# Version Control Guidance

Version control is a critical component of effective document management. This guidance provides recommended strategies for consistent document versioning, but specific IRBs and regulatory bodies may have different versioning requirements that should be followed.

Also refer to the Version Control Flowchart following this guidance.

1. Document dates
   1. The author of the document will ensure that 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
   1. The author of the document will ensure that 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
   1. The first draft of a document will be Version 0.1.
   2. 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
   1. 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.
   2. The first final version of a document will be Version 1.0. Include the date when the document becomes final.
      * If the study is under an Investigational New Drug (IND) or Investigational Device Exemption (IDE), Version 1.0 is generally the first final protocol version that is submitted to the Institutional Review Board (IRB) and/or Food and Drug Administration (FDA).
      * If the study is not under an IND/IDE, Version 1.0 is generally the first final protocol version that is implemented.
   3. Subsequent final documents will have an increase of “1.0” in the version number (e.g., 1.0, 2.0, 3.0).
5. Final documents undergoing revisions
   1. 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. 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.

Documenting substantive changes:

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.

# Version Control Flowchart

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.

##### First Draft

1st draft is Version 0.1 – subsequent drafts will increase by “0.1”

e.g., 0.2, 0.3, 0.4

##### 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

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.