Trial number: ☐☐☐☐

CONFIDENTIAL WHEN COMPLETE

UNIVERSITY OF BIRMINGHAM | BCTU Birmingham Clinical Trials Unit

CALIBRE

CHANGE OF STATUS FORM

IDENTIFYING DETAILS

Trial No.: ☐☐☐☐	Initials: ☐☐☐☐
Site Name: ……	
Date of change of status: D D / M M M / Y Y Y Y	

REASON FOR CHANGE OF STATUS

Why is the participant changing their status in the trial?

	No	Yes
Participant has died *If **yes**, please provide cause of death below and complete a **CALIBRE SAE Form**. Please notify the CALIBRE Trial Office within **24 hours** of becoming aware of participant's death.* *Please sign, print name and date at end of page. No further questions need to be answered on this form*	☐	☐
Cause of death Liver-related mortality	☐	☐
Cardiovascular-related mortality	☐	☐
Participant withdrawn from <u>some</u> or <u>all</u> aspects of the trial *Complete the Change of Status section on this form.*	☐	☐

CHANGE OF STATUS

To be completed for participants who withdraw from the trial

	No	Yes
Participant withdrawn from the trial intervention, but will be followed up in accordance with the schedule of assessments and, using any central UK NHS bodies for long-term outcomes (i.e. the participant has agreed that data can be collected at standard clinic visits and used in the trial analysis, including data collected as part of long-term outcomes).	☐	☐

Participant withdrawn from trial intervention and will no longer attend trial visits in accordance with the schedule of assessments. They will continue to be followed up at standard clinic visits and data may be obtained from any central UK NHS bodies to obtain long-term outcomes (i.e. the participant has agreed that data can be collected at standard clinic visits and used in the trial analysis, including data collected as part of long-term outcomes).	☐	☐
Participant withdrawn from the trial intervention and will no longer be followed up for the purposes of the trial and no further data will be collected (i.e. only data collected prior to the withdrawal can be used in the trial analysis).	☐	☐
Participant withdrawn, at the request of the **CALIBRE** Trial Office because of significant non-compliance with the **CALIBRE** trial protocol. The participant will not to be followed up for the purposes of the trial and no further data will be collected (i.e. only data collected prior to the withdrawal can be used in the trial analysis).	☐	☐

CRF completed by:

You **must** have signed the CALIBRE site training log and CALIBRE delegation log

Name: ……..
(please print)

Date: D D / M M M / Y Y Y Y

Signature: ……..