

Personal Consultee Declaration Form



A PHASE IIb, RANDOMISED-CONTROLLED, TWO-CENTRE CLINICAL TRIAL ON THE EFFICACY OF A HOME-BASED EXERCISE AND MOTIVATIONAL PROGRAMME IN PATIENTS BEFORE AND AFTER LIVER TRANSPLANTATION

Site name: QEUHB RFHL

Trial Number

Patient Initials:

Principal Investigator: _____

Please initial inside each box

1	I, First Name: _____ Surname: _____ have been consulted about the participation of First Name: _____ Surname: _____ in the ExaLT trial.	<input type="checkbox"/>
2	I confirm that I have read and understood the Personal Consultee Information Sheet , dated __/___/___ version number __. __ for the ExaLT trial. I had the opportunity to consider the information and ask questions, and have had these answered satisfactorily.	<input type="checkbox"/>
3	I fully understand the trial procedures, the risks and benefits, and I believe that it would be the participant's wish to continue participating in the research trial described in this form, under the conditions stated in it.	<input type="checkbox"/>
4	I understand that the participant has already agreed for their GP to be informed of their participation in this trial and that they may be contacted by members of the research team for follow-up information.	<input type="checkbox"/>

5	I understand that the participation in the ExaLT trial is voluntary I can recommend that the participant be withdrawn from the trial at any time without giving any reason. Their medical care or legal rights will not be affected. When/if the participant regains capacity, I understand that their wishes will supersede the opinion that I have given.	<input type="checkbox"/>
6	I understand that if I recommend that the participant be withdrawn from the ExaLT trial, the data/information collected up to the time of their withdrawal may still be used in the final analysis after being anonymised.	<input type="checkbox"/>
7	I understand that relevant sections of the participant's medical notes and data collected during the trial may be examined by individuals from the ExaLT Clinical Trial Team, University of Birmingham (Sponsor) representatives of the sponsor, from regulatory authorities, or from the NHS Trusts where this is relevant to them taking part in this trial. I give permission for these individuals to have direct access to their records.	<input type="checkbox"/>
8	I have read and understood the information in the Personal Consultee Information Sheet , about what will happen to the participant's personal data collected for this trial.	<input type="checkbox"/>
9	I understand and agree that any data collected that identifies the participant by name, e.g. Informed Consent Forms as well as contact address and email, will be transferred from where it is collected and stored at the Birmingham Clinical Trials Unit, University of Birmingham during the trial. After, the trial ends the data will be stored at a specialist, secure archiving facility, in compliance with current regulations. I agree to the transfer and storage of this information.	<input type="checkbox"/>
10	I understand that the information collected about the participant will be used for medical research or to support other related research in the future, the participant will not be identified in any way in sharing, analysis or reporting of the results.	<input type="checkbox"/>
11	I understand that if the participant has given their consent to take part in the optional mechanistic 'muscle' substudy, this will continue to apply for the duration of their participation in the ExaLT Trial.	<input type="checkbox"/>
12	I understand that if the participant has given their consent for audio/video recording of scheduled trial visits or telephone health calls, this will continue to apply for the duration of their participation in the ExaLT Trial.	<input type="checkbox"/>
13	I understand that if the participant has given their consent for the storage of pseudo anonymised samples (labelled using their unique trial number, initials, date, and time point) and for future biochemical test, this will continue to apply for the duration of their participation in the ExaLT Trial.	<input type="checkbox"/>
14	I agree for the participant to continue taking part in the ExaLT Trial.	<input type="checkbox"/>

