

Guidance on Documentation for Substantial Amendments

2nd of February 2022

Version 1.0

To facilitate the validation and review processes, the National Office for Research Ethics Committees strongly recommends that the following guidance in relation to substantial amendment (SA) documentation is incorporated into all submissions.

- Include the following table template, noting all documents submitted for the SA and the action required:

No.	Name	Action
1	Cover Letter	n/a
1.1	NREC SA Form	n/a
2	Protocol-version/date-clean [e.g., Protocol name-V1.1-01012021-Clean]	For NREC Review
2.2	Protocol-version/date- redline [e.g., Protocol name-V1.1-01012021-Redline]	For NREC Review
3	IB V.1	For Reference
4	Insurance Certificate	For Reference
5.	Site PI CV	For notification / non-substantial amendment

NREC Substantial Amendment Form

- Complete all fields, or include n/a if not relevant
- Complete **Section C** to provide a succinct description and justification of the SAs

C. Details and Justification for Proposed Substantial Amendment

Please complete Section C as it relates to the proposed Substantial Amendment. Where it requires a change(s) to study documentation, the proposed change(s) should be highlighted as Tracked Changes in the relevant document(s) and submitted along with this form to the National Research Ethics Committee. Please provide section references and page numbers for proposed changes to documentation in the table below.

Details and justification for the proposed Substantial Amendment.	Document Reference - Section/Page
Click or tap here to enter text.	Click or tap here to enter text.

Guidance on documents

- Number all documents
- Include clear document names (with version no./date)
- Include redline / track changes version of current documents
- Include clean version of proposed documents

General Submission Guidance

- All files submitted as requested
- Proof of payment submitted as part of application (i.e., payment remittance / bank transfer statement)
- Quote the NREC invoice number in the proof of payment document and / or email body
- Quote NREC code (if already assigned) in email subject
- If the SA submission is deemed invalid, all relevant documents must be resubmitted as a new submission.

Version Control

Date	Version Number	Previous Version
02/02/2022	1.0	n/a