OPTIMAL Withdrawal & Lost to Follow Up Form 14

Patient Initials	Date of Birth	Site Number	Trial Number
	d d - m m - y y y y	0	0

To be completed upon patient withdrawal or in case a patient is lost to follow up.

Please specify patient's status:

☐ **1= Lost to Follow Up** (*Please complete Sections (14.1 & 14.5)*
2= Withdrawal from trial (*Please complete Sections 14.2, 14.3, 14.4 & 14.5)*

14.1 Lost to Follow Up:

Date the patient was last known to be alive: (dd/mm/yyyy) d d m m y y y y

Reason patient was lost to follow up *(please choose <u>one</u> option only)*

☐ 1= Moved Away
2= Emigrated
3= Lost contact
4= Discharged to GP
5= Other (specify reason): ▶

14.2 Withdrawn

Date of patient withdrawal (dd/mm/yyyy) d d m m y y y y

14.3 Main reason for patient withdrawal (*please choose <u>one</u> option only*)

		If <u>Yes</u> please tick	Please give a reason wherever possible
i) Participant's decision		☐ →	
ii) Pregnancy		☐ →	
iii) Physical free light chain clearance	*(plasma exchange or high cut of dialysis)*	☐ →	
iv) Adverse Event		☐ →	
v) Disease Progression		☐ →	
vi) Other Reason(s)		☐ →	

14.4 Patient Trial Status

Please note all patients should remain on-study for follow-up and sampling purposes, unless the patient or clinician has specifically requested otherwise (fill all boxes).

i) Patient withdraws consent to trial treatment but will remain on follow up as per trial protocol. ☐ 1=Yes 2=No

ii) Patient withdraws consent from trial treatment and/or to follow up, but is happy for data to be collected through hospital notes, NHS records and associated databases even though they may not attend further follow-up visits. ☐ 1=Yes 2=No

iii) Patient withdraws consent to any further aspect of the OPTIMAL trial including future data collection. ☐ 1=Yes 2=No

iv) Patient withdraws consent for any previously collected tissue/blood samples to be used in future research. ☐ 1=Yes 2=No

14.5 Contact Details

Please provide contact details of patient's GP or referral hospital to assist with collection of data regarding patient's future health status (*only if patient has consented, and has not withdrawn such consent*).

☐ 1=Available
2=Not available

If <u>available</u>, please complete below:

Contact Name:		Contact's Role: (GP, Nurse etc.):	
Contact Tel:		Contact email:	
Contact Address:			

<u>Completion Guidelines for OPTIMAL Withdrawal & Lost to Follow up Form 14</u>

This form must be completed if a participant decides to, or is withdrawn from the trial completely or from trial intervention. Please note that all participants withdrawn from the trial should remain on the trial for follow-up and sampling purposes, unless the participant has specifically requested to be completely withdrawn with no follow-up. There is an option for the participant to decide in conjunction with the clinician, as to what level of follow-up they will participate in.

14.3 Main reason for patient withdrawal:

This should be the main reason for withdrawal only. Do not tick multiple reasons. If the reason is not listed, select other and always give further details. Death is <u>not</u> to be listed on the Withdrawal Form as a reason for withdrawal. There is a separate Notification of Death Form.

14.4 Participant's Trial Status

Please indicate which aspects of the trial the patient has withdrawn consent from:

i) Select option 1 if the patient is happy to complete all follow-up assessments, Quality of Life and sampling.
ii) Select option 2 if the patient does not want to actively participate but is happy for the trial to follow-up their status long term.
iii) Select option 3 **<u>ONLY</u>** if the patient wishes to withdraw consent for future information to be used as part of the trial.
iv) Select option 4 if the patient does not wish their tissue / blood to be stored for future research.

Completed by:
(Print)

Signature:

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Date completed: D D M M Y Y Y Y

For Office use only
Date form received: _____ Date form entered: _____ Initials: _____