Ambition Trial Coordinating Centre
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AMBITION-*cm*
AMBIsome Therapy Induction OptimizatioN

Work Practice Document: 14
Protocol violation reporting procedures

Title of study	High Dose AMBISOME© on a Fluconazole Backbone for Cryptococcal Meningitis Induction Therapy in sub-Saharan Africa: A Phase III Randomized Controlled Non-inferiority Trial		
Acronym	Ambition-cm – AMBIsome Therapy Induction OptimizatioN		
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Author(s)	David Lawrence Lead Clinician		20/07/2017
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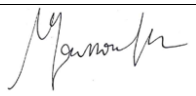
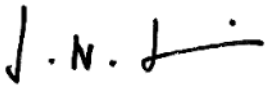
Reviewer(s)	Nabila Youssouf Trial Manager		20/07/2017
Approved by	Joseph Jarvis CI		20/07/2017

Revision History:		
Version Number	**Effective Date**	**Reason for Change**
1.0		First version

Working Practice Document 14: Protocol violation reporting procedures

Purpose

This document outlines the procedures to be taken in reporting a protocol violation.

Scope

This WPD applies to protocol deviation and violation reporting procedures.

Materials

Electronic Data Capture Tool

Deviations and violations that require reporting are 'mistakes' made by the study team. Something that would not happen again with a second chance. E.g. protocol procedure forgotten/missed, blood chemistries not done due to broken machine, patient included incorrectly etc.

An event out of the control of the team / equipment does not require reporting to the TMG but should be noted appropriately on the eCRFs and/or patient notes. E.g. patient refused to have bloods taken or an LP.

Deviation: If the event does not have an impact on participant safety or study outcome then the event is a DEVIATION rather than a violation. Complete section A of the Protocol Deviation-Violation eCRF ***ONLY***.

Violation: If the event has an impact on participant safety or study outcome it is a violation. The definition of a violation is as follows:

> **Violation**: Any departure from the approved protocol, trial documents or any other information relating to the conduct of the trial which may affect the safety or physical or mental integrity of the trial participants or the study outcomes.

If a violation occurs complete ***ALL*** of the Protocol Deviation-Violation eCRF. This eCRF contains questions relating impact of the violation on participant safety and study outcomes. Please include detailed free text in this section.

The description of the event should be detailed in full i.e. how it happened, what occurred.

Details of corrective and preventative action taken should then be included and the appropriate action taken.

- Complete the eCRF within 3 days of any trial site member becoming aware of a violation.

Training

Each staff member receives or has direct access to applicable Working Practice Documents (WPDs).

Each staff member reviews the applicable WPDs once a year.

All WPD training is documented and tracked in the training log located in the Investigator Site File (ISF)

New staff are trained on applicable WPDs within 30 days of employment and all WPDs within 90 days of employment.

Staff members whose duties fall within this WPD scope are retrained within 14 days of the approval of each WPD revision.

References

1. Declaration of Helsinki, 2013: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ accessed 12th June 2017
2. International Conference on Harmonisation (ICH) Guideline For Good Clinical Practice E6(R1), 1996
3. Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice E6(R2), 2016
4. Ambition Trial Protocol

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Staff signatures: (signing below indicate that you have read this WPD and understand the material contained in it)

Date	Name (Please print)	Signature