STANDARD OPERATING PROCEDURE
CONTROLLED DOCUMENT REVIEW

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Site Approval/Authorization to Adopt

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Document History

Version	Summary of Changes Made	Effective Date
1	Original document.	20-JUL-2017

1. PURPOSE

1.1. The purpose of this document is to outline the review periods for a range of Controlled Documents developed by VCHRI, and describes the process by which documents are reviewed and updated at regular intervals to ensure that they remain accurate and relevant to current standards of practice and regulatory requirements.

2. SCOPE

2.1. The procedure outlined in this SOP applies to any Controlled Document developed by VCHRI and adopted by a Qualified Investigator/Investigator or Sponsor-Investigator and their research team members for Clinical Trial/Study Site use at Vancouver Coastal Health Authority.

3. RESPONSIBILITIES

3.1. VCHRI Quality Assurance (QA) is responsible for overall maintenance of VCHRI Controlled Documents in accordance with this SOP.

3.2. VCHRI Core Committee is responsible for identifying and appointing Content Reviewers.

3.3. Content Reviewers are responsible for reviewing each document to:

- Ensure that the procedures and processes meet current regulatory requirements,
- Ensure that the procedures and processes are accurate and adhere to best practices,
- Identify materials that require further review or revision, and
- Detect and correct potential errors.

4. RELATED SOPS/DOCUMENTS

4.1. VCHRI SOP 201: Change Order Request – VCHRI Controlled Document
4.2. VCHRI SOP 021: Document Versioning and Approval
4.3. VCHRI FORM F204: *Document Review Form*
4.4. VCHRI FORM F203: *Change Order Approval Form*

5. DEFINITIONS

5.1. **Approval:** The formal signed and dated acknowledgement by an authorized individual that indicates a Change Order request was evaluated and accepted for implementation.

5.2. **Current Version:** The version of a document with the most recent date of Approval. This version supersedes all preceding versions.

5.3. **Content Reviewer:** An individual who is qualified by experience, skills, and training, and whose opinions are sought by VCHRI to review and approve the proposed document changes related to their specific area of expertise.

5.4. **Controlled Document:** A document that through the course of its lifecycle is reviewed, updated (amendment tracking), re-approved, and distributed several times. Earlier versions of the document must be retained in archive for reference and the history of the document tracked. Examples of Controlled Documents in clinical research at VCHRI are institutional-level research policies, research Standard

Operating Procedures (SOPs), guidance documents, and the associated forms and templates, which are written specifically to satisfy regulatory and institutional requirements.

For the purposes of this SOP, the term document refers to a controlled document, unless specifically stated otherwise.

5.5. **Document Management Log:** A log used to track and manage various versions of Controlled Documents created and modified by VCHRI.

5.6. **Effective Date:** The date that the new document version is placed into circulation and considered to take effect. Note that the Effective Date may be different from the Approval date. Effective Date may follow Approval date to allow time for staff training after the document has been approved.

5.7. **Obsolete Document:** Any document removed from circulation and not replaced with a new version because it is no longer relevant to current practices.

6. PROCEDURE

6.1. TYPES OF DOCUMENTS

6.1.1. The following are *Institution-level* Controlled Documents reviewed and maintained by VCHRI:

Document Type	Review Period
Research Quality Policies	Once every two years, or as required.
Institutional Research Policies	Once every two years, or as required.
Institutional Clinical Trials/Research SOPs	Once every two years since the last document update.
Research Guidance Documents	Once every two years since the last document update.
Research Forms and Templates	Once every two years since the last document update.
Research Quality Management System SOPs	Once every two years since the last document update.
Research Quality Management System Manual	Once every two years, or as required.

6.2. Initiating the Review

6.2.1. VCHRI QA compiles all latest versions of documents with Effective Dates older than two (2) years. A unique reference number will be assigned for each document to be reviewed.

6.2.2. VCHRI QA completes section 1 of FORM F204: *Document Review Form*, and prepares a draft file version of the document for review (for versioning procedure refer to SOP 021: *Document Versioning and Approval*).

6.2.3. VCHRI QA submits the following documents in electronic format to the appointed Content Reviewer(s):
1. FORM F204: *Document Review Form* (for each document),
2. The review document in PDF (a Word document can be requested), and
3. A copy of FORM F201: *Change Order Request Form* - to be used if changes are requested.

6.3. **Providing Reviewer Feedback**

6.3.1. The Content Reviewer completes FORM F204: *Document Review Form* electronically. On section 2 of the form, the Content Reviewer indicates in their opinion whether the document:
- Does not require revision (option A), or
- Requires revision (option B), or
- Needs to be made obsolete (option C).

6.3.2. If a new document should be developed, in the opinion of the Content Reviewer, in order to address a gap in the existing processes or standard operating procedures, the reviewer indicates this on FORM F204: *Document Review Form* (section 2 option D).

6.3.3. In determining whether the document requires revision the Content Reviewer should consider the following:
- Does the procedure accurately reflect current standards of practice?
- Do references require updating due to changes in regulations or policy in research?
- Are compliance requirements being met?
- Is the scope of the document too restrictive to a specific type of research?
- Are the responsibilities specific and accurate?

6.3.4. If the document should be revised or made obsolete, the Content Reviewer must include the justification and, as required, the supporting information in section 2 of FORM F204: *Document Review Form*.

6.3.5. The Content Reviewer returns all the completed forms with their feedback (and supporting information) by email to VCHRI QA.

6.3.6. Once received, the VCHRI Core Committee and VCHRI QA conduct an internal evaluation of feedback provided by the Content Reviewer(s).

6.4. **Documenting Approval**

6.4.1. **Document Does Not Require Revision**

6.4.1.1. If a document does not require revision, VCHRI QA completes Form F203: *Change Order Approval Form* Sections 1, 2, and 3, and closes the Review Reference Number on Section 7.

6.4.2. **Document Requiring Revision**

6.4.2.1. If a document requires revision per 6.3.4, VCHRI QA completes section 1 of Form F203: *Change Order Approval Form* to indicate that a revision is approved.

6.4.2.2. VCHRI QA prepares and provides the associated forms back to the Content Reviewer to initiate the change request process per SOP 201: Change Order Request, procedures 6.1.1 to 6.1.5. The Content Reviewer is now at this point the Requester (refer to VCHRI SOP201 Change Order Request) and must complete FORM F201: Change Order Request Form section 1.1 with the proposed revisions, and then submit the completed form back to VCHRI QA via email.

6.4.2.3. VCHRI QA assigns a Change Order # for the documents, reviews the submitted FORM F201: *Change Order Request Form*, and proceeds as per SOP 201: Change Order Request procedures 6.2.1 to 6.2.3, 6.3.1 to 6.3.3 and 6.4.1 to 6.4.4.

6.4.2.4. VCHRI QA fulfills the Content Reviewer responsibility in SOP 201 sections 6.3.2 to 6.3.3.

6.4.2.5. Finally a VCHRI Core Committee internal review is conducted.

6.4.2.6. The internal decision is recorded in section 3 of FORM F203: *Change Order Approval Form* indicating if the revision is:

- Approved or,
- Not Approved or,
- Needs further review (i.e., circulated for a second review per SOP 201 6.3.4).

6.4.2.7. Once the revision decision is made, VCHRI QA completes sections 6 and 7 of FORM F203: *Change Order Approval Form* in order to close the Change Order number and log the record on VCHRI database (Document Management Log.xls).

6.4.2.8. VCHRI QA then publishes the Approved revised document on the VCHRI website and, as appropriate, notifies the research staff of the new document version.

6.4.3. **Document Requiring Obsolescence and Starting a New Document**

6.4.3.1. The Content Reviewer has indicated a recommendation on the Form F204: *Document Review Form* either to make the current document obsolete (option C) or to draft a new document (option D).

6.4.3.2. VCHRI QA completes section 1 of FORM F203: *Change Order Approval Form* indicating either a new document is needed or the existing document is now obsolete.

6.4.3.3. VCHRI Core Committee conducts an internal review of the Content Reviewer's rationale to determine the impact of the proposed change(s) on other VCHRI's institution-level quality system documents. Names of VCHRI internal reviewers are entered in section 2 of Form F203: *Change Order Approval Form*. Finally, VCHRI QA indicates on FORM F203 section 3 the outcome of internal review whether the proposed revision(s) is:

- Approved or,
- Not Approved or,
- Requires further review (i.e., by external subject matter expert).

6.4.3.4. If further review is needed, VCHRI QA completes sections 4 and 5 to indicate further review is needed and the approval decision on FORM F203: *Change Order Approval Form*, then forwards a new FORM F202: *Change Order Review Form* to the assigned Content Reviewer(s).

6.4.3.5. Final determination is made by VCHRI QA whether to approve or not approve the proposed review change(s).

6.4.3.6. VCHRI QA signs FORM F203: *Change Order Approval Form* to close the Change Order number and updates the Document Management Log on the VCHRI's internal network drive.

7. REFERENCE(S)

7.1. Clinical Trials BC SOP (formerly BC Clinical Research Infrastructure Network) – Controlled Document Review

8. ATTACHMENT(S)

VCHRI FORM F204: *Document Review Form*

Vancouver CoastalHealth Research Institute

HEALTHIER LIVES THROUGH DISCOVERY

DOCUMENT REVIEW FORM

REVIEW REFERENCE # _____ *(issued by VCHRI QA)*

Reviewer Name: _____ **Reviewer Title: _____**

1. DOCUMENT INFORMATION

Date Review Initiated (yyyymmdd):	
Date to be Returned to VCHRI QA (yyyymmdd):	
Document Type:	
Document Number:	
Document Title:	
Document Version:	

2. REVIEWER FEEDBACK (once completed, pls. return to VCHRI QA by email: patrick.altejos@vch.ca)

Review Outcome	Action for Reviewer
A. No Revision Required ☐	Return Document Review Form to VCHRI QA
B. Document Requires Revision ☐	Explain below reason for change. Refer to SOP201 Change Order Request. Complete the applicable sections of FORM F201: Change Order Request form
C. Document to be made Obsolete ☐	Explain below reason for obsolescence
D. New Document Required ☐	Explain below why a new document is required

If you chose B, C, or D briefly explain why a revision, obsolescence or a new document is required:

3. VCHRI INTERNAL REVIEW

For Review	QA Action	
No Revision Required	Complete FORM F203: Change Order Approval Form, then update Document Management Log	☐
Document Requires Revision	Refer to SOP202 Controlled Document Review Section 6.4.1 for next steps, then update Document Management Log	☐
Obsolete a Document or Create New Doc.	Complete FORM F203: Change Order Approval Form, then update Document Management Log	☐

CLEAR FORM SUBMIT FORM