

This document includes the current questions in eProtocol. When preparing your initial application, this form can be used as a guide for collating answers prior to entering your responses in eProtocol.

Personnel Information.

First time applicants to Bellberry HREC must attach a copy of their full curriculum vitae (CV) and an updated version less than 2 years old must be provided thereafter. Please see BA G8 CVs & Investigator Qualifications for further information.

Principal Investigator.

Name.

Qualifications (e.g. MBBS, FRACP).

Title.

Email.

Phone.

Post code.

Sub-Investigator(s).

Name(s).

Email(s).

Nominated Contact(s).

Name(s).

Email(s).

Tax Invoice.

Name.

Email.

Study Sites.

Site/Location - the following question relates to the PI listed in this application. Please list the participating site name/s and address/s as you wish them to appear on your HREC letter.

1. Please list the site name/s and address details of each site for which the PI listed on this application will be responsible.

2. If the PI is responsible for more than one site, please advise what study activities will occur at each site and how the PI will maintain oversight (for example, consent may occur at one site and treatment at another). If not, please write N/A

Sponsor Source.

Is the study funded by an organisation?

If yes, by who?

Australian sponsor and contract research organisation (CRO) (if applicable) or organisation with sponsor responsibilities (insurance and indemnity).

International sponsor.

Application Page 1.

Research project title (please also include the protocol number in the study title).

Protocol number/study reference number.

Is this a first in human (FIH) study?

If not, what phase is this study?

Is this a multicentre application?

If yes -

Lead site only (first site to apply): Please list all known additional sites (Site/PI name only) and confirm which PICF pathway has been chosen for this study by entering 2 or 3 in the box below (see *BA F1.1.17 PICF Submission Pathways*). Additional sites only: Please provide the name of the PI for the lead site, and Bellberry application ID (if known). If you are unsure who is the lead site, please ask the sponsor. All sites: Please ensure study sites page is complete for your PI.

Is this an extension study request for a study that has previously been approved by Bellberry?

Is this study site a public health site? If yes, provide details below. If yes, please also state which public acceptance pathway this application is submitted to Bellberry under, e.g., NSW EPCT Framework, SA Health Research Ethics Policy, BETA.

Duration of project (must include any follow up periods).

Is this a new project?

Please provide a brief summary of the study. Include if Aboriginal or Torres Strait Islander participants, or participants under the age of 18 will be involved. Outline how local Aboriginal and Torres Strait Islander cultural values have been considered in the design and conduct of this research. Describe the process that will be used to satisfy the requirements for community consultation, engagement and governance that applies to this research. List any relevant ethics guidelines that have been consulted during the development of the research project. If a longer summary is required, please attach to page 7. Refer National Statement Chapter 4.7

Has the study been registered in a publicly accessible register? Refer National Statement Chapter 3.1.7

If 'yes', where? If 'no', please comment.

Does the study include any optional objectives (e.g., biospecimen sample, blood donation)?

If yes, please refer to Bellberry guidance document BA G5 Participant Information & Consent Form Development for guidance.

CTN project.

CTA project.

Is this application considered Lower Risk? Refer to the National Statement on Ethical Conduct in Human Research, Section 2.1 and Bellberry guidance *LER G1 Review Pathways - Higher Risk and Lower Risk Research*. If so, please complete and attach the document LER F1.1.16 Application for Lower Risk Review to this application.

Please comment.

Please describe the site consent process, including an explanation of who will obtain informed consent.

Dissemination of Project outputs and outcomes

Please outline the plan for reporting, publishing or otherwise disseminating the outputs/outcomes of research, state whether participants in the research will be offered a timely and appropriate summary of the project outputs/outcomes and state whether the planned dissemination of the outputs/outcomes contribute to knowledge or practice or serve the public.

Application Page 2.

Participation Population

Number of participants

Worldwide (including Australia).

Local site (please include in the PICF).

How will participants be recruited to this study? The recruitment strategy and the criteria for the selection of potential participants must be clearly described, including how and by whom they will be approached. Refer *National Statement Chapter 3.1 Element 2*.

If advertising is to be used, please attach all advertising material in the attachments section. Approval for all research advertising must be given. This includes print, electronic media and social media. If social media is being used a social media policy must be in place at each site that specifically covers the utilisation of advertising on social media platforms for participant recruitment. Please refer to *BA G9 Advertising Guidance* for further information.

Application Page 3.

Ionising Radiation

Is medical imaging involving ionising radiation being used in this study?

Please provide specific details (e.g., type of imaging procedure/s, number of procedures, body parts to be imaged).

If a participant was not enrolled in this study, would they still receive the equivalent number of exams involving the use of ionising radiation at the specified intervals as stated in the research protocol?

If not, please provide specific details of those procedures which are in addition to standard of care (e.g. type of imaging procedure/s, number of procedures, body parts to be imaged).

Where the ionising radiation exposure is in addition to that received as part of normal clinical management, an estimate of the radiation dose to be received by each participant is required (i.e. the effective dose and relevant organ doses). This should be in the form of a written report from a medical physicist. Please see *BA G13 Ionising Radiation Guidance* for further information.

Application Page 4.

Risks

All studies require insurance and indemnity. The partially executed HREC Indemnity is required to be sent to Bellberry for signature either via post or via a verifiable online service such as DocuSign or AdobeSign.

If sent electronically, please include the Application ID and the Principal Investigator's name in the subject line or content of the automated email.

Is the organisation, as listed on the Sponsor page of the application, taking responsibility for the insurance and indemnity? Please see *BA G15 Insurance & Indemnity Guidance* for further information.

If not, please state which organisation is taking responsibility for insurance and indemnification (required for all applications). For Investigator-led studies, this may be the Principal Investigator.

Application Page 5.

Ethics Committee

Has the study received other Australian ethics committee approval?

If yes, please attach the letter of approval in the attachments section.

Is the study currently under consideration by any other Australian ethics committee?

If yes, please include the name of the ethics committee.

Has the study product undergone any review by a comparable overseas regulator? (Refer to <https://www.tga.gov.au/list-countries-and-jurisdictions-determined-be-comparable-overseas-regulators-cors>)

If yes, please specify and attach relevant correspondence in the attachments section.

Has the study been rejected or had approval withdrawn by Bellberry HREC or any other HREC/IRB/regulator in Australia or internationally?

If yes, please specify the committee and their stated reasons. Attach relevant correspondence in the attachments section.

Application Page 6.

Declarations

Will the consent process comply with the *National Statement Chapter 5.3.6 (a)-(f)*?

If not, why not?

Do you or your Sub-Investigators have any actual, perceived or potential Conflict of Interest as per the *National Statement 5.3.11 or Chapter 5.6*?

If Yes, please disclose and describe how this will be managed and include relevant information in the PICF (*National Statement Chapter 2.2.6*).

Is an Investigator's Brochure (IB) applicable for this application? (Is the study product approved for the indication? If no, an IB is required).

The version of the IB provided should be less than 12 months old. If not, attach correspondence to advise why not, or when an updated version will be available.

For multi-centre studies, who will be responsible for disseminating study documents (e.g., protocol, IB, etc.) to additional sites?

A data management plan must be in place at each site which addresses intentions related to the generation, collection, access, use, analysis, disclosure, storage, retention, disposal, sharing and re-use of data and information; the risks associated with these activities; and any strategies for minimising those risks. Is a data management plan in place at this site? Refer to the *National Statement Chapter 3.1.44*. (If no additional information please enter N/A in the text box).

As the Principal Investigator, I confirm I have read and agree upon the information in this application.

As the Principal Investigator, I agree to conduct the study according to the documentation approved by the HREC following the current *National Statement on Ethical Conduct, ICH-GCP* and all other relevant legislation, policies, and guidelines, including Bellberry policies and guidance.

As the Principal Investigator, I also acknowledge responsibility for ensuring site-specific research governance policies and guidelines are complete before the commencement of the study.

As the Principal Investigator, I acknowledge that my submission may be subject to fees outlined in Bellberry guidance *BA G6 Application Fees*.

Application Page 7.

Attachments.

Add appropriate attachments. When submitting any updated documents, please attach a tracked changes and a clean version and DO NOT delete previous document versions. For multi-centre applications the documents for each additional site are required to be based on the documents as approved for the lead site. Please clearly specify any site-specific changes. Please see BA G1 Submission Requirements & Responsibilities and BA F1.1.1 Submission Requirements Checklist for further information.