Application form

Key points:

- The application form has had some minor question changes.
- Sites need to be mindful of these changes when applying and read all questions carefully.
- Declaration of the Principal Investigator has changed.
- Summary of the changes listed below.

Changes to wording or additional questions in the updated application form:

Please provide a brief summary of the study:
Include information such as whether Aboriginal or Torres Strait Islander (ATSI) participants, or participants under the age of 18 will be involved.

Aboriginal and Torres Strait Islander participants

- 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.

Publishing:

- 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.

Recruitment and consent:

- Describe the site consent process, including an explanation of who will obtain informed consent.
- 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.
- Will the consent process comply with the National Statement item 5.2.17 section (a)-(f)?
- If not, why not?

Advertising:

- 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 plan is required. Please refer to the Bellberry advertising guidance for further information.

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.

Insurance/Indemnity:

- All studies require insurance and indemnity. Please confirm that appropriate insurance and indemnity is/will be in place for this study.
- Please state which organisation is taking responsibility for insurance and indemnification (required for all applications)

Conflicts of interest:

- Do you or your Co-Investigators have any actual, perceived or potential conflict of interest as per National Statement 5.2.11 or 5.4?
- If yes, please disclose and describe how this will be managed.

Study document dissemination:

- For multi-centre studies, who will be responsible for disseminating study documents and approval letters to additional sites?

Principal Investigator declaration:

- The Principal Investigator has read and agrees upon the information provided in this application. The Principal Investigator is familiar with and has considered and addressed any relevant legislation, regulations, research guidelines and organisational policies in this application.

- The Principal Investigator agrees to conduct the study according to the documentation approved by the HREC; follow the National Statement on Ethical Conduct, ICH-GCP and all other relevant legislation, policies and guidelines. The Principal Investigator also acknowledges responsibility for ensuring site-specific research governance policies and guidelines are complete before commencement of the study.

See related documents:

Bellberry applications
BA F1.1.1 Submission requirements checklist