

FIEBRE Standard Operating Procedure FD.01		
Title	Procedure to request updates to eCRF forms	
<i>SOP Reference</i>	<i>Version</i>	<i>Date of effect</i>
FD.01	1.1.1	06 Jan 2019

SOP Development

	Name	Title	Signature	Date
Author	Kate Haigh	Clinical Governance Co-ordinator		
Reviewer	Sham Lal	Data manager		
Approver	Heidi Hopkins	Scientific Program Co-ordinator		

Review Tracker

Due date for next review	Reviewer name	Signature	Date reviewed
27 Feb 19			

Revision History

Version No.	Effective date	Reason for change

SOP User Confirmation

I acknowledge that I have read, understood and agree to follow this SOP

#	Name (print)	Signature	Date
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1 Title: PROCEDURE TO REQUEST UPDATES TO eCRF FORMS

2 Purpose: To describe the procedure to follow to request updates to electronic CRFs on ODK (Open Data Kit) utilised for collecting data for the FIEBRE study.

3 Responsible staff: [adjust based on site personnel]

4 Background & Rationale: The rationale for using CRFs in a study is to ensure that the data is collected in a way that minimises inter-observer bias and data collection errors. It is also necessary to ensure that the data collected is complete and traceable to the health care worker collecting the data and the patient who has consented to supply it. The CRFs will collect all the patient data that has been set out in the protocol. CRFs for FIEBRE study are in ODK format on tablets. It is of utmost importance that the ODK forms are up to date with any central or site-specific protocol or operational developments.

In order to minimise error and for audit purposes, requests for updates or changes to ODK forms should be made in a standardised manner, as detailed in this SOP.

5 Supplies and Materials

- Microsoft Word version of ODK form downloaded from the central FIEBRE Dropbox

6 Procedures:

6.1 Accessing current eCRF form

To access the current ODK form, enter Dropbox and choose these folders: FIEBRE -- CRFs -- CURRENT CRFs -- [choose site and ODK form as appropriate]

You will now have the Microsoft Word version of the form.

Save this document to your own computer/laptop at this stage, adding '_initials_date' following the form title. For example, if John Smith was making changes on the 6th January 2019, the form would be saved as the current title then '_JS_060119'.

6.2 Requesting changes to eCRF form

- Turn on the 'track changes' function before editing

- Edit on the form where you would like the change/s, which will be recorded using the track changes function. Also add 'comments' to make it clear where and why any changes have been requested
- Save the form again to your computer/laptop as per 6.1
- Email this updated form to Sham Lal (sham.lal@lshtm.ac.uk), data team, to request the update, copying in Kate Haigh (khaigh@mlw.mw), Clinical Governance Co-ordinator

7 Documentation: FIEBRE protocol (version 3.0, 31 Oct 2018) sections 10 and 12.