

DOCUMENT VERSION CONTROL FOR REB SUBMISSIONS – GUIDANCE DOCUMENT

Version control is the process by which different versions of a document are managed. It is a tool which tracks a series of documents, culminating into the final Research Ethics Board (REB) approved version. This provides an audit trail for the revision and update of the finalized versions. Having the versions identified appropriately allows the development of the document to be easily understood and allows a return to previous versions to determine when decisions on content were made. It is also used to ensure which document is in force at a particular time.

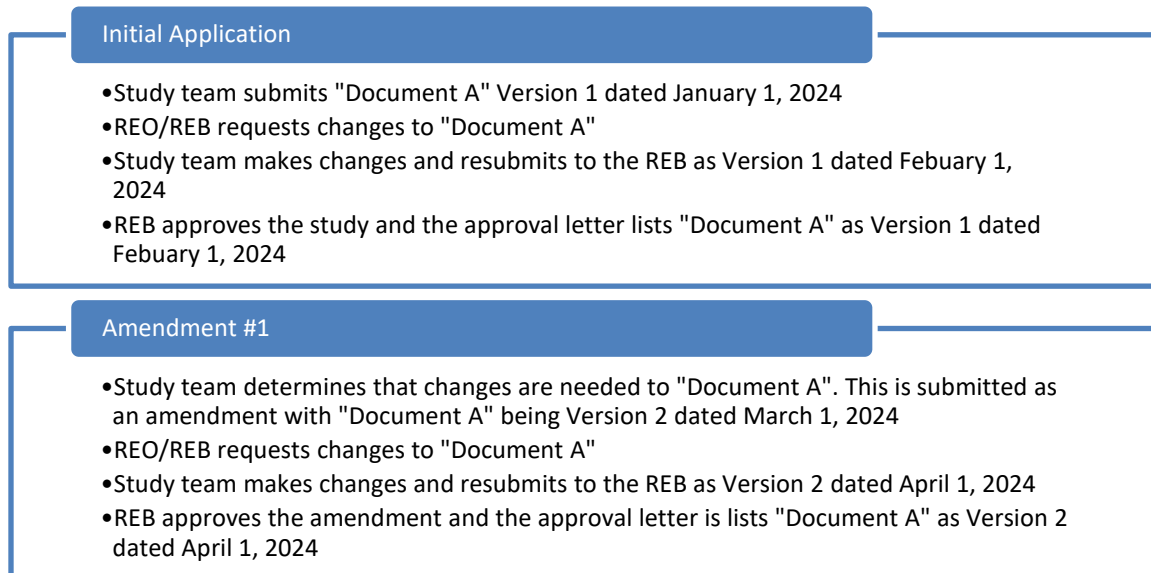
Version control should be used when more than one version of a document exists, or if there is to be more than one version in the future (i.e. protocols, recruitment materials, consent forms, data collection forms, etc.).

For eREB studies:

When submitting documents to the REB for the first time, both a version number and date should be included on the document (i.e in the footer of the document, etc.). If the Research Ethics Office (REO) or the REB requests revisions to the document submitted, the **resubmitted document should keep the same version number and only the date should be updated.**

Once REB approval has been granted for a document and the study team determines that changes are needed to the REB approved document, an amendment will need to be submitted. **When submitting the amendment , both the version number and date should be updated.** If the REO/REB requests revisions to this document, **the resubmitted document should keep the same version and only the date should be updated.**

See example below:



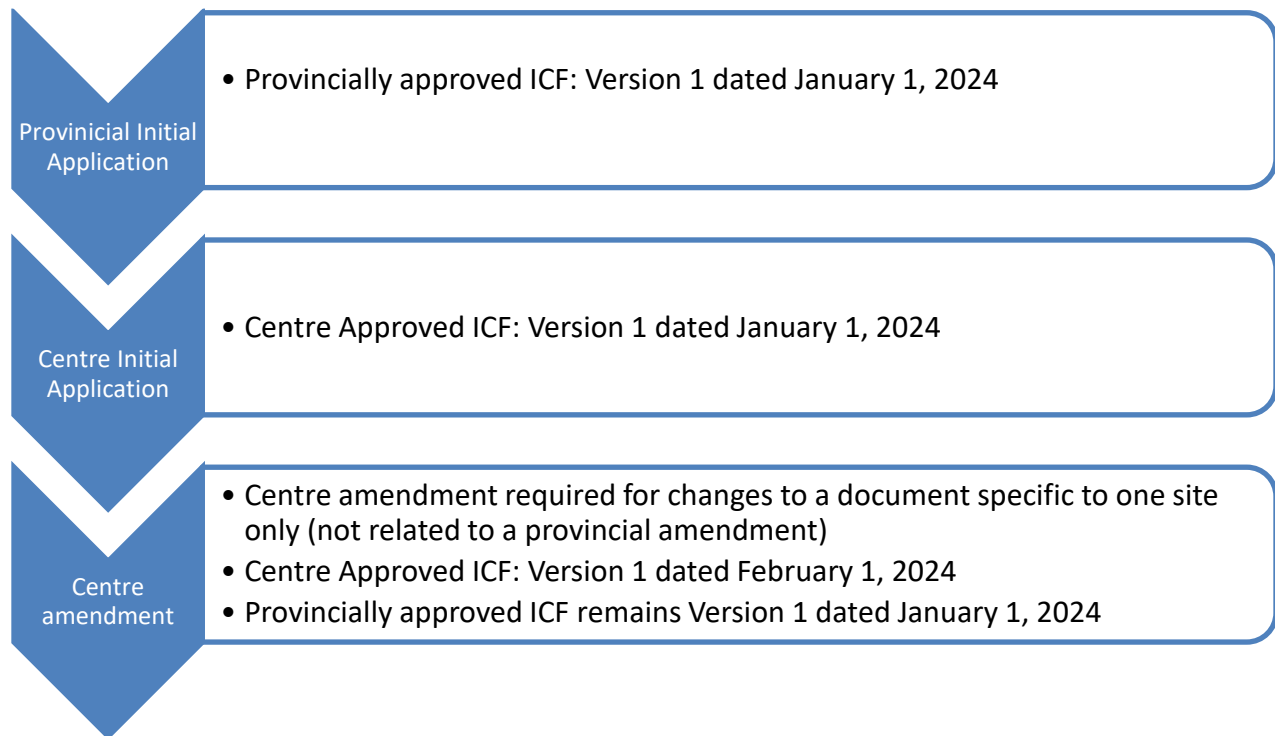
For CTO Studies:

For provincial applications, the same process as above should be followed.

For Centre applications where the only change in the Centre documents (e.g. informed consent form (ICF)) is the insertion of template language to the provincial documents (e.g. inserting Centre PI name/contact information, compensation amount in informed consent form) or addition of Documented Institutional Ethics Requirements (DIER), then **both the version number and date should match the provincially approved ICF.**

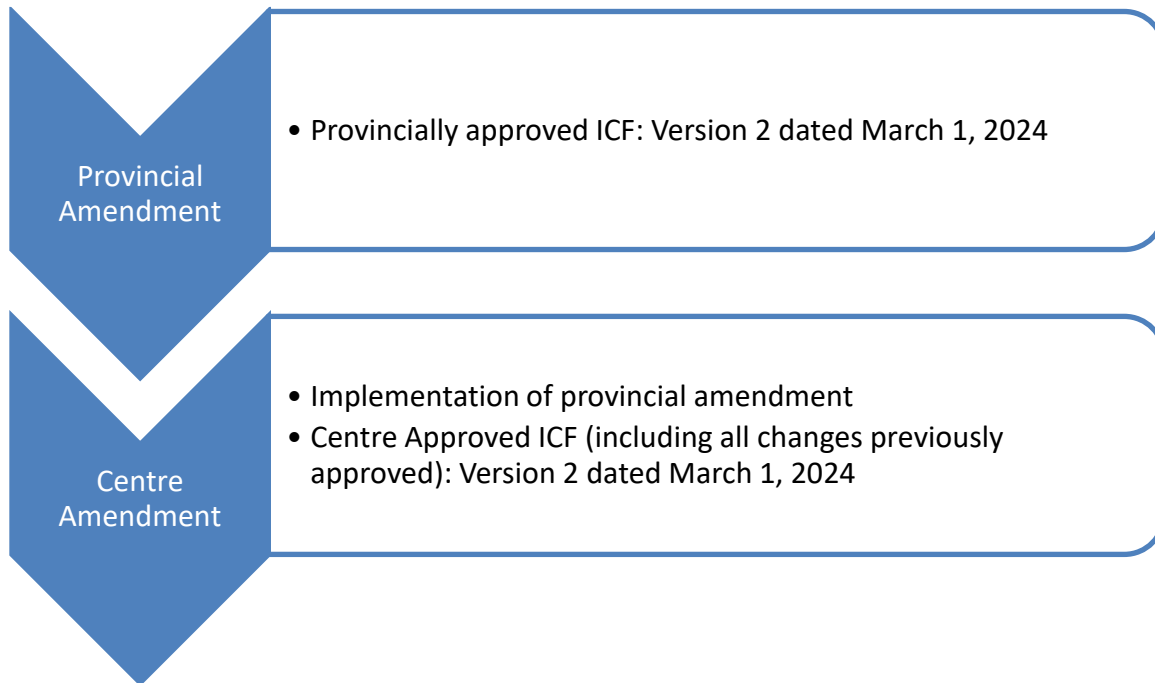
If there are subsequent Centre amendments that do not have a corresponding provincial amendment associated with it (e.g.. change in compensation amount at the site level, change in Centre PI, etc.), **then only the version date should be updated.** The version number should be the same as the provincially approved version.

See example below:



Subsequent provincial amendments will have a new version number and date listed on the documents.

Approved centres will submit a centre amendment that will incorporate all previously approved changes. See continuation of example below:



For more information or for any questions, please contact:

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