Institutional responsibilities

Key points:

- By the end of the first quarter of 2020, there will be changes to some documents that Bellberry requests, including site-specific documents.
- We are currently working with pilot sites & sponsors to test the new process and forms.
- Sites are encouraged to spend the coming months preparing for how they will manage their internal document flow, version control and authorisation process.
- These examples relate purely to what documentation is uploaded, and each site is still responsible for creating their own 'site application' in the system.

Study submission example:

Site A & **Site B** are the initial study sites. **Site C** to come on board in a few months. Site A is responsible for the initial submission.

Site A submits the complete study documentation including (but not limited to) Protocol, IB and Master PICF. Site A also submits a short document *(template to be provided by Bellberry)* with their site-specific clauses for inclusion in the PICF, or other documentation such as advertising.

Site B submits an eProtocol application including a short document *(template to be provided by Bellberry)* with their site-specific clauses for inclusion in the PICF, or other documentation such as advertising.

The study is approved, and sites **A** and **B** are free to include the clauses outlined in the short document into their site-specific documents. They do not need to send the final document to the HREC for approval. The sites are now responsible for their internal document flow, version control and internal authorisation process of their site-specific documents.

Site C is added three months after the initial approval. This site uploads a short document (template to be provided by Bellberry) listing what they are using as the current Protocol, IB, and Master PICF etc. They also upload a short document (template to be provided by Bellberry) with their site-specific clauses for inclusion in the PICF, or other documentation such as advertising. The HREC administration will check the listing to ensure the protocol, IB and other documents match what is currently approved for the study. The HREC will then review the summary of site-specific information, and if approved, **site C** will receive an approval letter listing these documents. The site is responsible for their internal document flow, version control and internal authorisation process.

During the study:

Example 1: **Site B** notices a typographical error in their contact phone number. They can change the site-specific PICF without notifying the HREC. The site is responsible for their internal document flow, version control and internal authorisation process.

Example 2: **Site C** – there has been no change to the Master PICF. However, the site wishes to change its site-specific reimbursement clause. **Site C** submits an amendment and describes the rationale in the amendment application form and then attaches a revision to their short document with the change to the reimbursement clause. The amendment is approved, and the site changes their site-specific PICF. The site is responsible for their internal document flow, version control and internal authorisation process.

Example 3: **Site A, B or C** - Submits an amendment to the protocol, IB and Master PICF on behalf of all sites. Each site will submit another short document with their site-specific clauses for inclusion in the PICF. All sites that made internal changes (during the study example 1) or had approved changes (example 2) must ensure these are reflected in their updated short document.

See related documents:
Bellberry applications
BA F1.1.12 Additional site application & site-specific wording cover letter