Purpose

To provide an outline of Participant Information and Consent Form submission options available for single-centre and multi-centre study applications submitted to Bellberry. The available pathways aim to streamline application submissions and reduce duplication of documentation between coordinating study sites.

Guidance

Study applications are required to follow one of three available pathways for submitting PICFs and supporting documents. The PICF pathway selected should be declared on page 1 of the initial application and followed throughout the study.

Submission of other documents should align with the selected submission pathway for the study, e.g., questionnaires, advertising, participant information cards, participant letters, GP letters, etc.

Pathway 1:

This pathway is only applicable to single-centre applications. A site-specific PICF should be submitted which includes all site-specific content and details for the submitting site. Similarly, all site-specific content and details should be included in all other submitted documents (See BA G1 Submission Requirements & Responsibilities).

Once the study site application is approved, the HREC approval letter will list the version, date and title of the site-specific PICF and approved documents.

If a change is proposed thereafter to approved PICF wording or master documents, this is required to be submitted via an amendment. (See MAR G1 Post-Approval Submission Guidance).

Where an additional site intends to join the study after the study has been approved, the study will need to transition to Pathway 2.

Pathway 2:

This pathway is best suited for applications requiring a flexible approach at the time of the initial application submission. This pathway can be used for applications where additional sites may potentially join the study in the future, regardless of how many additional sites may or may not join.

The first site to submit their study application is deemed the nominated ‘lead site’ and are responsible for submitting a master PICF(s) on behalf of all study sites. The master PICF should include template ‘placeholders’ to allow for site-specific content (See BA G5 Participant Information & Consent Form Development).

The lead site must also submit a Site-Specific Clauses document, which is typically a single-page summary of all placeholder content and proposed changes to the master PICF which are specific to their site. The Site-Specific Clauses document is required to be submitted in place of site-specific PICFs. (Please see BA F1.1.12 Site-Specific Clauses Document Template.)

All additional sites are responsible for submitting their own application and may submit this at any time while another study site is active with Bellberry, whether prior or post-lead site approval. An additional site must attach their own Site-Specific Clauses document in place of site-specific PICF(s), in addition to any documents specific to their site, e.g., the PI’s CV, site-specific advertising, a site-specific Radiation Safety Report, where applicable. Additional sites following this pathway are not required to attach any documents that have been submitted by the lead site.

Once the lead site application is approved, the HREC approval letter will list the version, date and title of the master PICF. The approval letter will also list the approved Site-Specific Clauses document for the lead site and each additional site that has submitted their application, and are also ready for approval.

If a change is proposed thereafter to approved master PICF wording or master documents, this is required to be submitted by the nominated lead site via an amendment on behalf of other study sites (See MAR G1 Post-Approval Submission Guidance). Where changes are relevant, sites may need to submit an updated Site-Specific Clauses document or amendment to update their application.

If for any reason the master documents are submitted on behalf of select study sites or as a site-specific document for an individual site, this must be declared on the amendment and a rationale provided.

It is strongly recommended that this pathway once selected, should not be changed to Pathway 1 during the study. In the circumstances where a study site is continuing the study after all other sites involved have completed study activities and closed, the remaining site may continue following PICF Pathway 2. As such, where further changes are proposed to the master PICF wording or master documents, the remaining site may submit these via an amendment as master documents. The master documents do not require transitioning to a site-specific format.

Where an already approved additional site takes over the nominated lead site responsibilities, the HREC does not need to be informed. However, if changes are proposed thereafter to the approved master PICF wording or master documents, the new lead site is required to submit these updates via an amendment and on behalf of all other sites.

Pathway 3:

This pathway is suitable for a multicentre study and similarly with pathway 2, the nominated lead study site is required to submit a master PICF and master documents on behalf of all sites. The master PICF should contain the specific wording for every site participating in the study. All inclusions should be formatted as ‘stacked placeholders’ embedded within the PICF, from which additional sites create and customise their site-specific PICFs from (See BA G5 Participant Information & Consent Form Development).

Once the lead study site is approved, the HREC approval letter will list the version, date and title of the master PICF(s), approved on behalf of all sites. The approval letter will also list any additional sites that have already submitted their applications and are ready for approval.

If a change is proposed thereafter to approved master PICF wording or master documents, this is required to be submitted by the nominated lead site via an amendment on behalf of all other study sites. Throughout the duration of the study, the HREC reviewers the master PICF as one complete document. (See MAR G1 Amending approved research – general overview).

All additional sites are responsible for submitting their own application and may submit this at any time while another study site is active with Bellberry, whether prior or post-lead site approval. An additional site must attach any documents specific to their site, e.g., the PI’s CV or site-specific advertising, where applicable. Additional sites following this pathway are not required to attach any documents that have been submitted by the lead site, e.g., protocol, IB, PICFs (Please see BA F1.1.1 Submission Requirements Checklist). The additional site application is reviewed by the HREC as being suitable to participate in the trial and submitted documents are listed on their approval letter.

Where an additional site submits an application after the study has been approved by Bellberry, the lead site may need to submit an updated PICF including any additional ‘stacked placeholders’, wording and details applicable to the newly submitted site, via an amendment. Where this is required, the updated PICF submitted

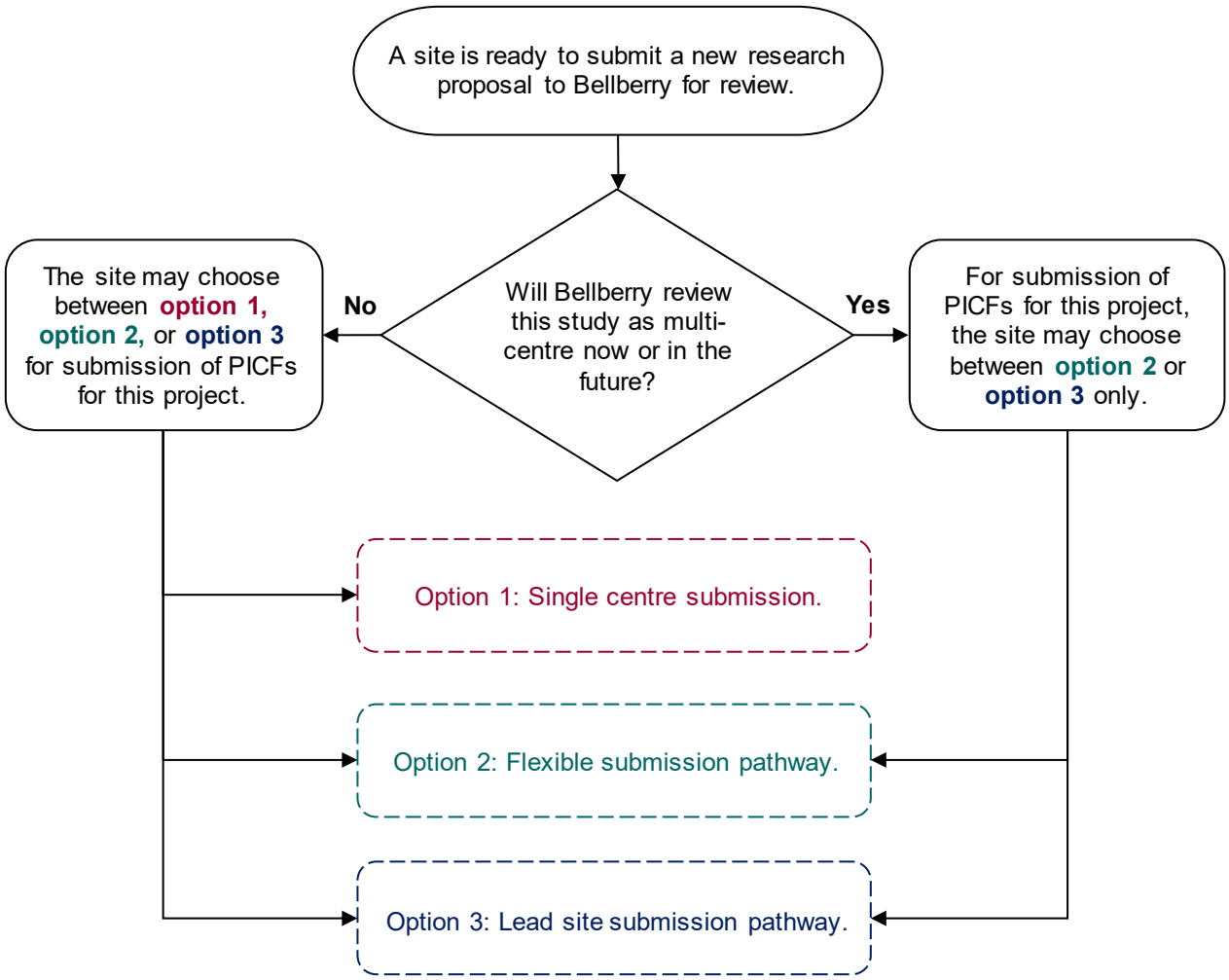
by the lead site will need to be approved before the newly submitted additional site is approved. Trial activities may commence at the additional site once an approval letter is issued.

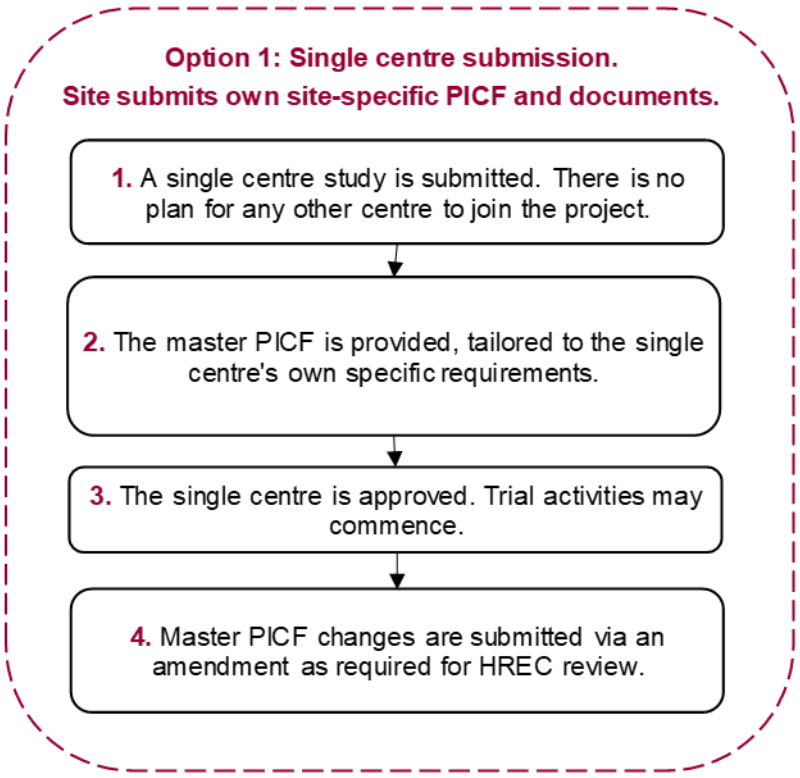
Where an additional site takes over the nominated lead site responsibilities, the HREC does not need to be informed. However, if changes are proposed thereafter to the approved master PICF wording or master documents, the new lead site is required to submit these updates via an amendment and on behalf of all other sites.

References

BA G1 Submission Requirements & Responsibilities
BA F1.1.1 Submission Requirements Checklist
BA G5 Participant Information & Consent Form Development
MAR G1 Post-Approval Submission Guidance

PICF Pathways Flowchart for Bellberry Submissions:




Option 1: Single centre submission.
Site submits own site-specific PICF and documents.
1. A single centre study is submitted. There is no plan for any other centre to join the project.
2. The master PICF is provided, tailored to the single centre's own specific requirements.
3. The single centre is approved. Trial activities may commence.
4. Master PICF changes are submitted via an amendment as required for HREC review.

Option 2: Flexible submission pathway.
All sites submit own site-specific information.

1. The first submitting site submits a master PICF on behalf of all study sites. The master PICF includes template 'placeholders' to allow for site-specific content.

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2. An additional submits an application, including their Site-Specific Clauses document and any other site-specific documents (This summary is submitted instead of a site-specific PICF).

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3. Once the lead site application is approved, the HREC approval letter will list the master PICF and master documents approved on behalf of all study sites. The approval letter will also list the approved Site-Specific Clauses document for the lead site and each additional site that has submitted their application, and are also ready for approval.

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4. If a change is proposed thereafter to approved master PICF wording or master documents, the nominated lead site submits this via an amendment on behalf of other study sites. Where impacted by changes, an updated Site-Specific Clauses document may also need to be submitted by some or all additional sites.

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5. A new additional site joins the study. This site submits their updated Site-Specific Clauses document to the HREC for review and any other documents specific to their site. The master PICF does not need to be updated.

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6. The additional site is reviewed by the HREC as being suitable to participate in the study. Their application is approved and submitted documents are listed on their approval letter.

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7. Trial activities may commence at the additional site.

Option 3: Lead submission pathway.
The initial submitting site is responsible for all PICF updates.

1. The lead study site submits a master PICF that includes comprehensive wording for all sites participating in the study. The inclusions appear as 'stacked placeholders'.

2. Once the lead site application is approved, the HREC approval letter will list the master PICF, approved on behalf of all sites. The approval letter will also list any additional sites that have already submitted their applications and are ready for approval.

3. Any proposed changes to the master PICF are required to be submitted via an amendment by the lead study site on behalf of all additional sites.

4. An additional site joins the study and submits an application, including any documents specific to their site, e.g., PI CV and advertising.

5. The additional site is reviewed by the HREC as being suitable to participate in the trial and submitted documents are listed on their approval letter.

6. Where required, the lead site submits an updated PICF including wording relevant to the newly submitted additional site, via an amendment. *Note: already approved sites do not need to update their site specific PICFs as changes to the master are only relevant to the newly commencing site.*

7. The updated master PICF is reviewed and approved by the HREC, approved on behalf of all sites, which will be listed in the approval letter.

9. Trial activities may commence at the additional site.