

Document/Submission	Prior to February 2021	From February 2021
<b>BA G1 Submission requirements and responsibilities</b>	Definition did not provide as much detail on additional site requirements.	<b>Updated to clarify definition.</b> Minor change to definition of additional site: “Sites other than the lead site involved in a multi-centre study. A separate application is required to be created and submitted in eProtocol for each Principal Investigator at each additional site seeking Bellberry HREC approval.”
<b>BA F1.1.1 Submission requirements checklist (external)</b>	Did not include requirement to submit a site-specific clauses document when PICF pathway 2 is selected. Did not define ‘lead’ site in the initial application vs when an amendment is submitted. Did not include as much detail on other submission requirements such as: radiation wording, site SOPs, the Western Australia Specific Module.	<b>Updated to clarify submission requirements.</b> Addition of requirement to submit a site-specific clauses document when the lead site chooses PICF pathway 2. Update to radiation wording for clarity. Updated in Master doc fields to clarify 'lead' site in the initial application vs when an amendment is submitted. The addition of site SOPs (not required unless requested by the HREC). The addition of the Western Australia Specific Module (if required).
<b>BA G5 PICF development guide including eConsent</b>	Did not include information that sites may be asked to respond to a question from the HREC relating to recruitment. Did not reference the National Statement.	<b>Additional statement added for information and clarity.</b> Recruitment: “Researchers must ensure they consider the National Statement on Ethical Conduct in Human Research 3.1.18 (a-e), and ICH GCP guideline 4.8 when developing any recruitment strategy and obtaining informed consent.”
<b>BA G6 Application Fees</b>	Major/minor amendment definitions not defined. Less information on fees included in fee table.	<b>Updated for clarity to users.</b> Major/minor amendment definitions, and additional information in fees table.
<b>BA F6.1.2 NSW EPCT fee form</b>	Did not stipulate that protocols are invoiced per site, IBs are invoiced per submission.	<b>Updated for clarity to users.</b> Updated to add clarity that protocols invoiced per site, IBs invoiced per submission.

<b>BA G7 Conflict of Interest</b>	Content remained the same as current version.	<b>No content changes.</b> Date change only as part of review cycle process.
<b>BA G8 CV's and Investigator Qualifications</b>	Did not request detail on specific training and current certification in research methods, clinical trials (where relevant) and ethical conduct.	<b>Updated to clarify submission requirements.</b> A copy of a researcher's current, full (updated within the last 12 months) Curriculum Vitae (CV), to include the following requirements and dates where applicable: evidence of any specific training and current certification in research methods, clinical trials (where relevant) and ethical conduct.
<b>BA G10 Participant payment and reimbursement</b>	Content remained the same as current version.	<b>No content changes.</b> Minor typographical error corrected.
<b>BA F13.1.3 Standard of care declaration - template</b>	Did not provide information that Bellberry do not mandate the completion and submission of this form when a PI has made a standard of care declaration in the eProtocol application.	<b>To inform users that the template is not mandatory.</b> Additional statement added: "Please note: Bellberry do not mandate the completion and submission of this form when a PI has made a standard of care declaration in the eProtocol application. If your institution requires the PI to provide a formal notification, the NHMRC provides the following wording. Please use this form as a template and place it on your institutional letterhead."
<b>BA F14.1.2 Pregnancy/pregnant partner data release - template</b>	Referred to 'obstetrician'. Did not include the following statement "It has also been explained to me that this information collection is not intended to take the place of medical care from my/my child's regular treating practitioner/s."	<b>Updated for clarity to users.</b> Change to the last dot point on page 2 'obstetrician' to 'practitioner/s'. It has also been explained to me that this information collection is not intended to take the place of medical care from my/my child's regular treating practitioner/s.