

## Amendment Guidelines

### Consider the following when preparing to submit an amendment

- Consider whether the documents listed in the guide are appropriate for your particular amendment. Once you have confirmed a particular document is not required, please put this information in the amendment form (eg. "PICF update not required as project is closed to accrual") to avoid a query further down the track.
- If there are changes to any of the study document(s), tracked and clean copies of these documents must be submitted as part of the amendment.
- If a study document is new (ie has not been submitted to the HREC before) this should be stated on the amendment form.
- A study protocol should contain up to date information regarding all study processes including recruitment, consent and study procedures. Therefore, if an amendment will change any of these study processes, an updated protocol (tracked and clean) must be submitted. This is to ensure that any new investigators can pick up the latest protocol and be able to conduct the study as per the approved protocol.
- To make sure your approval letters are correct, please take the time to carefully and accurately list the documents submitted on the amendment form. We will use this form to generate your approval letter.
- If a Participant Information and Consent Form (PICF) update occurs, please ensure any new wording is in **lay language**.

### Please ensure that:

- Documents in the amendment are appropriately named with document type, version no, version date (eg. protocol version 3\_1 Jan 2015) and that documents are not locked;
- The files are compressed before attaching to the email. If the file is too large please attach over a series of emails making it clear in the subject that this is what you are doing (eg. 2015.001\_Protocol amendment 3\_email 1 of 3).
- Each document is attached as a separate file, ie. not a combined document
- If the amendment includes documents that require an original signature such as CTNs, indemnities and/or contracts, please submit these in hard copy to the Office for Research with a copy of the amendment form. We will accept scanned signatures of the PI on amendment forms.

### Tips for Participant Information and Consent Forms (PICFs)

Lay language is defined as language that could be understood by someone with a reading age of 12 years old. Note PICF requirements below to ensure that the approval is not delayed in the review process:

- If a patient is likely to know certain medical terminology because of their condition, state this in the amendment form or as a comment on the tracked PICF so that we do not request alterations.
- The wording of 'subject' is not permissible so please change this to 'participant' where applicable within the new wording.
- Often a study Sponsor will insert the new wording from the global or AUS PICF template so please take the time to check that the wording in the Master/Site Specific PICF is acceptable to that of the HREC.