QUALITY SOP 21

Policy on Suspension or Premature Termination of Clinical Trials in the Clinical Research (Support) Unit

Reviewed and approved by:

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Note:

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SOP History:

Version	Date	Reason for Change	Author
1.0	December 2020	Initial Release	Maria Ryan

1. Purpose

A clinical research study may be suspended or prematurely terminated by the Sponsor, Principal Investigator or Ethics Committee for many reasons including but not limited to:

- Suspicion of an unacceptable risk to subjects
- Monitoring identifies serious or repeated non-compliance with the approved protocol

The purpose of this SOP is to provide guidance in the event a CR(S)U supported clinical study is suspended or prematurely terminated.

2. Objective

All CR(S)U supported clinical studies will follow the defined process in the event of suspension or premature termination.

3. Responsibility

The Sponsor and or PI is responsible for communicating to the site and the regulatory authorities, if applicable, if they have decided to suspend or prematurely terminate a clinical study supported by the CR(S)U. This communication must detail the reasoning behind this decision.

The Principal Investigator (PI) is responsible for ensuring, in the event of suspension or premature termination of a clinical study, that the health and welfare of participants are protected, participants get appropriate follow up care, appropriate agencies are notified and any protocol-specific procedures are followed.

4. Policy

It is the policy of the CR(S)U to work according to the applicable regulations and within the guidelines of the Declaration of Helsinki and Good Clinical Practice (GCP) as outlined in ICH Harmonised Tripartite Guidelines for GCP.

5. Procedure

5.1 Suspension or premature termination

- Whichever party that decides to take such action must notify the other in writing stating the reasons for the suspension or early termination of the study.
- If the study is terminated prematurely or suspended for any reason and if this was due to an immediate threat to the health or welfare of participants, the PI will promptly inform the participants and the EC. If the termination or suspension does not present an immediate threat to the health or welfare of participants, the PI should notify the EC to get approval of any information to be given to participants. The PI must provide appropriate therapy and follow-up to participants.
- If a study is suspended or prematurely terminated all documentation must be filed in the Investigator Site File (ISF).

5.2 Resuming a clinical study after a temporary suspension

- If it is decided that it is acceptable to resume a clinical study i.e. the reasons for suspending have been resolved, then the Investigator must write to the EC detailing why it is now reasonable to resume the research.
- The EC must issue written approval for the restart of the clinical study before any new subjects are enrolled/any study-related procedures are continued.

- If applicable for the study, the Investigator must ensure the Regulatory Authority have also been notified of the intention to resume the study and have issued "No objection" to this.

6. Abbreviations and definitions

Term	Definition
SOP	Standard Operating Procedure
CR(S)U	Clinical Research (Support) Unit
ICH GCP	International Conference on Harmonisation Good Clinical Practice
PI	Principal Investigator
EC	Ethics Committee

7. References

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) (Amended version E6 2016).
ICH Harmonised Tripartite Guideline for Good Clinical Practice. Geneva, International Federation for Pharmaceutical Manufacturing Association.