

iRehab - Summary of Ethical Amendments

Amendment Type-Number	Summary of Change	Relevant to All Sites
SA-01	Amendment to project timelines due to longer set-up time. Addition of written instructions for participants. Edits to SoECAT to make this site-specific. Minor edits to documents such as questionnaires, PILs, protocol and cover letter for smart watch. Inclusion of trial website screenshots for review. Inclusion of questionnaires for the Process Evaluation.	Yes
NSA-01	Addition of sites	No
NSA-02	Addition of sites	No
NSA-03	Addition of sites	No
NSA-04	Addition of sites	No
NSA-05	Addition of sites; site PI detail change	No
NSA-06	Addition of Postal Cover Letter	No
NSA-07	Change 1: Addition of different ways to contact patients to arrange the sit to stand test and intervention sessions and to complete the questionnaires. Change 2: Minor changes to trial documents, including the PIL (to reference mobile phones being available if patients don't have them) and changes to cover letters to include trial numbers for patients' information. Change 3: Updates to the protocol including reference to change 1 and also further clarification around the AE and SAE sections. Change 4: Minor change to the GP and consultant letters to correct a typographical error. Change 5: Minor amendment to the IRAS form to show that we are not sending GPs patient consent forms.	Yes
NSA-08	Addition of sites; site PI detail change	No
NSA-09	Minor change to topic guide for process evaluation elements which can be implemented by the qualitative researcher with no implications on sites or participants.	No
NSA-10	Addition of sites	No