RNHRD NHS FT Data Protection Act Research Form

R& D Reference:	*Office use only*	**Principal Investigator/ Lead Researcher:**		Dr Esther Crawley
Title of Research Project:	**Assessing the feasibility and acceptability of comparing the Lightning Process® with specialist medical care for Chronic Fatigue Syndrome or Myalgic Encephalopathy (CFS/ME) - pilot Randomised Controlled Trial.**			
Length of Project:		Months	10	Years 1
Source of Data:	☒ Patient	☒ Staff		☒ Other – Please specify:
	Almost all of the data will be from patients. However, interventions will be recorded so small amounts of data will exists in anonymised transcripts from staff and Lightning practioners delivering the interventions.			
Organisation involved in Research:	☒ RNHRD NHS FT	☒ University of Bristol		☒ Other – Please specify: Lightning Process
	Two members of the Lightning Process Executive are co-applicants for this study.			
Purpose of Research:	The overall aim of this study is to investigate the feasibility and acceptability of conducting a Randomised Controlled Trial (RCT) to investigate the effectiveness and cost-effectiveness of specialist medical care with specialist medical care plus the Lightning Process in treating CFS/ME in children. The specific objectives aim to inform the design of a full-scale, adequately powered randomised trial.			
Who is the research data/information going to be shared with?	Other NHS Organisations ☐ , RNHRD Staff ☐ , Private Company ☐ University staff / University students ☒ Other (please state):			
Please state type of data (e.g. computer database, paper records, video, audio photographs blood/urine samples), storage location during project.	Types of data being collected: 1. Questionnaire data, 2. Data collected from interview Storage of data location/s: Personal data will be stored on the RNHRD computer. The 13 digit ID number will be linked to personal data in this way. Once consent forms are signed, these will be kept in a locked filing cabinet, in a locked office, within another locked office at the University of Bristol. Questionnaire data will be stored on an encrypted password protected university server. Interview transcripts will be anonymised and then stored on an encrypted, password protected university server. All laptops and memory sticks are encrypted. All data is anonymised at source and no identifiying information is kept with data on questionnaires. Proposed secure Protection of Data e.g. laptops, memory sticks security, paper file storage			
How do you assure subjects about confidentiality of their information? Please attach Patient Information Sheet:	We have details of the anonymisation on the patient information sheets attached. We also include details of how data is stored on every consent form, a copy of which is kept by patients.			
How will the research data be securely protected, stored and destroyed at the end of the study?	Where is the proposed Secure storage of data; how and for how long? Transcripts will be anonymised and kept on a secure university encrypted password protected university server for five years. The data will be wiped by IT after 5 years. The memory sticks used for the interviews will be destroyed once the anonymised transcript has been put on to the university server.			

	No research data will be kept at the RNHRD. How will data be destroyed at the end of the study?				
Is the information being sent outside of the UK?	☐ Yes	☒ No	**Will patient consent be obtained?**	☐ Yes	☐ No
Is the information being sent outside of the EU?	☐ Yes	☒ No	**Will patient consent be obtained?**	☐ Yes	☐ No
Will patient case-notes be used?	☐ Yes	☒ No	**Will patient consent be obtained?**	☐ Yes	☐ No
I will ensure my Research project is compliant with the Data Protection Act, the Department of Health Code of Confidentiality and the RNHRD's code of conduct for employees in respect of confidentiality:					
Signature:			**Print Name and Date:**	CRAWLEY 26/5/2010	
Recommendations			**Signature and date of DPA Lead**		

NB: Double click left mouse button to 'check' boxes.