

DISC Participant Change of Status Form

Sponsor: University Hospitals of Leicester
NHS Trust

EudraCT Number: 2016-004251-76

Please complete this form when there is a change in the study status of a participant.

If the patient requests full withdrawal during a study visit, please ask the participant if they would be willing to complete the current study visit questionnaires. If they are willing, please complete this form once all questionnaires are completed for this visit.

If the patient requests full withdrawal between study visits, complete and date this form when the participant first requested withdrawal.

Participant study number: Site ID:

Principal Investigator:

Change in status date: / /
day month year

1. Participant status has changed

Did the participant receive their allocated treatment? Yes No

Participant is to be followed up remotely (follow-up without clinic visits)

Participant is being fully withdrawn

2. Participant has died

A Serious Adverse Event form has been completed: Yes No*

* If 'No', please complete a Serious Adverse Event Form and send to York Trials Unit

Date of death: / /
day month year

Participant study number:

Site ID:

Please provide further information for change in status:

Name of person completing form (if different to PI):

Signature of person completing form:

Assessor ID:

Date: / /
day month year

CONFIRMED BY PI/DELEGATED CLINICIAN

Name:

Signature:

Assessor ID:

Date: / /
day month year

Please send a copy of the form to York Trials Unit either by fax: 01904 321387 or email: Disc-Trial-Group@york.ac.uk and file the original form in your site files.