Standard Operating Procedure

noclor RESEARCH SUPPORT

NHS

Risk Assessment

Sponsored Research

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Standard Operating Procedure: Risk Assessment

Version History

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Authorship and Authorisation

Author Job Title:	Noclor Sponsor Representative		
Reviewed by:	Noclor Senior Management Group	Date:	8th March 2016
Authorised by:	Lynis Lewis, Noclor Service Director		
	Signature: Signed copy held by Noclor	Date:	14th March 2016

SOP Content

Standard Operating Procedure: Risk Assessment

1. Purpose

There are risks associated with specific activities and tasks during the course of any research study. For individual research studies, it is the responsibility of the investigators and the research team to manage the study in accordance with the approved protocol, relevant legislation, GCP and sponsor Standard Operating Procedures (SOPs) in order to control all significant known and potential unforeseen risks.

Noclor manage risk at an organisational level by applying proportionate and adaptive risk management systems to research studies sponsored by a Noclor Partner NHS Trust.

This Standard Operating Procedure (SOP) describes the risk management procedures for health research sponsored by a Noclor Partner NHS Trust.

2. Scope

This SOP should be followed by Chief Investigators (CIs) that are responsible for setting up and managing health research that is sponsored by a Noclor Partner NHS Trust to ensure that the risks associated with the research are assessed and managed in accordance with sponsor procedures.

3. Abbreviations

CI	Chief Investigator
CTIMP	Clinical Trial of Investigational Medicinal Product
SOP	Standard Operating Procedure
S/TMF	Study/Trial Master File

4. Procedure and Responsible Personnel

The sponsor should be aware of the potential foreseeable risks and hazards associated with a specific study and the 'harm' that the hazard would result in should it occur prior to agreeing to act as sponsor. Mitigation plans should be documented and applied where appropriate to manage the risks of the research on an ongoing basis.

The key contributor to the early identification of potential risks will be the Chief Investigator (CI). S/he should consider the risks of the proposed research during protocol development so that mitigation plans can be built into a workable and ethical protocol from the outset. Depending on the research study category, a detailed bespoke risk assessment may also be required outlining the specific risks associated with the study and plans to mitigate these risks.

Risk management is the responsibility of all parties involved and is a continuous process. The risk management plan for simple studies may be a single paragraph within the protocol, however for more complex clinical trials it will likely be a significantly more detailed monitor plan agreed to by the sponsor and the CI (detailing the programme of checks that will be carried out centrally by sponsor, by the trial co-ordinating team and locally at participating sites).

The procedures outlined in this section for risk assessment and management have been divided according to the following research study categories:

4.1 Clinical Trials of Investigational Medicinal Products (CTIMPs)

	Procedure	Responsible Personnel
4.1	**Clinical Trials of Investigational Medicinal Products (CTIMPs)** 4.1.1 The CI should involve the Noclor Sponsor Representative and Sponsor Pharmacy Representative as early as possible in the design and development phase of the trial to ensure that all risks are identified and any controls required to manage the risks are incorporated within the protocol. 4.1.2 The CI must populate the Noclor CTIMP Protocol Template Noclor/Spon/T01/0X. 4.1.3 The online sponsorship request form, refer to Sponsorship Request and Approval SOP Noclor/Spon/S02/0X, will request information from the CI on category of IMP risk of the proposed CTIMP. ▪ The IMP risk category is either Type A, B or C (A lowest risk, C highest risk) and relates to risks of participant safety in relation to the IMP ▪ The IMP should be categorised according to how much is known about the IMP and balanced against the level of risk that the trial participant would be exposed to outside of the trial ▪ The IMP risk category will be confirmed by Noclor during the sponsorship request review process 4.1.4 The CI will be asked to identify all 'other' potential risks on the online sponsorship request form ▪ Other risks associated with the research may relate to specific study procedures, complexity of organisational relationships, management and compliance/ conduct of the study, reliability of data etc 4.1.5 The sponsorship request form submitted to Noclor (via Noclor website to the Noclor IMS management system) will act as the foundations on which the trial specific risk profile will be discussed and documented. 4.1.6 The risk assessment will involve the multi-disciplinary team [Chief Investigator, Noclor Sponsor Representative and Sponsor Pharmacy Representative (as a minimum)] ▪ The CI will be invited to attend a face-to-face meeting with the Noclor Sponsor Representative and Sponsor	Chief Investigator (CI)/Noclor Sponsor Representative

Pharmacy Representative to discuss the study and risks prior to the decision on sponsorship being declared

4.1.7 The risk assessment must be documented and signed off by the Noclor Sponsor Representative and CI.

4.1.8 The risk assessment will be used to inform the overall approach for managing the study and the trial specific monitoring plan.

4.1.9 Trial Monitoring plan

4.1.9.1 The Sponsor must be assured that any monitoring plans to mitigate the identified risks for a study are proportionate to those risks (i.e to lessen the likelihood of their occurrence) and that they will be able to maintain oversight /discharge their sponsor responsibilities on the study thus ensuring that participants are safeguarded and results are reliable.

4.1.9.2 The monitoring plan will be developed and documented through a collaborative approach, with both the Noclor Sponsor Representative and CI contributing and agreeing to the plan.

4.1.9.3 The monitoring plan will detail the programme of checks that will be carried out locally at participating sites (self -checks); at site (monitor site visits) and remotely /centrally by the trial co-ordinating team (trial monitor/manager) and those required/requested by sponsor (or delegated party).

4.1.9.4 The monitoring plan will refer to all monitor report templates (and other monitoring tools that may be used). For CTIMPs, the monitor report templates/tools must be reviewed and approved by the Noclor Sponsor Representative (revision may be required to ensure the templates capture all the compliance checks required by sponsor as detailed in the monitor plan).

4.1.9.5 All CTIMPs will undergo at least one audit by the sponsor (or delegated person) according to Noclors' sponsor oversight procedures. This audit will be referred to in the monitoring plan.

4.1.9.6 The monitoring plan (and associated monitor report templates/monitoring tools) must be at least drafted (with the view to being signed off by both parties) prior to study activation; refer to Site Initiation and Activation SOP Noclor/Spon/S05/0X.

	4.1.10 The CI will be provided with all relevant mandated sponsor SOPs and templates for use in the trial and will be required to sign off on these as evidence of self-training at the latest prior to study being activated. Refer to Site Initiation and Activation SOP Noclor/Spon/S05/0X. 4.1.11 Review/revision of the risk management plan (risk assessment and/or monitoring plan) should be considered when, for example: there are amendments to the protocol or new safety information becomes available or there are reports of non-compliance etc. 4.1.12 Revisions should be documented (version /date and summary of changes in version history) and signed off before being distributed to relevant parties/ filed in the Trial Master File (TMF). 4.1.13 The CI is responsible for retaining all risk assessments and monitoring plans (draft, initial and subsequent revisions) in the TMF. 4.1.14 The CI should also refer to Research Management and Monitoring Noclor/Spon/S06/0X	
4.2	**Clinical Trials (non-CTIMPs)** 4.2.1 The CI will be asked for their initial contribution to the risk assessment through the online sponsorship request form (which is submitted via Noclor website to the Noclor IMS management system). Refer to Sponsorship Request and Approval SOP Noclor/Spon/S02/0X 4.2.2 The Noclor Sponsor Representative will review the sponsorship request form and arrange a face-to-face meeting with the CI to discuss the study and review the risks prior to a decision on sponsorship being made. ▪ The sponsorship request form will act as the foundation on which the trial specific risk profile will be discussed and documented. ▪ The meeting notes may be used as the document of initial risk assessment; however this will be dependent on the complexity of the study and identified risks. It is likely to be deemed more appropriate to document the risk assessment as a standalone document as this allows for version control of revisions in the future. 4.2.3 The initial risk assessment (however this is documented) should be used to inform the overall approach for	Chief Investigator (CI)/Noclor Sponsor Representative

	managing the study and any monitoring plans. 4.2.4 A trial specific monitoring plan should be developed and documented by the CI. The monitoring plan should be at least drafted and provided to the Noclor Sponsor Representative prior to study activation; refer to Site Initiation and Activation SOP Noclor/Spon/S05/0X. 4.2.5 The CI will be provided with all relevant mandated sponsor SOPs and templates for use in the trial and will be required to sign off on these as evidence of self-training at the latest prior to study being activated. 4.2.6 Review/revision of the risk management plan (risk assessment and/or monitoring plan) should be considered when, for example: there are amendments to the protocol or there are reports of non-compliance etc. 4.2.7 Revisions should be documented (version /date and summary of changes in version history) and signed off as appropriate before being distributed to relevant parties/ filed in the Trial Master File (TMF). 4.2.8 The CI is responsible for retaining all risk assessments and monitoring plans (draft, initial and subsequent revisions) in the TMF. 4.2.9 The CI should also refer to Research Management and Monitoring Noclor/Spon/S06/0X 4.2.10 The Noclor Sponsor Representative will carry out central monitoring checks. Audits on this category of research may be performed by the sponsor (or delegated person). Audits will either be routine/random or 'for cause' audits triggered as a result of concerns that require investigation or further to reports of non-compliance.	
4.3	**All Other Research** 4.3.1 The Chief Investigator (CI) will be asked for their initial contribution to the risk assessment through the online sponsorship request form. Refer to Sponsorship Request and Approval SOP Noclor/Spon/S02/0X 4.3.2 The Noclor Sponsor Representative will review the sponsorship request form. 4.3.3 The level of risk assessment required/performed by the Noclor Sponsor Representative for studies that are <u>not categorised</u> as clinical trials will be adapted to the specifics of the study for which the sponsorship request is being	Chief Investigator (CI)/Noclor Sponsor Representative

made.

4.3.4 Various factors will be considered from the information submitted via the online sponsorship request form in reaching the decision as to whether a further risk assessment is required or whether Noclor have enough information and evidence on which to base the sponsorship decision from review of the online form.

- Some of the factors that will likely be considered are: study type, study population, complexity of study, whether tissues/samples being collected stored, Chief Investigator expertise, whether third parties are involved, plans for monitoring etc

4.3.5 The risk assessment carried out by the Noclor Sponsor Representative will be documented on the specific study record on the IMS system.

4.3.6 The Noclor Sponsor Representative is at liberty to apply certain conditions to a specific sponsorship agreement/decision if deemed appropriate to mitigate risks.

For example: requesting revision to wording of protocol, adding in specific control measures/monitor checks or reporting requirements etc

4.3.7 The CI should manage the study in accordance with the protocol, current legislation, GCP and the Research Management and Monitoring (Sponsored Research) SOP Noclor/Spon/S06/0X.

4.3.8 The Noclor Sponsor Representative will review and manage risks of the research on an ongoing /ad hoc basis. For example: if there are amendments to the protocol, on receipt of a complaint, incident reports or missing reports such as annual progress reports /end of study notifications etc.

4.3.9 The Noclor Sponsor Representative will carry out central monitor checks according to Noclor sponsor oversight procedures. Audits on this category of research may be performed by the sponsor (or delegated person). Audits will either be routine/random or 'for cause' audits triggered as a result of concerns/incidents that require investigation or further to reports of non-compliance.

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 SOP in the S/TMF.

6. SOP Storage and Archive

For clinical trials, 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 copies of Sponsor SOPs (and the associated training records) that have been worked to for the duration of a research study in the Study/Trial Master File (S/TMF).

7. Associated Documents

Document Reference ID	Document Type	Document Title
Noclor/Spon/S02/0X	SOP	Sponsorship Request and Approval
Noclor/Spon/S05/0X	SOP	Site Initiation and Activation (Clinical Trials)
Noclor/Spon/S06/0X	SOP	Research Management and Monitoring (Sponsored Research)
Noclor/Spon/T01/0X	Template	CTIMP Protocol Template

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.

For clinical trials, the CI must e-sign the confirmation of self-training below prior to 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.

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

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

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 S/TMF.