

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.



Navigation Page (Get to this page from anywhere in your project by

Project Title: **Example project**
 Project Type: **Other clinical trial or investigation**
 Full project dataset

Project Filter

[Click here to go directly to the Project Filter questions](#) ←

Full Set of Project Data (Select this dataset to answer all the questions for your project)

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



Navigate ← Checklist Transfer Authorisations Save/print E-S

- Complete all necessary revisions to your application.
- Seek electronic authorisation(s) for the declarations in your form.



Checklist Transfer Authorisations ← Print E-Submission


! 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.

Document	Subtitle	Enclosed	Date	Version	Office Use	Reason not supplied		
Covering letter on headed paper		No						
Research protocol or project proposal	Example document	Mandatory	02/12/2013	1.0				

- Upload the revised document.

Update Document

Browse for a file on your hard drive to update this document or select from your already uploaded documents

Document Title	File Name	File Size	Upload Version	Upload Date	Document Type	Document Version	Document Date	AV Scan
> Example document	Example document_Dec2013_v1 -0.docx	15 Kb	1	18.06.2014 15:36	Research protocol or project proposal	1.0	02/12/2013	OK Delete

Update document from: Hard drive My Documents Project Documents

File: [Browse...](#)

Document Title:

Document type:

Document Version:

Document Date:

[Upload](#)

Make sure you enter updated information for the document i.e. its version number and date.





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

Update Document

Browse for a file on your hard drive to update this document or select from your already uploaded documents

Document Title	File Name	File Size	Upload Version	Upload Date	Document Type	Document Version	Document Date	AV Scan
> Example document	Example document_June2014_v2 -0.docx	15 Kb	2	19.06.2014 12:00	Research protocol or project proposal	v2.0	19/06/2014	Delete

[Close](#)


Document	Subtitle	Enclosed	Date	Version	Office Use	Reason not supplied		
Covering letter on headed paper		No						
Research protocol or project proposal	Example document	Mandatory	19/06/2014	v2.0				

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.


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




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: 


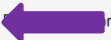



If the type of document you are adding is already in the checklist:


- 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.









	Copies of advertisement materials for research participants		No						
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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:

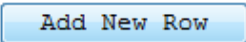

- First duplicate the row for the document type by clicking on  icon.







	 Information sheet (PIS)	Adult Participant Info Sheet	Yes	26/05/2014	v1-1					
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- 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.

	Participant information sheet (PIS)	Adult Participant Info Sheet	Yes	26/05/2014	v1-1					
	Participant information sheet (PIS)		No							

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.

Other documents										
	Other (please specify)		No							
Add Document										
Browse for a file on your hard drive or select from										
										
Other documents										
	Other (please specify)	Additional Supporting Document	Yes	18/06/2014	v1-0					

- 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.

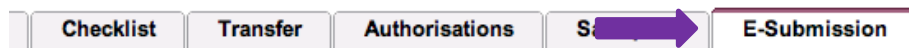
! IMPORTANT: You must contact the REC before you attempt to electronically submit your response so that they can enable the function.

You will need to tell the REC :

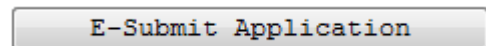
- That you are ready to electronically submit your response; and
- Whether your submission will include an updated form or if it is a documents only submission.

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

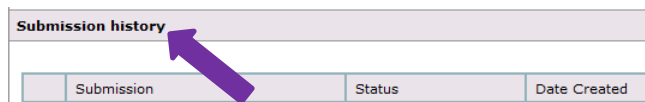
- Go to the E-submission tab for the form.



- When you are ready to submit your response, click



- 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.