Introduction

The purpose of this form is to provide an executive summary of the Bellberry HREC submission requirements.

Clinical studies should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with good clinical practice and the applicable regulatory requirements.

General notes:

For the purpose of an initial submission to Bellberry, the lead site is defined as the site that submits the initial application in a multi-centre project. This site takes responsibility for responding to the comments of the HREC. It is a decision for the sites and sponsor to determine whether the lead site continues to take responsibility for ongoing submissions (e.g., generic amendments and reports) on behalf of the additional sites. Please refer to Bellberry guidance document BA G1 Submission requirements and responsibilities for additional information.

All documents submitted to the HREC are to be titled in the document file name as they are required to appear on the HREC approval letter. Please refer to Bellberry guidance document BA G12 Version Control & Document Naming Conventions.

All eProtocol questions must be answered in full. Applications will be returned to the Principal Investigator where insufficient information is provided for the HREC to conduct its review. (See BA F1.1.5 eProtocol Application Content for additional information.)

Please refer to the final page for a list of documents that do not require submission. They are however required for the study and should be appropriately filed in the site study files. As part of Bellberry's routine monitoring, these documents will be inspected during a site monitoring visit or requested via a desktop audit.

Documents must not be deleted from the application after review by the HREC. A complete list of all submitted documents must be maintained in eProtocol.

When assessing changes to study documentation, minor administrative changes are the site's responsibility and do not need to be submitted to Bellberry. These include adding the site name, Principal Investigator details, study contact details (e.g., phone/email), amending footers, formatting, and other typographical errors. Sites must submit additions or deletions of ethical content to the HREC.

Document type	Submission requirements	Document Reference	Lead site requirements	Additional centre requirements
Protocol.	Clean, searchable copy containing index and bookmarks; must: include version and date and must be on behalf of all sites (unless states otherwise). Updates can be tracked or provided via a summary of changes.	BA G3 Protocol Development – Clinical study. BA G4 Protocol Development - Non-Clinical.	Yes.	No.
Protocol Clarification Letters.	As an amendment, the submission must include a description of the rationale for the document and any participant impact on Bellberry participants.	N/A.	Yes.	Initial submission: No Post approval: only if the additional site is submitting an amendment as 'lead'.
Master main PICF.	The initial application should include clean versions of documents only. When documents are updated, tracked and clean versions must be provided. The initial submitting centre is considered 'lead' and will submit Master documents on behalf of all centres. Post-approval, any centre can submit the updated Master document as 'lead' for that submission.	BA G5 Participant Information & Consent Form development BA F1.1.17 PICF Submission Pathways	Yes, (option 1, 2, or 3).	Initial submission: No Post approval: only if the additional site is submitting an amendment as 'lead'.
Other master consent documents.	Master versions required, if in use. For example: optional/ unspecified future research PICF, Pregnancy PICF, etc. A separate PICF may be required for some optional research objectives. The initial submitting centre is considered 'lead' and will submit Master documents on behalf of all centres. Post-approval, any centre can submit the updated Master document as 'lead' for that submission.	BA G5 Participant Information & Consent Form development	Yes (option 1, 2, 3).	Initial submission: No Post approval: only if the additional site is submitting an amendment as 'lead'.
Site specific clauses document.	If the lead site has chosen PICF pathway 2, each site is responsible for submitting their clauses document with their initial application. If the study has more than one PICF (Main, Pregnancy, etc.), the site must summarise the clause information on one document. If the document is amended during the study, a tracked and clean version is required.	BA F1.1.12 Site-Specific Clauses Document Template.	Yes (option 2).	Yes (if option 2 chosen by lead).

Document type	Submission requirements	Document Reference	Lead site requirements	Additional centre requirements
Certificate of translation.	Translation certificate includes version number and date of the approved English document the translated version is based on and conducted by an accredited translation service. Translation certificates from US/UK English to Australian/UK English are not required.	BA G5 Participant Information & Consent Form development	Yes.	Yes.
Attestation of content letter.	If transitioning from hard copy PICF to an ePICF (not electronic consent only), a letter of attestation is required and any deviations between the paper PICF and ePICF outlined.	BA G5 Participant Information & Consent Form development	Yes (option 1, 2, or 3).	Yes (if option 2 chosen by lead).
Variations to participant consent.	Waiver of consent: Protocol addresses items 2.3.10 (a)-(i) of the *National Statement*. Implied consent: Information sheet is provided to participants either as part of a survey or as a separate document. The initial submitting centre is considered 'lead' and will submit Master documents on behalf of all centres. Post-approval, any centre can submit the updated Master document as 'lead' for that submission.	BA G5 Participant Information & Consent Form development	Yes (Option 1, 2, 3).	Initial submission: No Post approval: only if the additional site is submitting an amendment as 'lead'.
Investigator's Brochure (IB).	Clean, searchable copy containing index and bookmarks; must: include version and date and must be on behalf of all sites (unless states otherwise). The IB is required to be reviewed annually and therefore should be dated within 12 months of the application date. If not, please justify in the application form. If the IB amendment requires update to PICF, the updated IB and PICF must be submitted together.	Guideline for Good Clinical Practice.	Yes.	No.
Product information.	If an approved drug for an approved indication is used in the study, a Consumer Medicine Information sheet (CMI) should be provided. An Investigator's Brochure is required if the approved drug is to be used in an unapproved way, e.g., new indication, dose, or mode of administration.	N/A.	Yes.	No.

Document type	Submission requirements	Document Reference	Lead site requirements	Additional centre requirements
Curriculum Vitae (CV).	Must be current (less than two years old), unabbreviated and include: qualifications, work history, postgraduate training, professional college affiliations, publications listings, and relevant research experience. CVs are not required for Co-Investigators (unless requested by the HREC).	BA G8 CVs & Investigator Qualifications.	Yes (if applicable at site).	Yes (if applicable at site).
HREC Indemnity.	HREC Indemnity required only. Updated if the following occurs: change in PI, study title, sponsor, or ABN. Amendment must state the reason for the change.	BA G15 Insurance & Indemnity Guidance.	Yes.	Yes (if not covered in lead site submission).
Radiation safety report.	Required, if applicable. Each site to complete the radiation question and either declare standard of care or submit a medical physicist report for their site and study. Post-approval, if the radiation risk changes, the HREC must be informed by way of an amendment, the PICF updated, and participants reconsented.	BA G13 Ionising Radiation Guidance.	Yes, if applicable (see submission requirements).	Yes, if applicable (see submission requirements)
Standard of care declaration.	Bellberry does not mandate the completion and submission of this form when a standard of care declaration is made in the eProtocol application. However, if an institution requires a formal document notification, this form may be used as a template.	BA F13.1.3 Radiation Standard of Care Declaration Template.	Not mandated.	Not mandated.
Conflict of interest management plan.	A plan outlining how a conflict of interest will be managed, if an actual, perceived, or potential conflict has been identified for a member of the study team.	BA G7 Conflict of Interest Guidance.	Yes.	Yes.
Advertising.	Must include version and date. Updates must include a tracked and clean copy. Study specific recruitment material that will be provided to a participant must be reviewed by the HREC and listed as an approved document.	BA G9 Advertising Guidance.	Yes (master version if to be used for all sites). A local version may be provided if not.	Yes (if advertising not relevant at other sites).
Third Party Vendor Documents	The material used by a recruitment vendor for participant matching or participant reimbursement is not within the ambit of the HREC approval. Please refer to the document reference column for what the HREC requires.	BA G9 Advertising Guidance. BA G10 Participant Payment & Reimbursement.	Not required.	Not required.

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Other participant documents.	Other participant documents such as surveys, questionnaires, ID cards, etc. are to be submitted as they will be provided to the participant. Updates must include a tracked and clean copy.	Nil.	Yes.	No, if provided by lead site.
Other HREC approvals or rejections.	If the research has been reviewed by another Australian HREC, correspondence between the other HREC and the researcher must be provided.	National Statement.	Yes.	No.
Letters from sponsor.	Letters informing the PI that there is an IB and/or Protocol update which should be submitted to the HREC, or other 'Dear Investigator' letters.	N/A.	Yes.	No.
Site procedures, manuals, SOPs or policies.	These documents are not required unless requested by the HREC.	N/A.	Yes (if applicable, see submission requirements)	Yes (if applicable, see submission requirements)
Journal Articles.	Required only when critical to the study justification or where the IB lacks adequate detail.	N/A.	Yes.	Yes.
Draft eCTN.	Not required, will be noted if provided.	CTN User Guide.	Yes.	No.
HREA.	Not required, will be noted if provided.	N/A.	Yes.	No.
VSM (Victoria Specific Module); WASM (Western Australia Specific Module).	To address the relevant state legislation, the Victorian and Western Australian Specific Modules must be completed for public site submissions from the relevant State.	VSM (Victoria Specific Module). WASM (Western Australia Specific Module).	If site is from a state that mandates submission.	If site is from a state that mandates submission.
Formal summary of changes to Protocol or IB.	Not required at initial submission unless specifically requested by the HREC.	N/A.	Yes.	No.
Application for Lower Risk Review Checklist.	Required at initial submission if applying for Lower Risk Review.	LER F1.1.16 Application for Lower Risk Review	Yes	No

Document type	Submission requirements	Document Reference	Lead site requirements	Additional centre requirements
Change in PI/CPI.	The HREC requires an updated HREC Only Form of Indemnity, CV (if not already provided to the HREC within the previous 12 months) and an amendment form in eProtocol advising of the change. The change to the Principal Investigator will need to be made in the Personnel Information section. Sites that wish to formalise a change of Principal Investigator/Co-ordinating Principal Investigator can use the templates listed in the document references column. Must be completed in a timely manner and as soon as practicable.	MAR G1 Amendment Guidance. MAR F1.1.6 Change of Principal Investigator Sample Form.	Yes (if there is a change in PI/CPI).	Yes (if there is a change in PI).
Safety reports.	Significant Safety Issues (SSI), Urgent Safety Measures (USM), ASR, DSUR, other general correspondence from sponsor (DSMB reports, composition of DMC) must be submitted on behalf of all Bellberry approved sites.	QM G10 Safety Reporting Guidance.	Yes (Q1, single submission, Q2 on behalf of all).	Yes (Q1, single submission, Q2 on behalf of all).
DMC/DSMB Letters/Charter/ TOR/Outcomes.	Only required if the HREC requests it via a caveat on their approval letter or if a Sponsors' policy requires the submission. If the latter, this should be stated on the submission form.	QM G10 Safety Reporting Guidance. Guideline for Good Clinical Practice.	Yes.	No.
Progress reports.	Due annually at the anniversary of the initial study approval. Each PI is responsible for submitting a progress report for their site.	MAR G4 Progress & Final Report Guidance.	Yes.	Yes.
Serious breaches.	Each site is responsible for their own submission. If a breach relates to several studies or sites (e.g., a sponsor data breach), submission may occur via the batch pathway, or one site takes lead for all under their Application ID.	QM G11 Serious Breach Report Form.	Yes.	Yes.
Final report.	Due at the end of the project/discontinuation, after the study is closed out at the site. Each PI is responsible for submitting a final report for their site.	MAR G4 Progress & Final Report Guidance.	Yes.	Yes.
Clinical Study Report	Not required, unless contains specific safety information requiring HREC review.	MAR G4 Progress & Final Report Guidance.	Yes (single submission, or on behalf of all).	Yes (single submission, or on behalf of all).

Documents that do not require submission to the HREC:

- Site approval forms
- Protocol signature pages
- Insurance certificates
- Standard indemnities
- Medical registrations
- Professional indemnities
- Signed HREC approval letters
- Third Party Vendor documents
- Screenshots of approved documents
- Paper versions of previously approved screenshots
- Site-specific PICFs (if PICF Pathway 2 or 3)
- Other site-specific documents where a Master version has been approved
- Translation certificates from US/UK English to Australian/UK English
- Cover letters
- Note to File documents
- Co-Investigator CV (unless requested by the HREC) or Nominated Contact CVs
- Social Media policy (must be in place at site)
- Notification of registration of trial in online register (e.g., clinicaltrials.gov, ANZCTR)
- CEP (Consumer Engagement Plan)