Holland Bloorview
Kids Rehabilitation Hospital

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.).

Note: This document does not apply to Standardized/validated documents which have their own versioning date/number. Include standardized/validated documents as separate attachments in the eREB application form.

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:

Initial Application

- Study team submits "Document A" Version 1 dated January 1, 2024
- REO/REB requests changes to "Document A"
- Study team makes changes and resubmits to the REB as Version 1 dated Febuary 1, 2024
- REB approves the study and the approval letter lists "Document A" as Version 1 dated Febuary 1, 2024

Amendment #1

- Study team determines that changes are needed to "Document A". This is submitted as an amendment with "Document A" being Version 2 dated March 1, 2024
- REO/REB requests changes to "Document A"
- Study team makes changes and resubmits to the REB as Version 2 dated April 1, 2024
- REB approves the amendment and the approval letter is lists "Document A" as Version 2 dated April 1, 2024

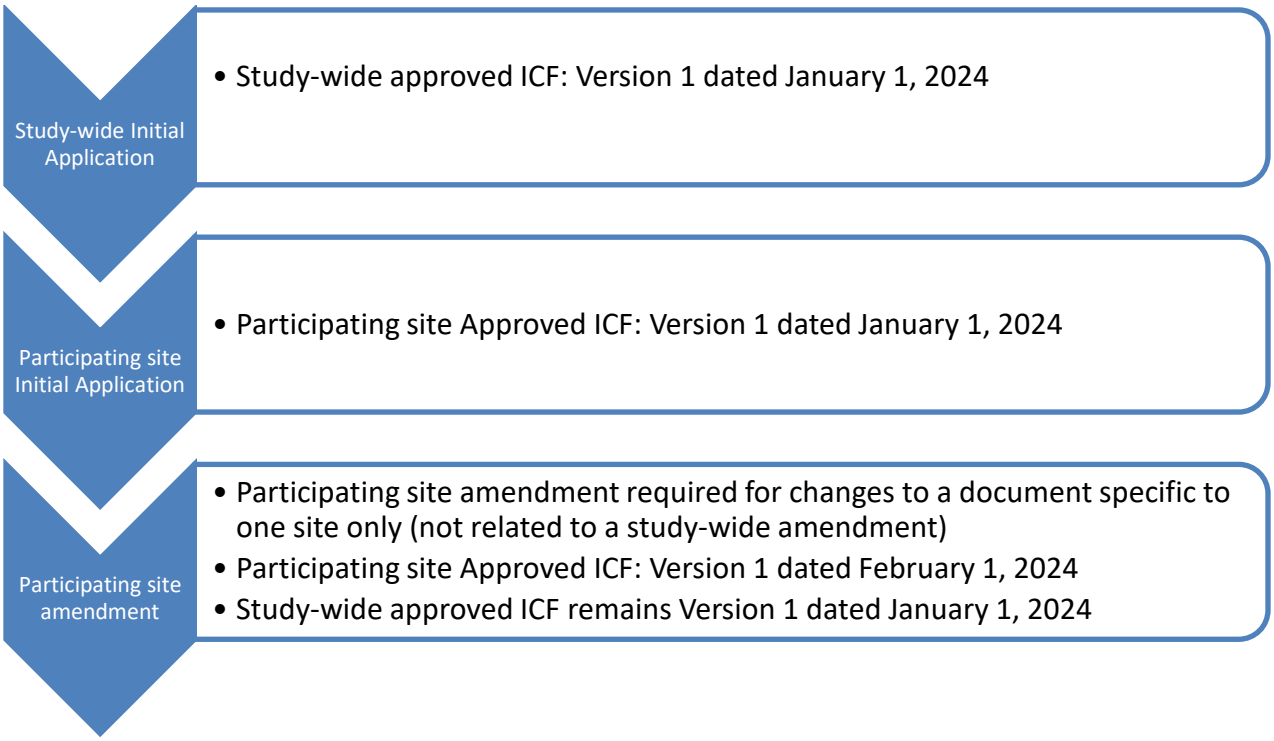
For CTO Studies:

For study-wide applications, the same process as above should be followed.

For participating site applications where the only change in the participating site documents (e.g. informed consent form (ICF)) is the insertion of template language to the study-wide documents (e.g. inserting participating site 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 study-wide approved ICF.**

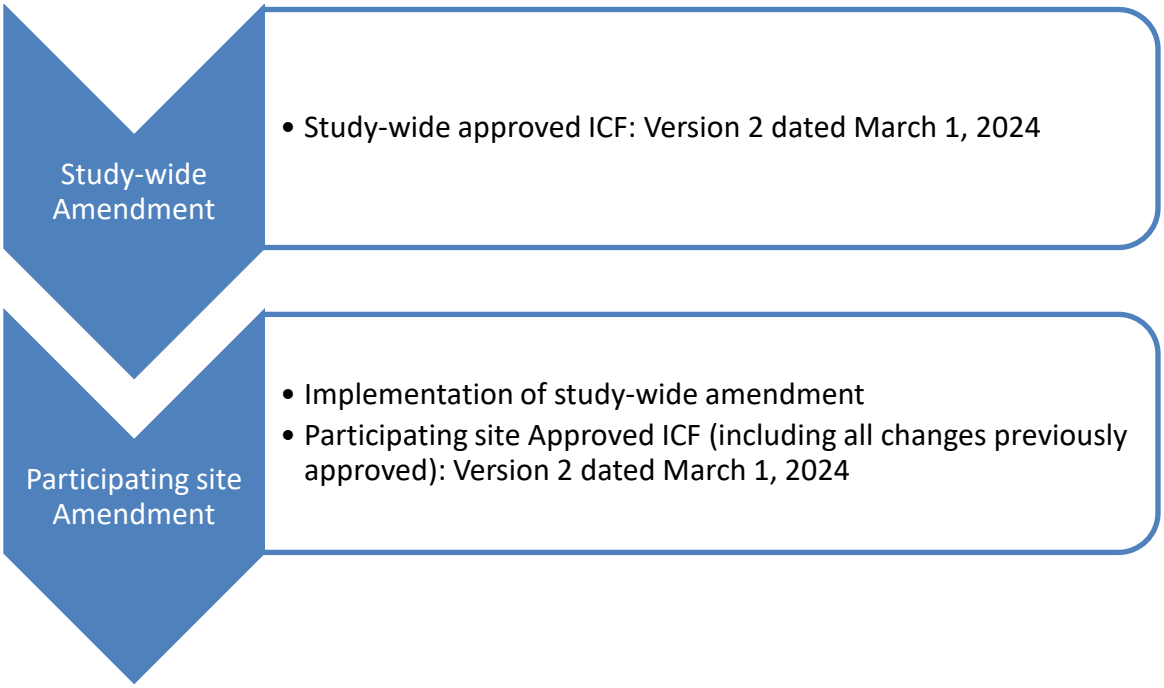
If there are subsequent participating site amendments that do not have a corresponding study-wide amendment associated with it (e.g.. change in compensation amount at the site level, change in participating site PI, etc.), **then only the version date should be updated**. The version number should be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

See example below:



Subsequent study-wide amendments will have a new version number and date listed on the documents.

Approved participating sites will submit a participating site 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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