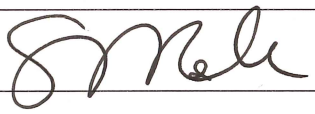
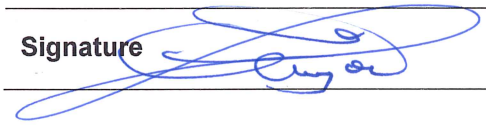
STANDARD OPERATING PROCEDURE

CHANGE ORDER REQUEST - VCHRI CONTROLLED DOCUMENT

SOP Number	201
Version Number	Version 1
System Level / Applicable to	Vancouver Coastal Health Research Institute Clinical Trials/Studies, Sponsor-Investigator Initiated Studies
Supersedes	Not Applicable
Effective Date	20-JUL-2017
Number of Pages (including cover)	7

Site Approval/Authorization to Adopt

Name	Stephania Manusha	**Title**	Director, Clinical Trial Administration
Signature		**Date**	July 20, 2017
Name	Patrick Altejos	**Title**	Coordinator, Research Quality
Signature		**Date**	July 20, 2017
Name		**Title**	
Signature		**Date**	
Name		**Title**	
Signature		**Date**	

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 describe the procedures for managing a Change Order request to a VCHRI Controlled Document. Compliance with this procedure ensures that each change proposed is adequately defined, reviewed, analyzed and documented before implementation.

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. The VCHRI Quality Assurance (QA) or designate, is responsible for:

- Ensuring Change Order requests are coordinated through proper review and Approval processes as outlined in this SOP,
- Convening the VCHRI Core Committee,
- Modifying the correct version of document(s) for review and approval by Core Committee, and as appropriate the Content Reviewers,
- Resolving issues during the course of a review,
- Verifying and providing impact assessment of proposed change(s) to existing documents and/or the quality management systems, as necessary.
- Setting the Effective Date for new or revised document versions, and
- Final Approval of documents.

3.2. The Requester is any research staff conducting a Clinical Trial/Study at Vancouver Coastal Health Authority that initiates the Change Order request of an institution-level Controlled Document (ex. VCHRI SOP or guidance document). The Requester is responsible for completing FORM F201: *Change Order Request Form* and submitting the completed form to VCHRI QA.

3.3. VCHRI Core Committee is responsible for:

- Appointing Content Reviewers,
- Assessing impact on existing associated institutional processes/systems or procedures, and
- Completing the final review and Approval process.

3.4. The Content Reviewer is responsible for timely review and feedback to ensure that the change(s) requested meet the requirements of VCHRI, reflect current good clinical practices for conducting Clinical Trials/Studies, and comply with the applicable regulations and institutional policies at Vancouver Coastal Health Authority.

4. RELATED SOPS/DOCUMENTS

4.1. VCHRI SOP 021: Document Versioning and Approval
4.2. VCHRI FORM F201: *Change Order Request Form*
4.3. VCHRI FORM F202: *Change Order 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. **Approval Date:** The date that the document has been approved prior to implementation. This date is the date of final signature by VCHRI QA on the FORM F203: *Change Order Approval Form*.

5.3. **Change Order (CO):** A formal process requesting changes in a Controlled Document in order to properly reflect the industry's current practices, policy and/or regulatory updates.

5.4. **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.

5.5. **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.

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

5.7. **Effective Date:** The date that the new document version is placed into circulation and takes 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.

5.8. **Institution:** The facility/site within Vancouver Coastal Health Authority where Clinical Trials/Studies are conducted.

5.9. **Requester:** Any Qualified Investigator/Investigator, Sponsor-Investigator, or research team member who uses VCHRI Controlled Documents and initiates a change on a document by making a Change Order request.

6. PROCEDURE

6.1. Requesting a Change Order

6.1.1. The Requester must download the FORM F201: *Change Order Request Form* on the VCHRI website, and complete the form electronically.

6.1.2. To revise the Current Version of a document, the Requester must enter the type (ex. SOP, Guidance, Work Instruction, etc.), number and version of the document to be revised.

6.1.3. The Requester must assess the impact of requested change on current standards of practice and institutional policies and procedures, consider whether the change complies with applicable laws and regulations, including Canada's Food and Drugs Act and Regulations, and provide the following information on FORM F201: *Change Order Request Form*:

- Document description and summary of change (page 1),
- Description of change(s) (page 2), describing each change and the reason for requesting the change, and
- Other VCHRI documents being used by the Requester's department that may be impacted by the change (page 3).

NOTE: Administrative changes (such as spelling and minor page formatting errors) do not need to be submitted through FORM F201. For Administrative changes, contact the VCHRI QA.

6.1.4. A separate FORM F201: *Change Order Request Form* must be submitted to VCHRI for each document that requires revision.

6.1.5. The Requester submits the completed FORM F201: *Change Order Request Form* to VCHRI QA by email, by following the submission instructions on the form. Provide references of supporting information for the change requested, such as applicable regulatory guidance document or institutional research policy.

6.2. **Evaluating the Change Order**

6.2.1. Once the completed electronic FORM F201: *Change Order Request Form* is received, VCHRI QA will assess the completeness of information provided and will conduct an impact assessment of proposed changes on existing procedures and processes described in other institutional-level Controlled Documents.

6.2.2. The impact assessment may identify other documents not used by the Requester's department, which may or may not need to be amended, as well. Each impacted document must be indicated in page 3 of FORM F201: *Change Order Request Form*.

6.2.3. If another document is impacted and needs to be amended as well, a separate FORM F201: *Change Order Request Form* should be completed for the document.

6.2.4. VCHRI Core Committee appoints the suitable Content Reviewer(s) based on breadth of experience, skills, and training related to the subject area regarding the proposed change.

6.2.5. VCHRI QA prepares electronic FORM F202: *Change Order Review Form(s)* and FORM F201: *Change Order Request Form(s)* along with any other necessary information for proper review of the document to assigned Content Reviewer(s).

6.3. **Reviewing the Change Order**

6.3.1. The appointed Content Reviewer reviews the entire Change Order review package provided by VCHRI QA, and provides feedback by completing the appropriate sections of the FORM F202*: Change Order Review Form*. Content Reviewer indicates if, in their opinion, the proposed change(s) should be approved or not approved.

6.3.2. Content Reviewer must indicate the specific reasons for approving as well as not approving ***EACH*** proposed change(s) on page 2 of the FORM F202: *Change Order Review Form*.

6.3.3. The Content Reviewer returns their feedback to VCHRI QA by email by submitting the completed electronic FORM F202: *Change Order Review Form* to VCHRI QA by email. If desired by the Content Reviewer, he/she may also submit the document with “track changes” in MS Word to show the recommended edits.

6.3.4. VCHRI QA along with Core Committee will evaluate the feedback received from the Content Reviewer(s). If a second-round review is deemed necessary, VCHRI QA indicates this on FORM F203: *Change Order Approval Form* and recirculates the Change Order review package for second round review as per steps 6.3.1 to 6.3.3. Appointed Content Reviewers for the second round may differ from those in the first round. Note: draft versions of the document will be controlled according to SOP 021: *Document Versioning and Approval*.

6.4. **Documenting Approval**

6.4.1. VCHRI QA and Core Committee review the document last and conduct the final evaluation to determine whether a document is approved or not approved.

6.4.2. Ad hoc meeting with all Content Reviewers may be scheduled to resolve issues that arise from the course of reviews or as a last step to finalize the review before Approval.

6.4.3. Once the reviews are completed and all issues have been resolved, VCHRI QA indicates the outcome and signs FORM F203: *Change Order Approval Form* in order to close the Change Order request with either Approval or No Approval for the change being requested.

6.4.4. Upon closure of the Change Order request, VCHRI QA ensures the following:

- If applicable, VCHRI QA prepares the updated version of the document for final signature and date, assigns proper document version controls and numbering (per SOP 021: *Document Versioning and Approva*l), and updates the document tracking history and Effective Date on the document,
- VCHRI QA publishes the Approved version of the document on the VCHRI website and sends notice of closure to the Requester, and
- VCHRI QA distributes the revised Current Version of the document to other staff, as required.

7. REFERENCE(S)

7.1. Clinical Trials BC (formerly BC Clinical Research Infrastructure Network) SOP - Change Control

8. ATTACHMENT(S)

VCHRI FORM F201: *Change Order Request Form*
VCHRI FORM F202: *Change Order Review Form*

CHANGE ORDER REQUEST FORM

(Completed by Requester)

Change Order # _____*(issued by VCHRI QA)*

1. VCHRI DOCUMENT INFORMATION

Please complete a separate Change Request form for each institutional document being revised. Examples of institutional documents are VCHRI Standard Operating Procedures (SOPs), VCHRI Guidance documents, VCHRI controlled Templates and Forms.

Name of Requester: _____

Research Department: _____

Document Type *Ex.SOP*	**Document Number** *Ex.001*	**Current Version Number** *Ex.01*	**Title** *Ex. How to Write an SOP*	**Revise**	**Make Obsolete** *VCHRI QA only*
				☐	☐

PLEASE SUMMARIZE THE PROPOSED CHANGE(S):

You may submit a draft MS Word copy of the document with your changes marked in 'track changes'. However Section 1.1 must be completed. Please email Patrick Altejos (patrick.altejos@vch.ca) to request for the MS Word file.

1.1 Document Changes

Describe each proposed change, explain why the change is required with supporting information from Regulatory Guidance documents, change in research policies, other VCHRI documents, etc. Please include deletions or additions that changes the meaning or intent of the document.

Change #	Document Page Number	Describe the Change	Reason for the Change
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

1.2 Impact on Other VCHRI documents being used by your department

Does the proposed change involve a change in other related VCHRI documents?

☐ **YES,** *in the table below please list the documents that are impacted and submit a separate change request form for each document listed*

✔ **NO**

Document Type *Ex.SOP*	**Document Number** *Ex.021*	**Title** *Ex. Document Versioning and Approval*	**Describe the impact of the change in other documents**

Submit completed form by email to patrick.altejos@vch.ca

CHANGE ORDER REVIEW FORM

Change Order # _____*(issued by VCHRI QA)*

Instructions for Reviewers:

Please review the document assigned to you to ensure that the proposed changes accurately reflect current standards of practice, and complies with applicable laws and regulations for the conduct of clinical research involving human subjects.

Once you have completed your review, please email this completed CO Review Form, to VCHRI QA by email to patrick.altejos@vch.ca.

REVIEW ROUND *(choose one)*

☐ **First Round Review**
☐ **Second Round Review**

Reviewer Name	Job Title	Date Review Completed

Please indicate why (or why not) the document should be made obsolete *(for obsolete documents only)*.

CLEAR FORM SUBMIT FORM

1. **Reviewer Response** *(for revised documents only)*

Entry # (corresponds to proposed changes in Change Request Form)	Reviewer Response	If Approve, please indicate additional reference to support the change, if applicable If Disapprove, please explain reason
1	☐ Approve ☐ Disapprove	
2	☐ Approve ☐ Disapprove	
3	☑ Approve ☑ Disapprove	
4	☐ Approve ☐ Disapprove	
5	☐ Approve ☐ Disapprove	
6	☐ Approve ☐ Disapprove	
7	☐ Approve ☐ Disapprove	
8	☐ Approve ☐ Disapprove	
9	☐ Approve ☐ Disapprove	
10	☐ Approve ☐ Disapprove	