ECTU Central Office SOP ECTU_DM_02: Designing a Specification to Record a Change of Status for a Study Participant

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Document Revision History		
Version No	Effective Date	Summary of Revisions
1.0	14-Nov-2018	• Initial creation/New document
2.0	08-Jan-2021	• Section 3.1.2 added and 'Withdrawn – Continued Consent for Data Linkage only' moved to this section • Section 3.2.7 removed
3.0	08 May 2024	• Updated at scheduled review. • Change to SOP title from 'Recording and Reporting a Change of Status) • Wording simplified throughout to reflect general withdrawal requirements and data retention post-GDPR • Specific other categories removed from section 4.1.2 • Wording changes to 4.2.3 for Cause of Death and 4.2.5 withdrawal reasons

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the procedure for designing a eCRF specification to contain adequate provision for collecting Change of Status data to allow a change of status for a study participant.

2.0 SCOPE

This SOP applies to all studies where the ECTU Data Management & Programming team are responsible for designing the eCRF specification.

3.0 RESPONSIBILITIES

The Data Manager or Assistant Data Manager is responsible for ensuring that the study eCRF contains adequate provision for collecting Change of Status data from study participants in line with this SOP and the study protocol.

The responsibility of recording the change in status of the Study Participant is carried out as specified in the protocol.

4.0 PROCEDURE

4.1 Participant Status

The study protocol will specify the circumstances in which a participant will be withdrawn from the study and the Change of Status eCRF should be designed to reflect this.

4.1.1 Standard Categories

As a standard unless stated otherwise in the study protocol, participants in a study will be categorised as one of the following during their participation in the study:

- **Active**
  The participant (or appropriate designee as defined in the protocol) has consented to take part in the study and is participating in some or all aspects of the study). The participant should automatically be Active in the study until their status is changed.

- **Withdrawn**
  The participant (or appropriate designee as defined in the protocol) has declined or is unable to participate further in some or all aspects of the study. This status may be split into more than one status (for example, Withdrawn from IMP only and Withdrawn from all aspects of the trial) depending on the withdrawal definitions stated in the protocol This status can be applied to any Active participant within the study.

- **Deceased**
  The participant has died whilst consented to the study.

4.1.2 Other Categories

The status defined in section 4.1.1 are applicable to all studies but it may be necessary to include more bespoke categories depending on the study requirements.
Other categories should be discussed and agreed with the Trial Manager or designee and Trial Statistician or designee during the specification stage.

4.2 Features of a Change of Status

The following must be included as part of the Change of Status CRF design:

4.2.1 The date of change of status must be recorded.

4.2.2 The status category (for example Deceased, Withdrawn etc) must be recorded.

4.2.3 For Deceased participants, the date of death must be recorded. It may also be appropriate to record the Cause of Death.

4.2.4 Where a participant has been withdrawn from the study, it must be possible to record who has withdrawn the participant (for example, Participant, Clinician).

4.2.5 Where a participant has been withdrawn from the study, it must be possible to record a reason for withdrawal. The study protocol may include reasons that will necessitate a participant withdrawal and where possible a list of options should be provided to minimise free-text data entry.

5.0 RELEVANT DOCUMENTS AND REFERENCES

SOP and WPD

- ECTU_SOP_TM_09 Planning for a Participant Withdrawal or Change of Status
- ACCORD SOP CR013 CRF Design and Implementation - SOPs | Accord