Submitting your response to a REC provisional opinion: guidance for applicants
20 June 2014

If you receive a provisional opinion from the Research Ethics Committee (REC) then you will need to respond to the issues that have been raised before a final opinion is given.

The provisional opinion letter will provide information about the issues that have been raised. To respond to these points you may need to submit an updated version of your application form and/or supply further supporting documents (this may include revised versions of documents you have previously supplied and/or new documents).

Your response to the REC must be electronically submitted from IRAS. Please follow the relevant set of instructions below, depending on the type of information you need to supply.

You must start by logging into IRAS, opening your project and navigating to the REC form.

Submit a revised version of the application form:

- If you need to add sections to your dataset (e.g. you need to supply information about radioactive materials that was not included in your initial application) then start by going to the project filter and updating your selections, as required.

- Click on Navigate and then go to the question(s) that you need to revise.

- Complete all necessary revisions to your application.

- Seek electronic authorisation(s) for the declarations in your form.

! Remember that when you change the data in your form, your electronic authorisations will invalidate so you will need to request them again.
Submit updated version(s) of previously supplied supporting document(s)

! IMPORTANT: To electronically submit supporting documents to the REC, they need to be uploaded to the form checklist.

- To update a document that you previously electronically submitted (i.e. a version of the document has already been uploaded to the form checklist).

- Click on the Checklist tab.

- Go to the row in the checklist that contains the document you need to update. Click icon.

- Upload the revised document.

  - Repeat steps above for each document you need to update.

  Previous versions of uploaded files are retained unless you delete them by clicking ‘Delete’ link. You can view the retained previously uploaded versions by clicking ‘>’ icon.

  TIP>> If you need to also supply a version showing updates as tracked changes then please follow process for submitting new supporting documents in next section.
Submit new supporting documents

! IMPORTANT: To electronically submit supporting documents to the REC, they need to be uploaded to the form checklist.

Start by clicking on the Checklist tab:

If the type of document you are adding is already in the checklist:

- Go to the row in the checklist that contains the document you need to add.
- If you have not previously added a document of this type simply click the icon and follow instructions to upload the document.

If you have need to add an additional version of a document that you have already submitted (e.g. you need to supply an additional variant of the participant information sheet or you need to provide clean and tracked changes versions of an updated document) then:

- First duplicate the row for the document type by clicking on icon.
- Then upload the file to the newly created checklist row by clicking the icon and following instructions provided. Please ensure you enter the document details.

If the type of document that you need to submit is not listed then:

- Add a new row at the end of the checklist by clicking button.
- In the newly created row, click the icon and follow instructions to upload the document. Ensure your document name describes the type of document you are adding.
- Repeat steps above for each document you need to add.
To electronically submit your response to the REC:

- Before proceeding please check you have completed all required changes and have obtained any authorisations that are needed.

- **IMPORTANT:** You must contact the REC before you attempt to electronically submit your response so that they can enable the function.

You will need to tell the REC:

- That you are ready to electronically submit your response; and
- Whether your submission will include an updated form or if it is a documents only submission.

Once you have contacted the REC and they have enabled electronic submission for your response:

- Go to the E-submission tab for the form.

- When you are ready to submit your response, click **E-Submit Application**.

- Refer to the submission history on this tab for updates on progress.

- When you click ‘E-Submit Application’, this will electronically send your response to the REC and disable the button preventing further submissions.

So:

- If you need to supply multiple items you are strongly advised to submit these in a single submission. That is, make all form and document updates that are needed before you click ‘E-submit application’.

- If you are unable to supply your response as a single submission you must contact the REC before you submit further information. This will allow the REC to re-enable the electronic submission.