noclor
RESEARCH SUPPORT

NHS

Temporary Halts

Clinical Trials

SOP Reference ID:		Noclor/Spon/S09/01	
Version Number	1.0	**Effective Date:**	1st March 2016

It is the responsibility of all users of this SOP to ensure that the correct version is being used. The definitive versions of Noclor SOPs are available from the Noclor website https://www.noclor.nhs.uk/training-resources either by checking the document library or by carrying out a specific document search

Standard Operating Procedure: Temporary Halts

Version History

SOP Reference ID	Effective Date	Reason for Change
SOP CA019 Version 1.0	18/11/2011	
Noclor/Spon/S09/01	01/03/2016	Newly created Noclor SOP (applicable to all Noclor partner NHS Trusts). New numbering system adopted so this SOP has been assigned first version. New SOP format. Procedures relating to Temporary Halts have been separated out from USM's.

Authorship and Authorisation

Author Job Title:	Noclor Sponsor Representative		
Reviewed by:	Noclor Senior Management Group	Date:	10th February 2016
Authorised by:	Lynis Lewis, Noclor Service Director		
	Signature: Signed copy held by Noclor	Date:	15th February 2016

SOP Content

Standard Operating Procedure: Temporary Halts

1. Purpose

A temporary halt to a research study is a stoppage (suspension) which was not envisaged in the approved protocol and where there is an intention to resume the study.

This Standard Operating Procedure (SOP) describes the procedures that must be followed to ensure that when a clinical trial sponsored by a Noclor Partner NHS Trust is temporarily halted the situation is managed, notified and recorded appropriately.

2. Scope

This SOP should be followed by Chief Investigators (CIs) that are responsible for setting up and managing clinical trials (CTIMPs and non-CTIMPs) to ensure that any temporary halts during the trial are managed in accordance with sponsor procedures and regulatory requirements (where relevant).

3. Abbreviations

CI	Chief Investigator
CTIMP	Clinical Trial of Investigational Medicinal Product
ISF	Investigator Site File
PI	Principal Investigator
SOP	Standard Operating Procedure
TMF	Trial Master File

4. Procedure and Responsible Personnel

A study maybe halted (suspended) for various reasons such as: on the recommendation of the IDMC (i.e further to review of new safety information); as an USM (refer to Noclor/Spon/S08/0X); further to a serious breach (refer to Noclor/Spon/S10/0X); due to IMP expiry/supply issues for Clinical Trials of Investigational Medicinal Products (CTIMPs) or where recruitment has to be halted for other reasons.

A temporary halt applies when a suspension is imposed on all sites; suspension of the study at a single site due to logistical reasons is not considered a temporary halt (unless the study is a single-site study).

The decision on whether a temporary halt should be imposed on a clinical trial sponsored by a Noclor partner will ultimately be the sponsor's decision and the decision-making process must be evidenced in the Trial Master File (TMF).

	Procedure	Responsible Personnel
4.1	**Notification** For clinical trials, where it has been agreed between the Chief Investigator (CI) and the Noclor Sponsor Representative that a temporary halt should be imposed on the study this should be notified to MHRA (for CTIMPs) REC and NHS/R&D as a substantial amendment within 15 days of the decision being taken	Chief Investigator (CI)

	to halt the trial, according to the Noclor amendment procedures Noclor/Spon/S07/0X.	
4.2	The CI is responsible for notifying the local investigators/sites and any other relevant parties (such as funder) of the temporary halt. Principal Investigators (PIs) should be provided clear instructions as to: 4.2.1 why the temporary halt has been imposed 4.2.2 when the halt is to be effective from 4.2.3 what the temporary halt means (is it just suspension to new recruitment or are patients on trial being suspended from treatment) 4.2.4 what and how to communicate with enrolled participants and any other instructions as relevant 4.2.5 what documentation to file at site in the Investigator Site File (ISF)	Chief Investigator (CI)
4.3	The CI should request confirmation of receipt from the PI's at sites that they have understood the instruction for the temporary halt (Noclor may request the evidence of this confirmation).	Chief Investigator (CI)
4.4	All information pertaining to a temporary halt should be retained in the TMF	Chief Investigator (CI)
4.5	To re-start a study after a temporary halt requires a 're-start' substantial amendment being submitted and approved by MHRA (for CTIMPs), REC and NHS/R&D. Other amendments to the protocol or supporting documentation may also be incorporated in the substantial amendment as required for the study to re-start. The substantial amendment should be prepared and submitted according to the Noclor amendment procedures Noclor/Spon/S07/0X.	Chief Investigator (CI)
4.6	CTIMPs that have been on a temporary halt will require official re-activation by the sponsor. Once the sponsor has been provided evidence of all required approvals/permissions and any other supporting information/documentation as required (for example, any specific instructions/re-initiation required for sites) notification, in the form of an email, will be sent by the Noclor Sponsor Representative to the CI to inform him/her that the study can re-start	Noclor Sponsor Representative (CTIMPs)
4.7	The CI is responsible for notifying sites that the study is active.	Chief Investigator (CI)

4.8	If the Chief Investigator (ultimately Noclor) decides not to recommence a study after the temporary halt, the end of study should be notified. For CTIMPs, this would be defined as an early termination to the trial and must to be notified to the MHRA and Research Ethics Committees (REC) within 15 days of the decision being made not to re-start. Refer to Noclor/Spon/S11/0X	Chief Investigator (CI)

5. Deviation from SOP

Noclor Sponsor SOPs define working methods which should be adhered to. However, occasionally for specific projects it may be necessary to deviate from the Sponsor SOP.

Formal written explanations/justifications of such deviations must be approved by Noclor Sponsor Representative prior to implementation (or they will be considered a non-compliance to sponsor procedures requiring reporting according to SOP Noclor/Spon/S10/0X).

The deviation from Sponsor SOP should be recorded on the SOP Deviation Form (Noclor/Inter/T12/0X) and sent to the Sponsor Representative for review. A copy of the completed and signed form should be filed with the T/SMF.

6. SOP Storage and Archive

The details of this SOP should be included on the study specific document inventory log (Noclor/Spon/T07/0X).

The Chief Investigator (CI) is responsible for retaining and archiving controlled copies of Sponsor SOPs (and the associated training records) that have been worked to for the duration of a trial in the Trial Master File (TMF).

7. Associated Documents

Document Reference ID	Document Type	Document Title
Noclor/Spon/S07/0X	SOP	Amendments (Sponsored Research)
Noclor/Spon/S08/0X	SOP	Urgent Safety Measures (Clinical Trials)
Noclor/Spon/S10/0X	SOP	Protocol Deviations, Non-Compliance and Serious Breaches (Clinical Trials)
Noclor/Spon/S11/0X	SOP	End of Study Notification, Close-Out and Reporting (Sponsored Research)

8. Appendices

9. Confirmation of Training

This SOP will be provided to the Chief Investigator (CI) and he/she will have the opportunity to ask specific questions to the author of the SOP.

The CI must e-sign the confirmation of self-training below prior to the study commencing.

The CI is responsible for ensuring that members of his/her study team are trained in the sponsor procedures (SOPs) that are relevant to their specific roles and responsibilities on the study.

I,

confirm that I have read and understood the content of this SOP and will work according to it.

Controlled copies of Sponsor SOPs should be filed in the relevant section of the Trial Master File (TMF). If this SOP replaces a previous version, the previous version should be retained in the TMF and marked through as superseded.

The SOP details should be added to the document inventory log (Noclor/Spon/T07/0X).

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10. SOP Training Log

All members of the co-ordinating trial team concerned by this SOP (according to the role and responsibilities they are being delegated by the CI and as they appear on the co-ordinating trial team delegation log) should sign the SOP training log.

	Full Name	By signing below I confirm that I understand and agree to work to this SOP	
		Signature	Date

This training log should be filed in the relevant section of the TMF.