1. PURPOSE

To standardize the Study Participant (SP)-related and clinical trial-related reasons and procedures for termination or withdrawal from a clinical research study.

2. SCOPE

Applies to Principal Investigator (PI) and, when delegated by the PI, additional Investigators, Study Coordinators (SCs), and other designated site personnel.

3. RESPONSIBILITIES

The PI is responsible for overseeing proper completion of necessary procedures per protocol for early SP termination. The SC and/or other designated site personnel schedules and assists with the conduct of these procedures.

4. BACKGROUND

SPs may be unable to continue participation in a clinical research study based on criteria set forth in the study protocol. In this case, the SP must be terminated from the active study in an organized and documented fashion, per Good Clinical Practices (GCPs). Although an SP is not obliged to give his or her reasons for withdrawing prematurely from a clinical trial, the Investigator makes a reasonable effort to ascertain the reason, while fully respecting the SP's rights.

5. PROCEDURE

The following are selected examples of participant-related and clinical trial-related reasons for SPs to be discontinued from a clinical trial by the Investigator:

5.1. Participant-related reasons

- 5.1.1. Failure to maintain a present level of compliance with clinical trial medication.
- 5.1.2. Failure to maintain adequate compliance with one or more aspects of a clinical trial protocol.
- 5.1.3. Failure to cooperate adequately with the PI or staff during clinical visits.
- 5.1.4. Failure to adhere adequately to protocol requirements within or outside the clinical environment.
- 5.1.5. SP's condition or disease progresses/deteriorates.
- 5.1.6. SP experiences a serious adverse event that requires discontinuation or withdrawal from the study according to the study protocol.
- 5.1.7. SP no longer meets the criteria for continuation in the clinical trial.
- 5.1.8. Abnormal laboratory values, either severely abnormal or including specific abnormalities that, according to protocol, require discontinuation.

5.1.9. SP found not to meet the original entry requirements.
5.1.10. Improvement and/or resolution of disease being studied.
5.1.11. Deterioration of SP's medical condition unrelated to disease being studied, as determined by the study protocol.
5.1.12. SP moved from area.
5.1.13. Failure of SP to return for an appointment or for a specific number of appointments.
5.1.14. Pregnancy (observation and follow-up procedures must be initiated).
5.1.15. Any combination of the above.
5.1.16. Withdrawal of SP's informed consent.
5.1.17. Death of SP.

5.2. Clinical trial-related reasons
5.2.1. Clinical trial is terminated at a preset date and some SPs are not completed.
5.2.2. Clinical trial is terminated prematurely because of unacceptable safety concerns of the study drug/device/procedure being tested; SPs currently in the trial are deemed to have been discontinued.
5.2.3. Clinical trial is terminated prematurely because the benefits observed do not ethically permit the trial to continue.

5.3. Types of SP withdrawal
5.3.1. SP voluntarily withdraws from study conduct.
5.3.2. SP voluntarily withdraws from study conduct and voluntarily withdraws access to protected health information (PHI).
5.3.2.1. Revocation of HIPAA for Research Authorization form should be completed.

6. TERMS & ABBREVIATIONS

GCP Good Clinical Practice
PI Principal Investigator
SC Study Coordinator
SP Study Participant

7. REFERENCES

7.1. ICH GCP Consolidated Guideline - Parts 4.3.4 and 4.12

8. ATTACHMENTS

None