ECTU Central Office SOP_TM_09: Planning for Participant Withdrawal or Change of Status

Version No:	5.0
Issue Date:	30 Nov 2023
Effective Date:	14 Dec 2023

Authorship and Approval			
Name and Designation	Author/Reviewer /Approval/ Authorisation	Date	Signature
Stephanie Cholbi, Assistant Trial Manager	Author	28 Nov 2023	See retained approval email dated 28 Nov 2023
Gill Scott, Trial Manager	Reviewer	28 Nov 2023	See retained approval email dated 28 Nov 2023
Gina Cranswick, Trial Management Team Lead	Approver	29 Nov 2023	See retained approval email dated 29 Nov 2023
Tanya Tharakan, QA Manager	QA Authorisation	28 Nov 2023	See retained approval email dated 28 Nov 2023

Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	14 Jun 2012	Initial creation
2.0	17 Jun 2016	Extensive amendments after scheduled review. Change of status definitions in 3.1. Sections 3.1.1 – 3.3.1 added Change of Status form amended and new Full Consent Withdrawal Form included in section 4.
3.0	14 Nov 2018	Updated at scheduled review. Change of title. Extensive changes to document in line with GDPR guidance.
4.0	08 Jan 2021	Inclusion of text in 3.3.2 for trials involving participants who do not consent for themselves. Clarification for rare events in section 3.6.1

5.0	14 Dec 2023	SOP updated to new SOP template. Responsibilities section now included. References to “GDPR” updated to “UK GDPR” in Section 2 and Section 4.5. File location removed from Section 5.0. Clarification of TM responsibilities in Section 4.1.

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes how a change of status for a study participant should be recorded and reported and how this change should be managed on the study database.

2.0 SCOPE

This SOP applies to all studies where an ECTU Trial Manager will be responsible for developing and managing the change of status feature for the study and only applies to studies where ECTU also provides the study database.

This SOP applies only to new studies (within the criteria stated above) in set-up after the effective date of this SOP. Any existing study where the change of status and participant withdrawal procedure has already been implemented prior to this (e.g. the eCRF/ pCRF has already been designed and approved) will continue with the established procedure taking note of the changes to UK GDPR and Data Retention outlined in section 4.5.

3.0 RESPONSIBILITIES

The Trial Manager or designee is responsible for the following:

- Ensuring that the change of status criteria is considered and defined during initial study set-up.
- Ensuring that a procedure for recording and reporting a change of status is in place prior to recruitment.
- Ensuring that all research staff are fully aware of and trained in the procedure for changing a participant status including explaining how data will be retained and used after withdrawal.
- Maintaining oversight of the number and type of status changes that occur during the study.

The Data Manager or designee is responsible for the following:

- Developing the specification for the change of status feature within the eCRF.
- Producing a pCRF to record the change of status (if applicable).

The IT Programmer is responsible for the following:

- Building the change of status feature in the study database according to the specification provided.

4.0 PROCEDURE

4.1 General Guidelines

4.1.1 A change of status is only applicable to participants who have consented to the study.

4.1.2 A change of status is applicable when a change of circumstance means that the participant is no longer able to actively participate in all aspects of the study.

4.1.3 If a participant is willing and able to participate in some but not all aspects of the study, a change of status may not be necessary but this must be clearly defined in the protocol or study-specific guidance.

4.1.4 The Trial Manager should check that a procedure for recording and reporting a change of status must be in place before a participant is consented to the study.

4.1.5 The Trial Manager will be responsible for ensuring that site research staff are fully aware of and trained on ECTU Central Office SOP "ECTU_DM_02 Recording and Reporting a Change of Status for a Study Participant". This should be part of the database training provided at the site initiation visit and evidenced in the Training Log.

4.2 Defining a Change of Status – General Guidelines

4.2.1 All participants consented to the study will have an Active status until a change of status is necessary.

4.2.2 A change of status must be applied if:

- The participant (or the person approached for consent/ Legal representative) decides not to continue with all aspects of the study for any reason
- A study clinician decides that the participant is no longer able to continue with all aspects the study
- The participant dies

If any of these apply, it must be possible to record the change of status and for this to be implemented on the study database. The pCRF/ eCRF must be designed to include these status updates.

4.2.3 Full details on participant status within a study can be found in ECTU Central Office SOP ECTU_DM_02: Recording and Reporting a Change of Status for a Study Participant.

4.3 Partial Participation in Study Activities – no change of status required

4.3.1 It is important that the criteria for withdrawing a participant is clearly defined before consent begins. Depending on the nature of the trial it may be possible for a participant to stop some aspects of their study involvement but still remain in the study. For example, a participant may wish to stop taking the study treatment (IMP) but can still continue with other aspects of study follow-up. In this instance, the participant's status should not be changed and they will remain as active in the study.

4.3.2 It is also important to note that protocol waivers are not permitted and that a participant should not be recruited if they are clearly not able to adhere to the study protocol from the outset.

4.3.3 The Trial Manager should ensure where possible that the protocol allows a participant to remain Active in the study for as long as they are willing and able to do so.

4.3.5 The Trial Manager should ensure that the Chief Investigator and Trial Statistician approve the criteria for partial participation to ensure the study outcomes are not affected.

4.3.6 The Trial Manager should consider ways to manage partial participation on the eCRF/ pCRF if necessary. For example, including a way of recording that a participant will no longer be taking the IMP (if applicable) but will continue with other aspects of the study. This should be discussed with the Data Manager and IT Programmer.

4.4 Studies incorporating Data Linkage

4.4.1 For studies that include extended participant follow-up, post end-of-study via data linkage, and where the participant withdraws themselves or is withdrawn by a clinician, it must be established at the point of withdrawal whether they consent to be included in this after their withdrawal.

4.4.2 A separate withdrawal status will be applied to these participants so that they can be identified and included in data linkage even though they have withdrawn. The status of these participant's will be 'Withdrawn – Continued Consent for Data Linkage Only'.

4.4.3 The Trial Manager will be responsible for ensuring that any data linkage aspect of the study is considered when developing the change of status procedure. This would involve discussions with the Health Economist, and any resulting amendments that may arise will be conveyed to the DMP Team.

4.5 UK GDPR and Data Retention

4.5.1 If a participant withdraws from the study, any data collected up to the point of withdrawal will be retained. In specific cases, data may be removed but only following discussion with the Sponsor, Chief Investigator and Trial Statistician.

4.5.2 Where applicable, the Trial Manager is responsible for ensuring that the PIS and Consent Form provided to a participant clearly states that study data will be retained after withdrawal or ensure that a UK GDPR Participant Information notice is sent to all existing participants that states this, at the time of withdrawal.

5.0 RELEVANT DOCUMENTS AND REFERENCES

- ECTU Central Office SOP ECTU_DM_02: Recording and Reporting a Change of Status for a Study Participant (On ECTU Shared Drive)
- ACCORD Policy POL005 Protocol Waivers - Policies | Accord
- ACCORD CR007 Study Documents - SOPs | Accord
- Participant Information Quality Standards - Health Research Authority (hra.nhs.uk)