Monitoring Approved Research

MAR F1.1.3

Amendment pathways flowchart

Public

Prepare amendment within eProtocol (see BA F2.1.9). 4. Other amendments: 1. Administration - other correspondence: 2. Protocol amendment (see 3. Investigator brochure (IB) update: This may include: PICFs Use this section for administrative changes BA G3 and BA G4): An IB should be updated every 12 months (including site-specific summary or general correspondence (e.g. changes to and provided to the HREC for review. The Please provide the following documents; see BAF1.1.17); study staff, email addresses, updating HREC information in the appropriate following information is required to be questionnaires; advertising forms of indemnity, CV updates, etc.). For fields: version number; date; included: IB name; version no. and date; (including social media plans, other changes to approved documentation whether changes to the PICF when the IB was last reviewed; impact on etc.). Please provide a summary that is related to a protocol amendment, IB, are required. If relevant, safety or efficacy; whether changes to the of the proposed changes, etc., use sections 2, 3 or 4. Please note, provide further information PICF are required. If relevant, provide ensuring all relevant information using section 1 will restrict the use of other regarding why the PICF is/isn't further information regarding why the is included for the HREC. sections of the form. required to be updated. PICF is/isn't required to be updated. Multi Centre Applications: If the amendment is being submitted on behalf of multiple sites, please declare by selecting 'Yes'. 5. Attachments: Attach the relevant documents to section five of the amendment. A clean and tracked version is required for all documents previously reviewed for this study. When submitting new or updated documents for HREC review, please ensure the document has a version number, date and that version control is maintained. (See BA G12 for additional information). Please also note that the document names must appear exactly as you wish them to appear on the approval letter. Submit for HREC review: Once the amendment preparation is complete the Principal Investigator is required to complete the declaration on Page 6 (select Application Information, Page 6 ' Declarations'), Once completed, click Submit Form.

Last review: 30/08/22, next review: 30/08/24 Page 1 of 2

Page 7 (initial application): Upon approval of the amendment, Bellberry administration will upload the approval letter to Page 7 of each multi-centre application for this study. The site is responsible for checking that their study documentation matches the approval letters. Any anomalies must be submitted by way of an amendment (post-approval).

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