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2.0	08-Jan-2021	• Section 3.1.2 added and 'Withdrawn – Continued Consent for Data Linkage only' moved to this section • Section 3.2.7 removed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
4.0	09 Oct 2026	• Further definition of Withdrawn and Deceased categories added to section 4.1.1 • Reference to retention of status history added as section 4.2.6

		• Minor wording wording changes throughout

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the procedure for designing an 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 designee) 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The study protocol will specify the circumstances in which a participant will be withdrawn from the study and the Change of Status eCRF should be designed to reflect this.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 considered Active until their status is changed.

  Depending on the study design, Active may be the only active participant status, or additional subcategories may be used to reflect different levels of ongoing participation. For example, alongside Active, “Active – but no longer taking IMP” may be used where the participant has discontinued a particular aspect of the study (i.e. taking the IMP) but continues with others (i.e. follow up questionnaires).
- **Withdrawn**
  The participant (or appropriate designee as defined in the protocol) has declined or is unable to participate further in **all** aspects of the study.

In certain circumstances, as defined in the study protocol, Withdrawn may be split into more than one status to reflect different levels or types of withdrawal (for example, Withdrawn from data linkage and Withdrawn from all aspects of the study). Any such statuses should be applied in accordance with the withdrawal definitions stated in the protocol.

This status can be applied to any Active participant within the study.

- **Deceased**
  The participant has died whist consented to the study. This status can be applied to any Active participant in the study. Where applicable, and as defined in the study protocol, it may also be applied to participants with Withdrawn statuses depending on the withdrawal definitions and status requirements specified in the protocol.

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 Chief Investigator or 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.

4.2.6 Where possible, the full status history, including all previous statuses, should be retained in the eCRF. This should particularly be considered if multiple statuses can be applied.

5.0 RELEVANT DOCUMENTS AND REFERENCES

ECTU Website

- ECTU SOP TM09 Planning for a Participant Withdrawal or Change of Status

ACCORD Website

- ACCORD SOP CR013 CRF Design and Implementation

ECTU_SOP_DM_02 Designing a Specification to Record a Change of Status for a Study Participant v4.0

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