Standard Operating Procedures (SOP) for:			
Unlocking a locked site for data edition or amendment for the International Surgical Outcomes Study (ISOS) electronic case record form (eCRF)			
SOP Number:	**ISOS_01**	Version Number:	**1.0**
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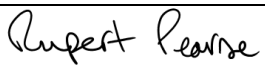
Signature	
Date	14.05.2014

Purpose and Objective:

To outline the procedure for the management of data amendment requests made by ISOS investigators once they have locked their site (hospital) to further data entry to the eCRF.

Background

Data collected for ISOS is uploaded to an internet based eCRF. Once investigators have uploaded their data and have verified that the data are complete and accurate, they can lock their site data so no further changes or additions can be made. Once this occurs, local investigators are able to view and download their complete data set. If following review, any errors or omissions are identified in the dataset then changes may be requested by investigators at that site. A standard procedure is therefore needed to ensure this process is valid and robust.

	Responsibility	Activity
1	Lead Investigator at ISOS site	1. To email the ISOS management team at data@isos.org.uk with a complete list of data corrections requested. 2. Each data point change should include: • site name • patient ID • which fields need to be changed • the corrected data point • reason for the correction
2	ISOS Management Team	1. Review the proposed corrections and raise queries as necessary 2. Notify the local co-ordinator at the site whether their proposed changes have been accepted or declined within five working days 3. If the proposed corrections are rejected, a reason will be provided. 4. If the corrections have been approved, the local co-ordinator will be informed that the eCRF for their site is unlocked to allow data corrections.
2	Lead Investigator at ISOS site	1. Once the eCRF has been unlocked for a given site, the local co-ordinator will need to authorise un-signing of the individual patients' CRF(s) in question before investigators can make corrections. 2. **ONLY** proposed changes that the ISOS team are aware of should be made. The eCRF audit trail will be used to verify those changes which have been made. 3. If additional changes have been made without prior review, the local co-ordinator will contacted to clarify the reason. We may not be able to include a hospital in the final data analysis if significant changes to the data have been made without a

		satisfactory explanation. 4. Once the agreed corrections have been made, the site eCRF should again be locked to further data entry