

Track changes in research submissions

- Following a review by the Metro South Health Human Research Ethics Committee (MSHREC) or Metro South Research Governance Office (MSRGO), the Principal Investigator/Coordinating Principal Investigator (CPI) will receive a letter, via the Ethical Review Manager (ERM), with queries to be addressed before the project can receive ethical clearance or governance authorisation.
- More than 90% of research projects reviewed by the MSHREC require a response to queries raised in the process of HREC review.
- It is common for the HREC or Site Specific Assessment (SSA) contract changes to request changes to the study documents in these queries. For the MSHREC or MSRGO to confirm that the requested changes have been made, track changes must be used.
 - Please note: When a document is submitted to MSHREC or MSRGO or the first time as part of the initial submission (i.e., not as an amendment or revision), no track changes are required.

Revision

- When revising documents in accordance with queries or for an amendment, it is important to use track changes to assist the MSHREC or MSRGO reviewer to identify any new, amended or deleted text.
- Easy identification of changes to the study documents will assist with timely reviews and approvals. Updated documents submitted without track changes will be returned to the researcher.

Functionality of track changes in Microsoft Word

1.1 Turning track changes on and off

- In Microsoft Word, select the 'Review' tab then select 'Track Changes'.
- When Track Changes are on, the 'Track Changes' button will be highlighted. In the Word web app, when Track Changes are on, a 'Reviewing' button will be highlighted on the right-hand side of the Ribbon. Deletions are marked with a strikethrough, and additions are marked with an underline. If there are multiple people editing the document, different authors' changes will be shown in different colours.
- When Track Changes are off, the 'Track Changes' button will not be highlighted. In the Word web app, when Track Changes are on, the 'Reviewing' button will change to either 'Editing' or 'Viewing'. This means that Word will stop marking any changes made, but the coloured underlines and strikethroughs will still be shown in the document. It is important to ensure that no changes are made to the document when Track Changes are off.

1.2 Accepting track changes (ethics approved submission)

- Once a submission has been approved, the tracked changes can be accepted. To do so, select the 'Review' tab, then select the 'Accept' button, then select 'Accept all changes'.
- Although there is also an option to select 'Accept all changes and stop tracking', we do not recommend selecting this in case one of the investigators is to make any changes in the future and forgets to re-select 'Track Changes'.

1.3 Accepting track changes (SSA submission)

- For a MSH lead study, where a contract is provided, the MSRGO will be responsible for removing tracked changes, the contract will be made final when all changes are accepted by all parties.
- Where a study is not a MSH study and the contract has been reviewed in track changes by the MSRGO, the MSRGO will give permission for the contract to be made final and track changes to be accepted by the sponsoring party.

1.4 When to use track changes

- Any time that a document is updated, both clean and tracked changes copies should be resubmitted to the MSHREC and if applicable MSRGO. This will be either as a response to a request for further information, or as an amendment.
- Please ensure that only the changes relevant to that resubmission are showing. For example, if you are submitting an amendment, only the changes made for the current amendment should be showing. Changes that were made previously and have already been approved should be accepted prior to changes being made for the current amendment.
- When a contract has been submitted for MSRGO review via MSH-RGO@health.qld.gov.au email address.

ERM

- All updated documents need to be uploaded to ERM with both a tracked changes copy, for review purposes, and a clean copy, to keep on file for future reference and for monitoring purposes.
- RGO review of contracts will be performed outside of ERM via the MSH-RGO@health.qld.gov.au email address.
- Updated/amended documents must also include an updated version number and date in the document name and the document footer.
- Documents submitted without appropriately updated version control will not be accepted. For more information about version control please see MSH work instruction WI2023-288 Research quality management systems.

1.5 Uploading track changed documents into ERM

1. Open the HREA form within ERM and go to the 'Upload' page.
2. Upload the clean version of the protocol under Q4.1

3. Under Q4.2 choose 'Yes', if not already selected, to bring up the list of supporting document types.
4. For the Protocol and Participant Information and Consent Form there are specific 'tracked' options available so please use these selects to upload against.
5. See below example of how to add clean and tracked versions of the Participant Information and Consent Form (PICF):

Participant information and consent forms

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Participant information and consent form	PICF V1 - [REDACTED]	PICF V1 - [REDACTED].docx	15/08/2022	1	3.2 MB	Download	
Participant information and consent form	Qual PICF V1 - [REDACTED]	Qual PICF V1 - [REDACTED].docx	15/08/2022	1	103.8 KB	Download	
Participant information and consent form	PICF V2 - clean - [REDACTED]	PICF V2 - clean - [REDACTED].docx	21/10/2022	2	265.3 KB	Download	
Participant information and consent form	PICF V3 - clean - [REDACTED]	PICF V3 - clean - [REDACTED].docx	17/11/2022	3	236.7 KB	Download	
Participant information and consent form	Qual PICF V3 - clean - [REDACTED]	Qual PICF V3 - clean - [REDACTED].docx	17/11/2022	3	86.4 KB	Download	

Participant information and consent forms (Tracked)

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
PARTICIPANT INFORMATION AND CONSENT FORM (TRACKED)	PICF V2 - tracked - [REDACTED]	PICF V2 - tracked - [REDACTED].docx	21/10/2022	2	273.7 KB	Download	
PARTICIPANT INFORMATION AND CONSENT FORM (TRACKED)	PICF V3 - tracked - [REDACTED]	PICF V3 - tracked - [REDACTED].docx	17/11/2022	3	283.9 KB	Download	
PARTICIPANT INFORMATION AND CONSENT FORM (TRACKED)	Qual PICF V3 - tracked - [REDACTED]	Qual PICF V3 - tracked - [REDACTED].docx	17/11/2022	3	94.4 KB	Download	

- For other documents such as questionnaires, this does not have a separate 'tracked' section, so clean and tracked copies should both be uploaded in the section as below:

Questionnaires

Type	Document Name	File Name	Version Date	Version	Size	View
Questionnaire	Survey of Women V1 - [REDACTED]	Survey of Women V1 - [REDACTED].doc	15/08/2022	1	3.1 MB	Download
Questionnaire	Survey of Women V2 - tracked - [REDACTED]	Survey of Women V2 - tracked - [REDACTED].doc	21/10/2022	2	197.0 KB	Download
Questionnaire	Survey of Women V2 - clean - [REDACTED]	Survey of Women V2 - clean - [REDACTED].doc	21/10/2022	2	195.5 KB	Download
Questionnaire	Survey of Women V3 - clean - [REDACTED]	Survey of Women V3 - clean - [REDACTED].doc	17/11/2022	3	196.0 KB	Download
Questionnaire	Survey of Women V3 - tracked - [REDACTED]	Survey of Women V3 - tracked - [REDACTED].doc	17/11/2022	3	196.5 KB	Download