*Bellberry’s dedicated batch submission team will acknowledge receipt of your batch request within 48 hours of receipt.* ***If you have not received acknowledgement of your batch request within 48 hours, please contact Bellberry on 08 8361 3222.***

*Completing and submitting this form gives Bellberry the authority to process submissions in eProtocol on behalf of the site/sponsor. Before completing this form, the requestor must ensure they have discussed the submission with the relevant sites/sponsor to avoid duplication of work. Following this, our standard procedure of review and decision outcome will take place.*

*Please email this form to* *bellberry@bellberry.com.au*

*Please note: a batched submission may attract a fee. When available, this will be published here:* [*https://bellberry.com.au/im-a-researcher/our-fees/*](https://bellberry.com.au/im-a-researcher/our-fees/)*.*

**Requestor:**

**Organisation:**

*(Name the requestor’s organisation, i.e. the research site, sponsor or CRO.)*

**Invoice details for batch submissions:**

*(Include who the invoice should be made out to, company, address and billing reference. Cost will be confirmed by Bellberry in application receipt email.)*

**Or: Bill the tax invoice contact provided in eProtocol** [ ]

Where relevant, please complete the eProtocol questions provided in the following form(s) and attach to this batch submission:

* MAR F1.1.2 Amendment form (eProtocol questions)
* MAR F2.1.1 Safety reporting (eProtocol questions)
* MAR F3.1.3 Protocol violation form (eProtocol questions)
* MAR F4.1.1 Progress report (eProtocol questions)
* MAR F1.1.6 HREC notification template - change in PI
* MAR F1.1.7 HREC notification template - change in CPI

**Amendments**

**Please summarise the proposed amendment and consider the following**

* Please outline what will happen with participants in screening, on treatment and in follow-up.
* How will participants be informed of these changes?
* If the changes will impact ongoing IMP supply to participants, please comment.
* If the changes require a change to the risk-based monitoring or other monitoring arrangements, please comment (e.g. means for sending urgent data to sponsors when physical site monitoring is unavailable).
* Duration of impact (fixed vs until further notice), please comment.
* Measures taken after temporary halt/early termination of trial.
* Does the amendment require a PI change at any site?
* If this is a protocol or IB update, is there a change to the PICF? Please attach clean and tracked versions of documents to your batch submission. (This incurs a general amendment fee as per the standard Bellberry fees.)

**Attachments**

Attach relevant documents. It is important to accurately name the attachments as you want them to appear in the approval letter.

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| --- | --- | --- | --- |
| **Item Number**  | **Document Title** | **Version** | **Date** |
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***(Add rows as required.)***

**Please list the sites/studies to which this request relates**

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| --- | --- | --- | --- | --- | --- |
| **HREC ID** | **Study Title** | **PI Name** | **Site Name** | **Recruitment Status**  | **Relevant Attachments**(List relevant item numbers\*) |
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 ***(Add rows as required).***

*\*Please stipulate whether all attachments provided are applicable to each listed study (by listing each attachment item number in the ‘relevant attachments’ column).*

*If only some of the attachments provided are relevant to some studies, please include the applicable attachment item number(s) in the ‘relevant attachments’ column.*