James Hogg iCAPTURE Centre for Cardiovascular and Pulmonary Research

STANDARD OPERATING PROCEDURE

Title:	**Procedures and Associated Forms**		
Procedure:	BB.005.01	**Supercedes:**	none
Originator and Date:	Lise Matzke 21OCT2008	**Effective Date:**	21OCT2008
Review Frequency:	annually	**Approved By:**	The iCAPTURE Centre Privacy Team
Total Number of Pages: 15			

Revision History		
Date	**Reviewer**	**Summary of revision**
20Apr2009	Crystal Leung	Reformatted to iCAPTURE format

Purpose

The purpose of this procedure is to provide instructions for the creation, review, approval, implementation, periodic review, inactivation, control and use of Standard Operating Procedures (SOP) and associated forms used and maintained by the iCAPTURE Biobank.

Responsibilities

This procedure is applicable to Biobank specific initiatives. Other SOPs may be accepted by the Biobank Team.

Definitions

Associated Form	Any form that is used as a quick guide to the user for a certain procedure. This also includes forms that the user may fill out and file during the procedure.
CAF	Change Action Form

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Management	The Manager or Team Lead responsible for reviewing and approving procedures and associated forms.
Quality Assurance (QA)	Biobank staff responsible for ensuring that the composition or revision of SOPs follow BL-SOP-01 and other applicable SOPs and external standards.
Reviewer	Reviewers are content/subject matter experts and in a senior position of the division or area affected. Most often this is the Team Lead.
SOP	Standard Operating Procedure. Document used to control the method and requirements by which the involved parties will perform their activities.
SOP Manager	Biobank staff responsible for signing off on all SOP documents, archiving original SOP documents and managing accessibility through the web portal.

User Responsibilities

User responsibilities for procedures

- The user will retrieve the most current version and follow the procedure as written.

Note: Procedures that are printed are uncontrolled copies and are considered to be for reference use only. All printed copies are to be discarded when no longer in use.

User responsibilities for associated forms

- Retrieve the most current version.
- Provide the required information requested on the form.
- Submit or file the form as appropriate.

Author(s) Responsibilities

The author(s) will:

- Gather all the relevant information for the creation or revision of SOP.
- Compose or revise the SOP following the formats and process issued in BL-SOP-01.
- Incorporate any changes that have been submitted in an approved CAF.
- Submit SOP for review once the changes have been made.
- Determine the appropriate Reviewer(s) and Approver(s).

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Reviewers Responsibilities

The content/subject matter expert reviewer will ensure that the procedure or associated form:

- Meets the requirements of this and relevant procedure(s)
- Provide content that is consistent with other areas
- Incorporates the information as stated in the approved CAF
- Is accurate, easily understood, and can be followed as written

Quality Assurance Responsibilities

Quality Assurance personnel are designated by the SOP Manager in their area of work and are responsible for

- Reviewing all submitted SOP revisions from their area ensuring that they are consistent with BL-SOP-01 and that they do not conflict with pre-existing SOPs.
- Ensuring that any outstanding audit or due diligence commitments have been addressed in the new or revised SOP.
- Ensuring that the new or revised SOP is compliant with any applicable external standards.
- Ensuring that SOPs are reviewed every year.

SOP Manager Responsibilities

The SOP Manager is responsible for:

- All the Quality Assurance issues listed above.
- Communicate the implementation of new SOPs to Biobank members affected by the changes.
- Manage the SOPs on the web portal such that they are current and available.
- Coordinate changes to SOPs during the lifetime of the document.
- Chair or designate a chair for SOP committee meetings.
- Provide final approval of new or revised SOPs.
- Approve CAFs.

Creating a New Document

Composition

Any member of the Biobank team can initiate the creation of a new SOP or associated form with the following steps:

- Assemble a composition team that will include a minimum of:
    - A lead author
    - QA representative
- The composition team will:

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  - Gather and document all necessary information to create the procedure or associated form.
  - Organize the content of the procedure or associated form.
  - Identify training needs.
  - Ensure all review requirements are met by the procedure.
  - Network with other areas to ensure that the procedure can be implemented as written.
- Once the procedure or associated form has been written the lead author will then:
  - Route for review and ensure that all parties are satisfied with the changes made.
  - Ensure that the procedure or associated form is written in compliance with the requirements of this procedure.
  - Escalate any unresolved issues to Management.

Reviewing

Once the new SOP and associated forms are composed, the lead author will initiate the review process by routing the following to each reviewer:

- Procedure
- All associated forms
- Approved change proposal
- Initial documents if they are available

Determining the Reviewers of a Procedure or Associated form

The lead author will follow the table below to determine the Reviewers. If any position is open at the time of review, the individual at the next highest level will complete the review.

Areas Involved	Minimum Reviewers
1	• Content/subject matter expert • Quality Assurance representative
2 or more	• Content/subject matter expert • Senior staff from each of the areas involved • Quality Assurance representative

Note: In some cases the content/subject matter expert and management and or senior staff may be the same individual.

Review period

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The review period should be no more than four weeks unless otherwise stated by the BC Biobank Executive.

Handling unresolved issues
If issues cannot be resolved during the normal review process, the reviewer will escalate the issue and bring it to the Biobank team.

Approval requirement

- The procedure or associated forms must be approved by all specified approvers before it can be made effective.
- The quality assurance representative will approve the procedure or associated forms only after all other approvals have been obtained.

Approvers
The lead author will use the following list to determine the required approvers. If any required approver position is open at the time of approval, the approval will be completed by the individual at the next highest level within the Biobank.

- Lead author
- Team Leads from each affected area
- SOP Manager
- Quality Assurance representative

Initiating approval
The lead author will initiate the approval process by routing the following to each required Approver.

- Procedure or associated form
- Documentation of comments during the review process
- Approval Form

All of the above approvals must be obtained by the lead author before routing the following to Quality Assurance representative

- All of the documents listed above
- All completed Approval Forms

Approver responsibilities
All approvers are responsible for:

- Verifying that the process for writing and reviewing the procedure or associated form has been followed and all documentation is complete and accurate.
- Ensuring that all comments have been appropriately addressed and the information, as stated in the documentation of comments, is incorporated in the procedure or associated form.
- Indicating either approval or disapproval of the procedure or associated form

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    - When disapproval is indicated, documentation for the reason should be included on or attached to the approval form.
- Completing and returning the completed Approval form to the submitter by the due date.

Handling disapprovals

If any Approver has disapproved the procedure or associated form the lead author will:

- Review the comments with the composition team.
- Make the required changes to the procedure or associated form, highlighting the changes.
- Re-route all relevant documentation for review and approval.

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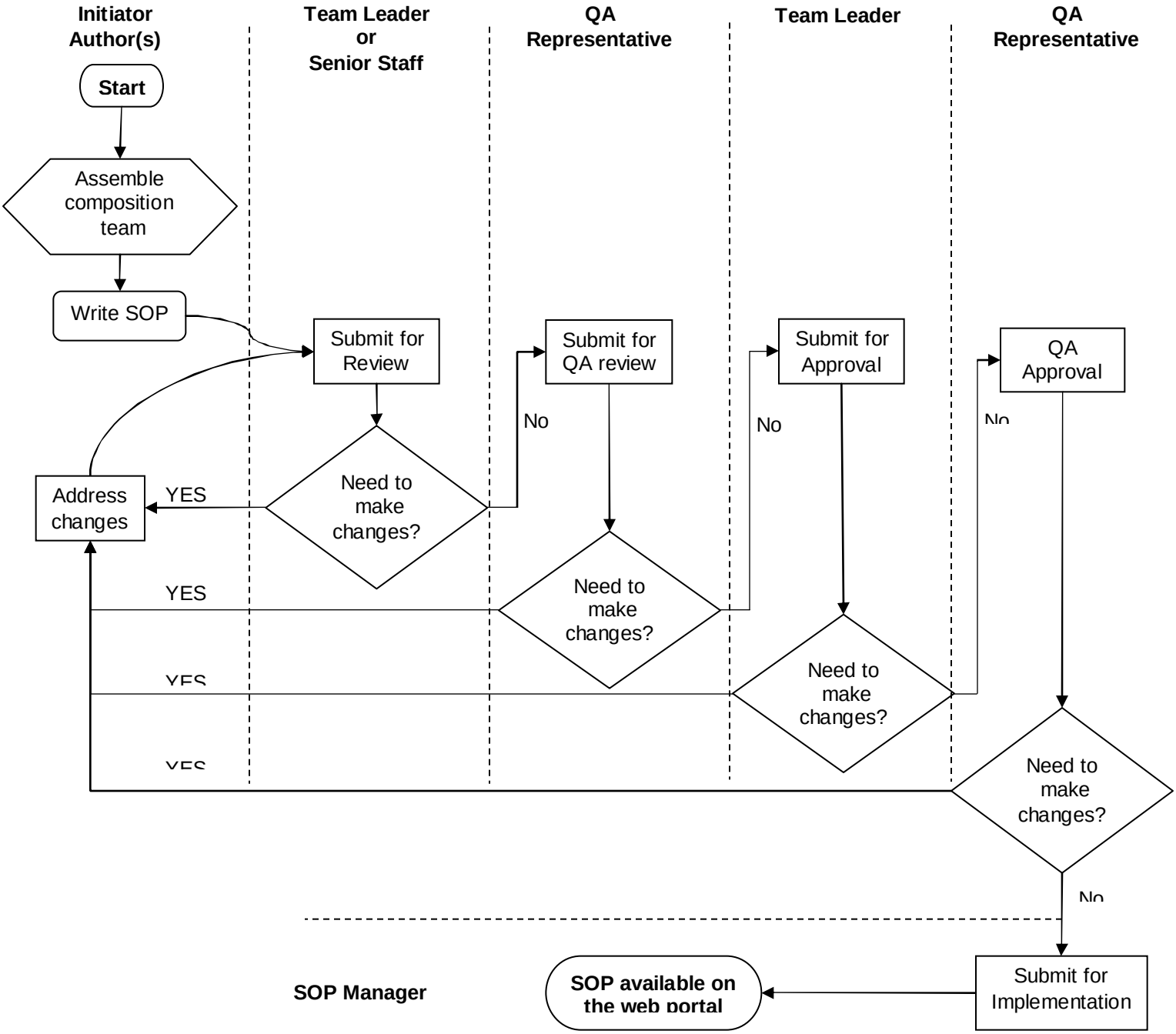
Creating a new SOP Overview



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Submission to the SOP manager

Once the SOP has undergone the final approval process, the original document will be archived and made available on request to the Biobank Manager. The SOP manager will also ensure that all team members are appropriately trained and aware of any changes in SOP.

Change Initiation

Suggesting a change

Any member of the Biobank team can suggest the revision or inactivation of a procedure or associated form by completing a "Change Action Form" (CAF) located on the web portal and submitting it to the SOP Manager. Once the CAF is approved and archived the SOP manager will notify the initiator. It is up to the discretion of the SOP manager whether an SOP should be immediately removed from the web portal during its revision and approval process or not.

Note: If any changes made to the procedure or associated form were not covered in the original change proposal, the lead author will bring the recommended changes to the BC Biobank Executive where approval for the new changes can be obtained

Processing a CAF

Upon receipt of a CAF the SOP manager will:

- Review the CAF.
- Clarify the provided information if necessary.
- Should the change proposal need further discussion, elevate the issue to the BC Biobank Executive.
- Approve the CAF and notify the initiator.
- Archive the CAF in a local file.

Editing and Approval of SOP

Once the CAF has been approved, editing of SOP goes through the same process as with creating a new SOP described on page 9.

Periodic Review

SOPs will be reviewed every year on the renewal date of the original use date. The review process in this case will be initiated by the QA representatives.

Inactivation

Inactivation of an SOP can only occur once a CAF form has been approved which describes the reasons for its inactivation.

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Once the inactivation has been approved the SOP Manager will continue the process by setting a date set at their discretion.

To complete the inactivation the SOP Manager will:

- Remove the SOP from the web portal so as to make it unavailable to users
- Send a change notification to all potential users of the SOP
- Retain a copy of the original CAF

Implementation

Upon notification of the approved changes to a pre-existing or the creation of a new SOP the SOP Manager will:

- Ensure that the following statement, centered, in the footer is added: "Printed Copies are not Controlled"
- Import the electronic version of the SOP or associated form in PDF format into the Web portal.
- Add the effective dates as appropriate

When the procedure or associated reaches the effective date the SOP Manager will ensure that:

- The SOP or associated forms are available to users
- Notify all users of any training associated with the new changes.

Formatting Requirements for Procedures

All procedures will contain the following information in the order listed below:

Procedure number	The procedure number will be located on each page in the header, aligned right and will: • Be unique to each procedure • Be assigned by the SOP Manager • Consist of a prefix from the table describing the affected teams, "SOP", a two-digit procedure number and a two-digit approved revision number. Each revision number will be a sequential whole number (e.g. BL-SOP-01-01)
Page Number	The page number will be located in the footer, aligned right, and will appear on every page and reflect the total number of pages.
Title	The title is located on the top of the first page and will be descriptive of the procedure's content. The same title will also be included in the footer, aligned left.
Supersedes	The phrase is "This is the first revision' will appear in this section if the procedure is new. Otherwise the superceded procedure number will be added.

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Effective Date	The effective date will: • Be set to allow time for user training • Be listed as "draft" until approval has be received • Be entered after approval has been received by the SOP manager
Periodic Review date	The periodic review date will: • Be listed as "draft" until a periodic review date is determined. A maximum of one year can be set. • Be entered after approval has been received and the effective date set.
Purpose	The purpose will state why the procedure was written and/or why the procedure is needed.
Area involved	This section will contain: • "This procedure is applicable to the following teams:" • A list containing team numbers of all areas required to follow the procedure
Reasons for revision	This section will contain **one** of the following; • "This is the ___ revision of this procedure" • Detailed description of the revisions for minor revisions • "This procedure has been revised in its entirety" for major revisions. If it deemed appropriate by the SOP manager and/or the composition team, a list of the major revisions may follow this statement.
Table of contents	This section will contain: • A table with the first topic being the *Definitions* section • The starting page of each section
Definition	This section will contain: • A list of terms specific to the procedure followed by their definition.
Body of the procedure	The body of the procedure will: • Be divided into topics and sub topics • Have language and sufficient detail to make the procedure practical to the user • Address roles and responsibilities

Formatting Requirements for Approval Page

The approval page will include:

- The same header and footer as the procedure.
- "Procedure Approval Form" as the form title.
- Procedure title.
- Supercede information.

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- Effective date.
- Periodic date.
- A list of all the approvers including their printed name, title within the Biobank Team, signature and date.

Note: The approval form will only be kept in the archives with original copy and will not appear on the web portal.

Formatting Requirements for Associated Forms

Form format	All forms will contain the following information in the order listed below
Form number	The Form number will be located on the header of each page aligned right and will: • Be unique to each form • Be assigned by the SOP manager • Consist of the affected team code, the **"FORM"** prefix, the associated SOP number, a one letter indicator identifying the form, and a two digit revision number. Each approved revision of a form will be sequential whole number. Example: BL-FORM-01-A-01
Page number	The page number will be located in the footer, aligned right, and will appear on every page and reflect the total number of pages.
Title	The title will be located on the top of the first page, centered, and will be descriptive of the form's content. The same title will also be included in the footer, aligned left.
Supercedes	The phrase is "This is the first revision' will appear in this section if the form is new. Otherwise the superseded form number will be added.
Effective Date	The effective date will: • Be listed as "draft" until approval has be received • Be entered after approval has been received by the SOP manager
Body of the form	The body of the form will: • Have language and sufficient detail to make the form practical to the user. • Contain secure fields which will not allow the user to change the content of the form, only enter requested information.

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Document Control

Primary files for procedures and associated forms will be stored in two places, both of which have controlled and limited access:

- The local archive – electronic copy on the James Hogg iCAPTURE Centre network and pdf/hard copy on file with the Biobank Manager.

Content of Local Archives	The Local Archives will contain an electronic and hard copy of: • The document sent for each review and/or approval for current, superceded and inactivated procedures and associated forms • Completed Approval forms • Completed Inactivation documentation if applicable • Documentation of comments if applicable

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Appendix I
Change Action Form

Note: The Change action form is available on request from the Biobank Manager.

SOP #	**Area code-SOP - SOP ## - Revision ##**
Title:	
Description of requested changes:	

Requester's Printed name		**Signature**		**Date(DD-MM-YR)**
Approver's printed name		**Signature**		**Date(DD-MM-YR)**

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Appendix II
Procedure Template

Note: The procedure template is available on request from the Biobank Manager.

Title:	**Insert Title Here**		
Procedure:		**Supercedes:**	none
Originator and Date:	Lise Matzke 21OCT2008	**Effective Date:**	21OCT2008
Review Frequency:	annually	**Approved By:**	The iCAPTURE Centre Privacy Team
Total Number of Pages:			

Revision History		
Date	**Reviewer**	**Summary of revision**

Purpose

State why the procedure was written and/or why the procedure is needed.

Areas involved

This procedure is applicable to the following teams:

•	•

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Definitions

SOP	Standard Operating Procedure. Document used to control the method and requirements by which the involved parties will perform their activities.

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