Introduction

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

Clinical trials 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.

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. (See BA G1 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.

All eProtocol questions must be answered in full. Applications will be returned to the Principal Investigator where insufficient information is provided for the committee to conduct its review.

Site approval forms, protocol signature pages, insurance certificates, standard indemnities, medical registrations, professional indemnities, signed HREC approval letters, site-specific PICFs and other site-specific documents 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 Committee. A complete list of all submitted documents must be maintained in eProtocol.

Document type	Submission requirements	Document Reference	Lead site requirements	Additional site 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; BA G4 Protocol development, non-clinical.	Yes.	No.
Master PICF.	Must include version and date. Updates must include a tracked and clean copy.	BA G5 PICF development including eConsent.	Yes, (option 1, 2, or 3).	Yes (if option 2 chosen by lead).
Other consent documents.	Master versions required, if in use. For example: optional/ unspecified future research PICF, Pregnancy PICF, etc. A separate PICF must be submitted for any unspecified future research.	BA G5 PICF development including eConsent.	Yes (Option 1, 2, 3).	Yes (if option 2 chosen by lead).
Certificate of translation.	Translation certificate includes version number and date of the approved English document the translated version is based on. Include on the approval letter a statement such as “these certificates were also included in the review”.	BA G5 PICF development including eConsent.	Yes.	Yes.
Attestation of content letter.	If transitioning from hard copy PICF to eConsent, a letter of attestation is required and any deviations between the paper PICF and ePICF outlined.	BA G5 PICF development including eConsent.	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.	BA G5 PICF development including eConsent.	Yes (Option 1, 2, 3).	Yes (if option 2 chosen by 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.	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.
Curriculum Vitae (CV).	Must be current (less than one year old) and include: qualifications, work history, postgraduate training, professional college affiliations, publications listings, and relevant research experience. CV’s are not required for Co-Investigators (unless requested by the HREC).	BA G8 CVs and investigator qualifications.	Yes (if applicable at site).	Yes (if applicable at site).

Document type	Submission requirements	Document Reference	Lead site requirements	Additional site requirements
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 and indemnities.	Yes.	Yes (if not covered in lead site submission).
Radiation safety report.	Required, if applicable. If a subsequent medical physicist report indicates a higher risk category than previously identified, the PICF must be updated for all sites and all participants reconsented.	BA G13 Ionising radiation.	Yes, if applicable, on behalf of all sites (latest ARPANSA guidance).	Yes, if applicable, on behalf of all sites (latest ARPANSA guidance).
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.	Yes.	Yes.
Advertising.	Must include version and date. Updates must include a tracked and clean copy. Any material that will be provided to a participant must be reviewed by the HREC and listed as an approved document.	BA G9 Advertising.	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).
Social media plan.	Required if recruiting via social media. Must include version and date. Updates must include a tracked and clean copy.	BA G9 Advertising.	Yes (if relevant at site).	Yes (if relevant at site).
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.
Victorian specific module.	To address Victorian legislation the Victorian Specific Module must be completed for every ethics application with a site in Victoria.	Victorian Specific Module.	Yes.	Yes.
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.
Safety reports.	Individual SUSAR or SSI Single site submission only. ASR, DSUR, Other general correspondence from sponsor (DSMB reports) must be submitted on behalf of all Bellberry approved sites.	MAR G2 Safety reporting.	Yes (Q1, single submission, Q2 on behalf of all).	Yes (Q1, single submission, Q2 on behalf of all).
DMC Letters/ Charter/TOR.	Only required if: The HREC requests it via a caveat on their approval letter; or a sponsors' policy requires the submission.	Guideline for Good Clinical Practice.	Yes.	No.
Progress reports.	Due annually at the anniversary of study approval. Each site is responsible for submitting their own progress reports.	MAR G4 Progress and final reports.	Yes.	Yes.
Serious breaches.	Each site is responsible for their own submission. If a breach relates to several studies (e.g. a sponsor data breach), submission may occur via the batch pathway.	MAR G3 Protocol violations and serious breaches.	Yes.	Yes.
Final report.	Due at the end of the project or if discontinued. Each site is responsible for their own submission.	MAR G4 Progress and final reports.	Yes.	Yes.