FUNDED BY NIHR | National Institute for Health and Care Research

WARWICK CLINICAL TRIALS UNIT

Ulster University

(Form to be on Trust headed paper)

iRehab CONSENT FORM

Trial Title: Remote multicomponent rehabilitation in survivors of critical illness after hospital discharge: The iRehab Trial

Co-Chief Investigators: Dr Brenda O'Neill and Professor Danny McAuley

Trial ID Number:

Site Name: [Pre-populated for site]

Principle Investigator: [Pre-populated for site]

Please initial box
(Participant or person taking consent if via telephone)

1. I confirm that I have read the iRehab Participant Information Leaflet (Version Date). I have had the opportunity to consider the information, ask questions and have these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of my NHS hospital records, medical notes and data collected during the trial, may be looked at by responsible individuals. This is only where it is relevant to my taking part in this research. These responsible individuals may be from the University of Warwick, Ulster University, Queen's University Belfast, the research team, regulatory authorities, and NHS Trusts. I give permission for these individuals to have access to my records. ☐

4. I understand that part of the iRehab rehabilitation programme can be delivered by an online video platform (BEAM). If I am randomised to the iRehab rehabilitation programme group and can access this, I will be asked to register. Registering will require me to agree to the Terms and Conditions and to provide my name and email address. ☐

5. I understand that the information held and maintained by my hospital will be used to provide information about my hospital admission and health status. I agree for Warwick Clinical Trials Unit and Ulster University to hold and link this data to the data I provide for this trial. ☐

6. I agree to my General Practitioner and hospital consultant being informed of my participation in the trial. This may include any safeguarding concerns or necessary exchange of information about me between my GP and the research team. ☐

7. I understand that the information collected about me may be used to support other research in the future and may be shared anonymously with other researchers. Any future research will be ethically approved where necessary. ☐

8. I agree to be contacted by a member of the iRehab team if there are any questions or queries for me during the trial. ☐

9. I agree to being sent text messages and/or emails by the iRehab team for the purposes of the trial. I understand that a third-party service may be used to send text/ or email messages or enter questionnaire data related to the trial and agree to my contact details being provided to facilitate this. ☐

10. I agree to my video/telephone consultation, exercise and support sessions being observed and recorded. This is to monitor quality and to provide the iRehab team with an understanding of topics and issues that generated discussion. ☐

11. I have contacted my next of kin and I confirm that they have agreed for the trial team to hold their details and contact them if needed. ☐

12. I understand that questionnaires or conversations with the iRehab team might highlight health problems (physical or mental) that may require further treatment, and the team may need to inform healthcare staff, including my General Practitioner (GP). ☐

13. In the unfortunate event that I lose capacity I agree that data already collected about me can be used by the trial team. ☐

14. I agree to take part in the above trial. ☐

YES / NO

15. **OPTIONAL (delete YES or NO as appropriate and initial box):** I agree for my contact details to be passed to member of the research team to see if I would possibly like to be interviewed to discuss my experience of being involved in this trial. ☐

_____	_____	_____
Name of Participant (please print)	Date dd/mm/yyyy	Participant Signature
_____	_____	_____
Name of Person taking consent (please print) (To be listed on the Delegation Log)	Date dd/mm/yyyy	Signature

Please complete if consent was completed on behalf of the participant (for telephone/video consent):

I _____ (Name of Person taking consent (please print); To be listed on the Delegation Log) have completed this consent form with and on behalf of_____(Name of Participant - please print) _____

Date: _____ (dd/mm/yyyy)

NB: Original to be retained in Investigator Site File, one copy for patient.