

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

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Authorship and Approval			
Name and Designation	Author/Reviewer /Approval/ Authorisation	Date	Signature
Stephanie Cholbi, Assistant Trial Manager	Author	13-Apr-2026	 Stephanie Cholbi (13-Apr-2026 08:14:04 GMT+1)
Gill Scott, Trial Manager	Reviewer	13-Apr-2026	 Gillian Scott (13-Apr-2026 09:25:33 GMT+1)
Aryelly Rodriguez Senior Statistician	Reviewer	28-Apr-2026	
Tony Wackett Data Management & Programming Architect	Reviewer	13-Apr-2026	 Tony Wackett (13-Apr-2026 09:36:44 GMT+1)
Gina Cranswick, Trial Management Team Lead	Approver	10-Apr-2026	
Tanya Tharakan, QA Manager	QA Authorisation	29-Apr-2026	 Tanya Tharakan (29-Apr-2026 10:26:59 GMT+1)

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.

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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.
6.0	15 May 2026	Section 4.4.2 updated to reflect how to capture participants who withdraw from study interventions but will continue to be active in the study for the purposes of data linkage follow-up. Other process changes to reflect current practise.

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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.
- Ensuring that all documentation relevant to the development and implementation of the 'change of status' are retained in the trial master file.
- Producing a pCRF to record the 'change of status' (if applicable).

The Data Manager/ Software Programmer or designee is responsible for the following:

- Developing the specification for the 'change of status' feature within the eCRF.
- 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.

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- 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, either in the eCRF, on a pCRF/ Data Collection Sheet or both.
- 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 or requested via opt-out, as applicable.
- 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

Note: If the participant withdraws and subsequently dies, the status must **not** be changed from the withdrawn status.

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** Further 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.

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- 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, if not already identified by the CI or Trial Statistician.
- 4.3.5** The Trial Manager should ensure that the Chief Investigator and Trial Statistician approve, via email, the criteria for partial participation to ensure the study outcomes are not affected. The email will be retained as a PDF in section 9.1 of the TMF.
- 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, Software Developer and Trial Statistician.

4.4 Studies incorporating Data Linkage

- 4.4.1** For studies with extended follow-up via data linkage after the end of the study, consent for inclusion in such linkage after withdrawal must be confirmed at the point of withdrawal (by either the participant or clinician).
- 4.4.2** A separate withdrawal status will be applied to these participants so that they can be identified and included in data linkage despite having been withdrawn. The status of these participant's will be recorded as 'Withdrawn - consent for data linkage retained'.
- 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 trial team, and any resulting modifications that may arise will be conveyed to the Data Management & Programming (DM&P) and the Digitally Enabled Clinical Trials (DECT) 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 ACCORD template of the Patient information Sheet (PIS) is used, which includes information on consent to the study and how participants' information will be used and protected. It should clearly state that study data will be retained after withdrawal. Alternatively, a UK GDPR (or other applicable GDPR legislation or guidelines for participants outside the UK) Participant Information Notice should be provided to all existing participants at the time of withdrawal, clearly stating this.

5.0 RELEVANT DOCUMENTS AND REFERENCES

[ECTU Website](#)

- ECTU_SOP_DM_02: Recording and Reporting a Change of Status for a Study Participant

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[ACCORD Website](#)

- ACCORD Policy POL005 Protocol Waivers
- ACCORD CR007 Study Documents

Others

- [Participant Information Quality Standards - Health Research Authority \(hra.nhs.uk\)](http://hra.nhs.uk)

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