DMID INFORMATION SHEET

Document Version Control Guidelines

Purpose

To provide guidelines for the version control of all documents created to support clinical research. Documents may include, but are not limited to protocols, informed consent forms, manuals of procedures, study standard operating procedures, study advertisements, and case report forms.

Background

Version numbering provides document reviewers with information at a glance. For example, if a document version number is 2.0 (whole number) it is known that this document has been reviewed and finalized twice since its initial creation. If a document version number is 4.6 (number with a decimal point and numbers greater than zero to the right of the decimal point), it would indicate that the document has been final four times and is currently undergoing additional revisions which have not been finalized.

General Guidelines

The following guidelines must be adhered to for documents created for DMID-supported clinical research:

- Initial drafts will begin version numbering at 0.1, where each subsequent draft will increase sequentially (e.g., 0.2, 0.3, etc.). Numbers greater than zero to the right of the decimal point indicate that the document is a *draft.*
- All documents will also include the version date, indicating the date the document is revised or edited.
- Finalized documents will include a version number and version date such that the version number is now a whole number (e.g., version 2.0, dated 28-Sep-2008)
- Version numbers and version dates must be included in the document header or footer and appear on succeeding pages of the document. A version number and version date may also be included on the document first page such as the first page of a protocol.
- Where the document version number and version date appears on the first page and in the header/footer, ensure consistency in all places.
- In the event, a manufacturer (or other study partner) wishes to adhere to a different document versioning system, include both the manufacturer's and DMID version numbering with corresponding dates on all documents.

Version Control of DMID Reviewed Documents

1. Final document version numbers:
    a. The Clinical Project Manager (CPM) 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 1.0.

2. Final documents undergoing revisions:

    a. Final documents undergoing revisions will be X.1 for the first version of the revisions. Subsequent revision versions will increase by 0.1 (e.g., the third draft of version 2.0 would be 2.3). When the revised document is deemed final, the version will increase by 1.0 over the version being revised (e.g., after version 2.3, will be 3.0).

    b. A list of changes from the previous document will be kept. The list of changes will be cumulative and identify the changes from the immediately preceding version number. The list can be incorporated into the new document or kept in the project files.

    c. Generally, the first final protocol version submitted to FDA is 1.0 if it is an IND study. If it is not an IND study, the first final protocol version to be implemented is 1.0.

Sample Document Lifecycle with Versioning