| Document/Submission | Prior to 2 November 2020 | From 2 November 2020 |
|---|---|---|
| **Master and site-specific PICFs, and other participant facing documents** | The first submitting/lead site (in conjunction with the sponsor) determines the format of the master PICF and submits to the Bellberry HREC for review and approval.<br><br>Additional sites submit site specific PICFs/other participant facing documents to the Bellberry HREC for review and approval. | The first submitting/lead site selects a pathway to determine how the master study documentation will be submitted. All additional sites align with the nominated pathway.<br><br>Master documents are submitted to a Bellberry HREC for review and approval.<br><br>Sites do not submit site specific PICFs/other participant facing documents to Bellberry HREC.<br><br>Site specific documents are submitted to the site Research Governance Officer (RGO) (if applicable). Sites without an RGO must develop their own process for managing document flow and internal approvals.<br><br>*Current/ongoing studies:*<br>Most studies will naturally align with either PICF pathway 1 or 3 (see BA F1.1.17 PICF submission pathways). Pathway 2 relates to studies that have used a master PICF, and every site has submitted a site-specific PICF with all changes (e.g. to radiation, reimbursement, etc).<br><br>If these clauses have already been approved in a site-specific PICF and the master is updated, the site can continue to imbed their previously approved clauses into the new PICF. If the site wishes to change a clause, the site must submit an amendment using the BA F1.1.12 site specific clauses template. |

| | | |
|---|---|---|
| **Initial application and reviews** | Bellberry reviews additional sites post lead site approval. Each site submits their own study documentation and receives an individual letter as they are approved.<br><br>Example: Application ID 2020-01-800 is submitted Thursday, September 10th. The study is suitable to be added to the agenda for Wednesday, September 23rd, 2020. Additional sites 2020-01-800-AA and 2020-01-800-AB submit on Monday, September 21st. The lead site (2020-01-800) is reviewed and will enter cycles of comments post-meeting. Once the committee is ready to approve the study, site 2020-01-800 receives a HREC approval letter. When the committee is ready to approve site 2020-01-800-AA, the site receives a HREC approval letter. | The additional site submissions will be reviewed at the same time as the first submitting/lead site is entering cycles of comments, post-HREC review. When the first submitting/lead site is ready for approval, Bellberry will also add any additional sites that have fulfilled the HREC's requirements to the lead sites approval letter. An individual letter will only be dispatched if a site is not ready for sign off at the point of initial approval.<br><br>Example: Application ID 2020-01-800 is submitted Thursday, September 10th. The study is triaged and added to the agenda for Wednesday, September 23rd, 2020. Additional sites 2020-01-800-AA and 2020-01-800-AB submit on Monday, September 21st. The first submitting/lead site (2020-01-800) is reviewed and will enter cycles of comments post-meeting. Additional sites 2020-01-800-AA & 2020-01-800-AB are now reviewed out of session by the Chair/reviewers. If required, they will also enter cycles of comments. Once a decision has been reached by the committee to approve the study, if sites AA and AB are also ready for approval, they will all be listed on the first submitting/ lead site letter. |
| **Sites approved post initial approval** | Additional sites are responsible for uploading all study documents before Bellberry can assess the site for approval. | Additional sites are only responsible for submitting documents pertaining to them (e.g. CV, social media plan, advertising). When an additional site is approved, Bellberry administration will upload all previous approval letters to eProtocol page 7 of the additional site. |
| **Amendments and safety reporting** | Any approved site can submit an amendment or safety report. Amendment form question 4 asks the submitter to list all centres/sites to which the amendment applies. The HREC will review the submission for the specified centres/sites. | Any approved site can submit an amendment or safety report. Review will occur on behalf of all sites if the submission relates to core study documentation in a multi-centre study. In the event the amendment or safety report does not apply to all sites, the submitting site must provide an explanation.<br><br>Safety acknowledgement letters will still use the AER code as a reference (e.g. 2020-01-800-AER-1). |

| | | |
|---|---|---|
| **Serious breaches** | Protocol violations and serious breaches accepted as a PVR submission in eProtocol. | Deviations and violations are not required for submission.<br><br>The PVR form is now titled 'Serious Breaches". Questions have been updated to reflect the NHMRC's serious breach questions. Acknowledgement letters will still use the 'PVR' code as a reference e.g. 2020-01-800-PVR-1. See MAR G3 Serious breaches for further information. |
| **Progress reports** | Progress reports were due on the anniversary of each site's approval. | Minor changes have been made to the progress report form to incorporate the need for submissions to include an update on any conflict of interest changes for the research team, and for a comment on compliance with any: governance approvals; submission of amendments; safety reporting; annual progress reporting; notification to the HREC of regulatory audits; appropriate use of data; caveats placed on the approval; statutory and licensing obligations.<br><br>Progress Reports are now due annually on the anniversary of the first application/lead site approval. |
| **Site monitoring and desktop auditing** | Bellberry undertake physical site monitoring and audits. Sites selected may be for a specific cause or selected at random. | Bellberry will monitor sites and studies remotely via desktop auditing. When it is safe to do so, Bellberry will return to physical site monitoring while continuing to undertake desktop audits. Sites selected for monitoring may be for cause or selected at random. The Bellberry quality team will email all relevant forms for a desktop audit to the Principal Investigator and nominated contacts. |

**Related documents**

***Bellberry Applications***

| | |
|---|---|
| BA G1 | Submission requirements and responsibilities |
| BA F1.1.1 | Submission requirements checklist |
| BA F1.1.5 | eProtocol application questions |
| BA F1.1.7 | HREC Process Flowchart |
| BA F1.1.12 | Site specific clauses template |
| BA F1.1.17 | PICF Submission pathways |
| BA G15 | Insurance and indemnities (replaces BA F1.1.8) |
| BA F15.1.1 | Insurance and indemnity FAQs |
| BA F15.1.2 | MA Clinical HREC Indemnity – prefilled with Bellberry details |
| BA F15.1.3 | MTAA Device HREC Indemnity prefilled with Bellberry details |
| BA F15.1.4 | Bb Non-Clinical HREC Indemnity- prefilled with Bellberry details |
| BA G12 | Version control and document naming conventions |

***Monitoring Approved Research***

| | |
|---|---|
| MAR G1 | Amending approved research - general overview |
| MAR F1.1.2 | Amendment form questions |
| MAR F1.1.3 | Amendment pathways flowchart |
| MAR G2 | Safety reporting |
| MAR F2.1.1 | eProtocol questions |
| MAR G3 | Serious breaches |
| MAR F3.1.1 | Serious breaches report form - sponsor |
| MAR F3.1.2 | Serious breaches report form - third party |
| MAR F3.1.3 | Serious breaches (eProtocol questions) |
| MAR F4.1.1 | Progress reports (eProtocol questions) |
| MAR G6 | Site monitoring and desktop auditing |

**Bellberry reception: 08 8361 3222**
**Staff contacts:**
**Quality Manager:** AlisonBarr@bellberry.com.au
**Quality Lead:** TessPenglis@bellberry.com.au
**Team Leader:** SallyGordon@bellberry.com.au
**HREC Officer:** KatrineScharling@bellberry.com.au