<insert local letterhead details>

Patient Consent 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: ☐☐☐ *(please enter when known)*

Patient Initials: ☐☐☐

Principal Investigator: _____

Please initial inside each box.

1	I confirm that I read and understood the participant 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.	☐
2	I understand that I am being invited to take part in a research study (clinical trial). I am not taking part in any other research study or clinical trial at this time, which the ExaLT trial team are not aware of.	☐
3	I understand the risks and benefits, and I freely give my informed consent to participate in the research study described in this form, under the conditions stated in it.	☐
4	I understand that my participation in the ExaLT trial is voluntary and that I am free to withdraw from the trial at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that even if I withdraw from ExaLT trial, data collected up to my time of withdrawal may still be used.	☐
5	I understand that relevant sections of my 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 my taking part in this research. I give permission for these individuals to have direct access to my records.	☐

6	I have read and understood the information in the patient information sheet about what happens with my personal data collected for this trial.	☐
7	I agree to my GP being informed of my participation in this trial and that they may be contacted by members of the research team for follow-up information.	☐
8	I understand and agree that data collected that identifies me 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, 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.	☐
9	I understand that the information collected will be used for medical research only and that I will not be identified in any way in the analysis and reporting of the results. I understand that even if I withdraw from the trial, information already collected about me may be included in the final analysis after being anonymised.	☐
10	I understand that the information collected about me will be used to support other related research in the future and may be shared anonymously with other researchers.	☐
11	**I agree to take part in the ExaLT Trial.**	☐
12	[**OPTIONAL**] I understand the reason and give my consent when it is necessary to record either by audio or video recording, one or more of my scheduled trial visits or telephone health calls. This will involve transferring the recording for examination by the researchers, so they can review me undergoing the intervention. YES [ ] NO [ ] please tick (if the answer to this question is 'NO', you may still take part in this study)	☐
13	[**OPTIONAL**] I give my consent to having a nominated personal consultee (e.g. family, friend) to act in my best interests in the event that I lack capacity (e.g. confusion due to underlying liver disease) to give an opinion about my ongoing participation in the trial. I have provided contact details of my nominated personal consultee(s). YES [ ] NO [ ] *please tick* ***(if the answer to this question is 'NO', you may still take part in this study)***	☐

14	[**OPTIONAL**] I give my consent to participate in the 'muscle' sub-study undertaken at baseline (**Visit 1**), 6 weeks (**Visit 2**) and 24 weeks after liver transplant (**Visit 9**). I understand that these visits will be longer in duration (approximately 2 hours longer). I understand the nature of the study procedures involved include the collection of up to 21mls of blood taken at each visit (as above). I understand it may be required to send these blood samples to partners (including commercial companies) to help analyse the samples and answer the study questions. YES [ ] NO [ ] *please tick* *No longer applicable* [ ] ***(if the answer to this question is 'NO', you may still take part in this study)***	☐
15	**OPTIONAL**] I give my consent to participate in the 'muscle' sub-study undertaken at 48 weeks (**Visit 6**) if I have not had a liver transplant within the intervention time window of 52 weeks. This will follow the same process as in **Visit 1** and **Visit 2** YES [ ] NO [ ] *please tick* *No longer applicable* [ ] ***(if the answer to this question is 'NO', you may still take part in this study)***	☐
16	[**OPTIONAL**] I agree that any remaining blood samples donated by me in the 'muscle' sub study, and accompanying general health information, can be stored for use in future research provided ethical approval for these additional studies has first been obtained. I understand that the samples may be shared with a wide range of researchers and institutions and that there is a possibility of commercial and/or therapeutic applications. Otherwise, the samples will be safely disposed of at the end of the study. YES [ ] NO [ ] *please tick* *No longer applicable* [ ] ***(if the answer to this question is 'NO', you may still take part in this study)***	☐
17	Queen Elizabeth Hospital participants only: [**OPTIONAL**] I agree that urine samples donated by me in the 'muscle' sub study, and accompanying general health information, can be stored for use in future research provided ethical approval for these additional studies has first been obtained. I understand that the samples may be shared with a wide range of researchers and institutions and that there is a possibility of commercial and/or therapeutic applications. Otherwise, the samples will be safely disposed of at the end of the study. YES [ ] NO [ ] *please tick* *No longer applicable* [ ] ***(if the answer to this question is 'NO', you may still take part in this study)***	☐

To participate in the ExaLT Trial you MUST consent to points 1-11 above and initial the corresponding boxes. Points 12-17 are OPTIONAL and please tick 'YES' or 'NO' and initial your answer.

Name of patient	Date	Signature
Name of person taking Consent	Date	Signature

Once completed: Original to be kept in Investigator Site File; 1 copy for the participant; 1 copy to be filed in medical notes. 1 copy to be sent to BCTU.