

Version Control Guidelines

Refer to the Version Control Flow Chart following the guidelines.

1. Document dates

a. The author of the document will ensure the date the document is created or revised is identified on the first page and, when possible, is incorporated into the header or footer of the document and appears on every succeeding page.

2. Version numbers

a. The author of the document will ensure the current version number is identified on the first page and, when possible, is incorporated into the header or footer of the document and appears on every succeeding page.

3. Draft document version number

- a. The first draft of a document will be Version 0.1.
- b. Subsequent drafts will have an increase of "0.1" in the version number (e.g., 0.2, 0.3, 0.4, ...0.9, 0.10, 0.11).

4. Final document version number and date

- a. The author (or investigator) will deem a protocol or other document (consent/assent form, case report form, manual of procedures) final after all reviewers have provided final comments and the comments have been addressed.
- b. The first final version of a document will be Version 1.0. Include the date when the document becomes final. Generally, the final version is submitted to the Institutional Review Board (IRB) and/or FDA.
- c. Subsequent final documents will have an increase of "1.0" in the version number (1.0, 2.0, etc.).

5. Final documents undergoing revisions

a. Final documents undergoing revisions will be Version X.1 for the first version of the revisions. While the document is under review, subsequent draft versions will increase by "0.1" (e.g., 1.1, 1.2, 1.3, etc.). When the revised document is deemed final, the version will increase by "1.0" over the version being revised (e.g., the draft 1.3 will become a final 2.0).

6. Documenting substantive changes

a. A list of changes from the previous draft or final documents will be kept. The list will be cumulative and identify the changes from the preceding document versions. The list of changes made to a protocol and consent/assent should be submitted to the IRB with the final protocol and consent/assent documents.

Generally, the first final protocol version submitted to the FDA is 1.0 if it is an investigational new drug (IND) study. If it is not an IND study, the first final protocol version to be implemented is 1.0.

Version Control Flow Chart

Version Control Document Date Date the document is created or revised is identified on the first page and, when possible, is incorporated into the header or footer of the document and appears on every succeeding page. **Version Number** Current version number is identified on the first page and, when possible, is incorporated into the header or footer of the document and appears on every succeeding page. First Draft 1st draft is Version 0.1- subsequent drafts will increase by "0.1" **First Final** First final version will be Version 1.0 **Revisions to a Final Version** Final documents undergoing revisions will be Version X.1 For the 1st revision; subsequent drafts will increase by "0.1" E.g., 1.1, 1.2, 1.3. All changes will be documented **Subsequent Finals** Version number will increase by "1.0"

above the version being revised e.g., 1.x becomes 2.0, 2.x becomes 3.0.