

## Guidance for Investigators: Participant Documents – Version Control

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<b>Section:</b> Investigator	<b>No. Pages:</b> 2	<b>Date Created:</b> Sep 15
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### PURPOSE

To achieve a consistent approach for maintaining the history of the document using the footer details.

Bellberry understands that sites will have their own internal SOP for version control. However, below are some suggestions and guidelines about how consistency can be maintained when updating documents.

When initially creating documents for review, or when you have received the document from the Sponsor, it is recommended that the following details have been included in the footer.

<b>Table 1: Information to include within the footer</b>
Protocol Number or a short version of the Study Title
Site name
Document title e.g. PICF (Abbreviated – Participant Information Consent Form)
Version Number
Date (e.g. DDMMYYYY)
Page X of X

Footer requirements will vary depending on whether it is a Generic/Master PICF or if it is a Site Specific PICF.

Below are some examples of what is recommended at both the initial submission of the document and also when updates/changes are made to the document.

### GENERIC/MASTER SUBMISSION – Version Control

It is recommended that the lead site submits a Generic/Master version of the PICF to Bellberry HREC for approval. All of the above details as specified in Table 1 are included in the footer when the initial document is submitted for review.

***Example footer Generic / Master initial submission:***

Protocol No 123 OR Study Title, Master version PICF, V1, date 25 Feb 2015.  
Page X of X.

Once the PICF has been approved, when updating the Generic/Master PICF, all changes/updates need to be made to the latest approved version of the Generic/Master PICF.

***Example footer Generic/Master:***

Protocol No 123 OR Study Title, Bellberry Master PICF, V2, dated 03 March 2015.  
Page X of X.

### SITE-SPECIFIC SUBMISSION-Version Control

If only one site is participating in the study and they do not wish to create a Generic/Master PICF, they may submit a Site-Specific document for review by Bellberry HREC. All of the details listed in Table 1 are recommended to be included in the footer.

***Example footer Site-Specific Single Site initial submission:***

Protocol No 123 OR Study Title, Site name, PICF, V1, dated 25 Feb 2015. Page X of X.  
When updating documentation for a single-site, the document title should remain the same and the only changes made to the footer should be to the version number and date.

When updating documentation for a single-site, the document title should remain the same and the only changes made to the footer should be to the version number and date.

***Examples footer Site-Specific Single Site:***

Protocol No 123 or Study Title, Site Name, PICF, v2, dated 03 March 2015. Page X of X.

When an additional site submits their study application, a Site-Specific version of the approved Generic/Master PICF is required for review.

All additional sites should reference both the approval Generic/Master and their Site Specific PICF with the footer of the document.

***Example footer Site-Specific Additional Site initial submission:***

Protocol No123 OR Study Title, Site Name, PICF, V1, dated 15 March 2015.  
Based on Master PICF, V1, dated 25 Feb 2015. Page X of X.

Below is an example of a footer for a Site-Specific PICF amendment based on the latest updated and approved Generic/Master PICF. When submitting an amendment to update the Site-Specific PICF the latest approved Generic/Master PICF V2, dated 03 March 2015. Page X of X.

***Example footer Site-Specific Additional Site:***

Protocol No 123 or Study Title, Site Name, PICF V2, dated 15 March 2015.  
Based on Master PICF V2, dated 03 March 2015. Page X of X.

**Here are some additional tips for successful version control when submitting with Bellberry HREC:**

**Please refer to Attachment 3 Participant Information Sheet - Sample, for guidelines regarding suggested context and structure for PIS.**

PIS and Consent components must be submitted as ONE complete document and titled PICF.

Once the PICF has been created, please ensure that this and any other document is attached into eProtocol with the file name as you/the sponsor wishes them to appear on the Approval letter. The document file name/title is to remain the same throughout the duration of the study. The only changes to the document filename should be to the version number and date.

However, if the title of a HREC approved document is changed, an amendment must be submitted to notify the Bellberry HREC.

Site-Specific changes should be presented as a tracked changed copy using the latest approved Bellberry Generic/Master Clean document as its basis. **A clean copy of this document must also be submitted with the tracked change copy** as the clean copy is the document that will be approved and will appear on the approval letter.

**Do not delete any previous versions of any updated documents.** It is important that these remain as a reference for document control.