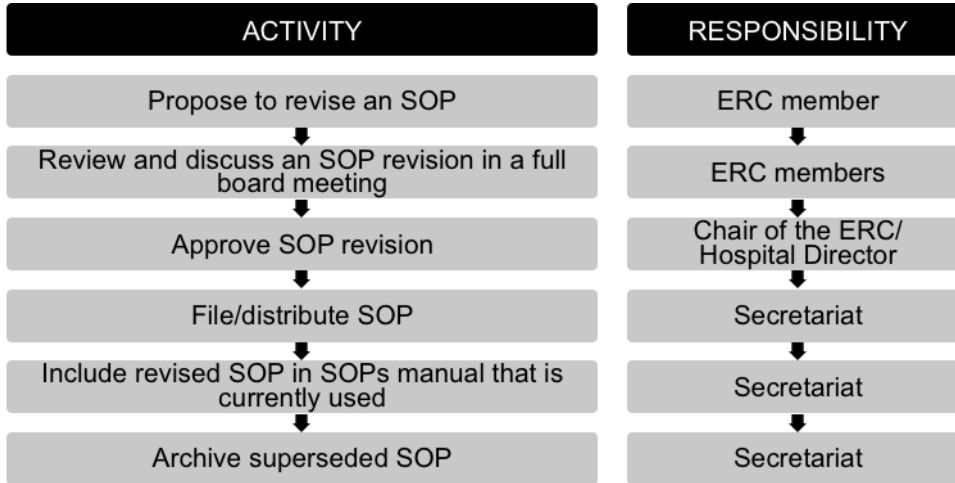
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### 5.9.1. Process Flow/ Steps



### Detailed Instructions

- 5.10. As the IRB sees fit, an existing SOP may be revised. A revision should be substantial (correction of grammatical errors is not considered substantial; a change in the identifier of an SOP is considered substantial). Minor changes refer to editorial, grammatical, or administrative changes that have no substantial effect on procedures. Major changes, on the other hand, are those that have a substantial effect on procedures, definitions, requirements, and similar considerations.
- 5.11. When an SOP is difficult to understand or does not cover what it should, a revision may become necessary.
- 5.12. When the need for a revision of SOP has been identified and agreed on, a draft will be written by a designated member of the IRB. A draft of the revised SOP will be discussed by the IRB members. The draft version will be reviewed by the Chair who will submit it to the Hospital Director for approval
- 5.12.1. Any member of the board may propose for the revision of the SOPs. Any proposal for revision must be written and submitted to the board for review, approval, coding, and inclusion into the document.
- 5.12.2. The proposal is discussed and acted upon through full board review.
- 5.12.3. The SOP team drafts the revision, noting that the SOP identifier reflects the chronological number and date of the revision. If an SOP supersedes a previous version, indicate the previous SOP version and the main changes in the historical form.
- 5.12.4. The Chair submits the draft to full board review where IRB members deliberate on the draft.

## Bicol University College of Medicine - IRB

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- 5.12.5. The Chair submits the approved draft to the Bicol University College of Medicine Dean for final approval.
- 5.12.6. The Bicol University College of Medicine Dean approves the revised SOP by signing on the appropriate section of the cover page.
- 5.12.7. The approved revised SOP will be implemented from the date of approval by the Dean.

#### **5.13. File and distribute the revised SOP**

- 5.13.1. Upon approval of Bicol University College of Medicine Dean, the Secretariat distributes revised SOP to Bicol University College of Medicine IRB members, updates the SOPs manual, and publishes the SOP through the University website.
- 5.13.2. The Secretariat maintains an updated SOP's manual in the Hospital, but retains the original manual in the archives.
- 5.13.3. The Secretariat distributes the printed copy of the approved SOPs to the Bicol University College of Medicine IRB members and staff; with an electronic copy published through the Hospital website.
- 5.13.4. The Secretariat retains one complete originally signed SOPs copy.

#### **5.14. Archive superseded SOP**

- 5.14.1. The Secretariat archives the superseded version of the SOP in the historical file maintained by the Bicol University College of Medicine IRB
- 5.14.2. Superseded SOPs are clearly marked "superseded" with the year of archiving stamped in the cover page.