Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please enter a short title for this project (maximum 70 characters)
SMILE – Specialist Medical Intervention & Lightning Evaluation

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product
( ) Clinical investigation or other study of a medical device
( ) Combined trial of an investigational medicinal product and an investigational medical device
( ) Other clinical trial or clinical investigation
(●) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
( ) Study involving qualitative methods only
( ) Study limited to working with human tissue samples, other human biological samples and/or data *(specific project only)*
( ) Research tissue bank
( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	( ) Yes	(●) No
b) Will you be taking new human tissue samples (or other human biological samples)?	( ) Yes	(●) No
c) Will you be using existing human tissue samples (or other human biological samples)?	( ) Yes	(●) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

[x] England
[ ] Scotland
[ ] Wales
[ ] Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

(●) England
( ) Scotland

- ○ Wales
- ○ Northern Ireland
- ○ This study does not involve the NHS

4. Which review bodies are you applying to?

- ☑ NHS/HSC Research and Development offices
- ☐ Social Care Research Ethics Committee
- ☑ Research Ethics Committee
- ☐ National Information Governance Board for Health and Social Care (NIGB)
- ☐ Ministry of Justice (MoJ)

5. Will any research sites in this study be NHS organisations?

◉ Yes ○ No

5a. Do you want your application to be processed through the NIHR Coordinated System for gaining NHS Permission?

◉ Yes ○ No

If yes, you must complete and submit the NIHR CSP Application Form immediately after completing this project filter, before proceeding with completing and submitting other applications.

6. Do you plan to include any participants who are children?

◉ Yes ○ No

7. Do you plan to include any participants who are adults unable to consent for themselves through physical or mental incapacity? *The guidance notes explain how an adult is defined for this purpose.*

○ Yes ◉ No

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service in England or Wales?

○ Yes ◉ No

9. Is the study, or any part of the study, being undertaken as an educational project?

○ Yes ◉ No

10. Is this project financially supported by the United States Department for Health and Human Services?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the clinical care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

Integrated Research Application System
Application Form for Research administering questionnaires/interviews for quantitative analysis or mixed methodology study

NHS
National Patient Safety Agency
National Research Ethics Service

Application to NHS/HSC Research Ethics Committee

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
SMILE – Specialist Medical Intervention & Lightning Evaluation

Please complete these details after you have booked the REC application for review.

REC Name:
South West 2 Research Ethics Committee

REC Reference Number:
10/H0206/32

Submission date:
24/05/2010

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Assessing the feasibility and acceptability of comparing the Lightning Process□ with specialist medical care for Chronic Fatigue Syndrome or Myalgic Encephalopathy (CFS/ME) - pilot Randomized Controlled Trial.

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Dr	Esther	Crawley
Post	Senior Lecturer		
Qualifications	Ba(Hons), BM BCh, MRCPH, FRCPCH, PhD		
Employer	University of Bristol		
Work Address	Centre for Child and Adolescent Hea		
	Hampton House		
	Cotham Hill		
Post Code	BS6 6JS		
Work E-mail	esther.crawley@bristol.ac.uk		
* Personal E-mail			
Work Telephone	01173310753		

* Personal Telephone/Mobile 07974025260

Fax

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Dr	Jane	Carter
Address	RNHRD,		
	Upper Borough Walls		
	BATH		
Post Code	BA1 1RL		
E-mail	jane.carter@rnhrd.nhs.uk		
Telephone	01225465941		
Fax			

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	n/a
Sponsor's/protocol number:	n/a
Protocol Version:	Version 5
Protocol Date:	10/05/2010
Funder's reference number:	ASH1062-64,LIN1750

International Standard Randomised Controlled Trial Number (ISRCTN): n/a

ClinicalTrials.gov Identifier (NCT number): n/a

European Clinical Trials Database (EudraCT) number: n/a

Project website: n/a

Ref.Number Description	Reference Number

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. This summary will be published on the website of the National Research Ethics Service following the ethical review.*

The overall aim is to study the feasibility and acceptability of conducting a randomized controlled trial (RCT) to

investigate the effectiveness and cost-effectiveness of Specialist Medical Care compared to Specialist Medical Care plus the Lightning Process in treating CFS/ME in children. This study uses qualitative methods to understand the issues that relate to the successful design and implementation of a full-scale RCT.

A6-2. Summary of main issues. *Please summarise the main ethical and design issues arising from the study and say how you have addressed them.*

PURPOSE & DESIGN: The main objective for this study is to assess the feasibility and acceptability of conducting a RCT investigating the effectiveness and cost effectiveness of Specialist Medical care compared to specialist medical care plus the Lightning Process. This is important because over 250 children a year receive the Lightning Process for CFS/ME and there are currently no reported studies investigating the effectiveness or complications of the Lightning Process in children. As with all interventions, proper evaluation is necessary.
Before doing an RCT we need to know whether recruitment is possible and acceptable to families. We need to understand more about the differences and similarities between both interventions in terms of process, design, and setting. In addition, we need to develop appropriate outcome measures for any trial and test the feasibility and acceptability of investigating the health economic consequences of each intervention.

EXPERTISE AND ADVICE: The co-applicants provide a wide range of appropriate skills including: trial experience Alan Montgomery; qualitative experience – Nicola Mills and Jenny Donovan; statistical expertise – Jonathan Sterne; health economic expertise – Will Hollingworth; ethical expertise - Zuzana Deans.

RECRUITMENT – Children and their families will be informed about the study at assessment by the Specialist Bath CFS/ME team, given the patient information sheet and consent will be obtained for contact from a research nurse and a qualitative researcher. They will have sufficient time to discuss the study with their clinician. The research nurse will then contact the family and arrange to visit them at a convenient location (usually at home) to discuss and provide further information about the study (see below).
INCLUSION/EXCLUSION – children will be included if they have CFS/ME and are aged between 12 and 18 years of age and able to attend outpatient clinics. Children will be excluded if they are housebound, or do not have CFS/ME as their primary diagnosis or do not speak sufficient English to enable them read the patient information sheets and consent form. Children will be excluded if they are unwilling to take part in either of the intervention arms (for example if they are unwilling to participate in groups).
CONSENT –The research nurses will explain the study design, the uncertainties about intervention, the known advantages/disadvantages of the interventions, the options available outside the RCT, and the right not to take part or withdraw at any time. Those children and families willing to take part in the study will be asked to sign a consent form.
RISKS, BURDENS AND BENEFITS - children attending either arm may not benefit from the interventions. This is true for specialist medical treatment as well the specialist medical care plus the Lightning Process. Both interventions include a burden attending outpatient appointments or group sessions respectively. In addition, there is the added burden of qualitative interviews to examine the view points of participants and their families before and after the interventions.
However, parents and children with CFS/ME already attend significant out patient appointments. Our experience with qualitative interviews suggest that families and children find them acceptable and indeed previous qualitative studies in this patient group, suggest that parents in particular welcome the opportunity to talk about their experience of CFS/ME.
It is not clear whether there will be benefits for children as we do not know whether one treatment is better then another for this patient cohort.

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

To assess the feasibility and acceptability of conducting a randomised controlled trial to investigate the effectiveness and cost-effectiveness of specialist medical care compared with specialist medical care plus the Lightning Process.

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

1. Investigate appropriate patient-reported outcome measures for the RCT including evaluating existing measures of school attendance, mood, fatigue and function.
2. To develop resource use questionnaires to assess the impact of care on health service use and productivity.

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

There is a limited evidence base for the treatment for children with CFS/ME. There is one randomised controlled trial (RCT) investigating long term follow up comparing cognitive behavioural therapy (CBT) and waiting list (delayed CBT)

and one controlled trial investigating outpatient multidisciplinary rehabilitative treatment (graded activity/exercise and supportive care) compared to supportive care alone.
The Phil Parker Lightning Process is a trademarked intervention that is used for a variety of conditions including CFS/ME. In 2009, over 250 children attended groups to access the Lightning process as an intervention for paediatric CFS/ME. The Lightning Process has been developed from osteopathy, life coaching and Neuro-linguistic programming (NLP). The intervention includes three group sessions on consecutive days. Families currently pay approximately £620 to attend the Lightning Process course.
There are currently no reported studies investigating the effectiveness or side effects of the Lightning Process in children. As with all interventions, proper evaluation is necessary if it is to be brought into mainstream practice.

A13. Please give a full summary of your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

NULL HYPOTHESIS: It will not be feasible to recruit children and their families to a RCT comparing the Lighting Process with Specialist Medical Care.
STUDY DESIGN AND METHODOLOGY: We have chosen an RCT to reduce bias in either intervention arms. In addition, qualitative research methods will be integrated into this feasibility study. This is because the Lightning Process has received extensive publicity and so it will be important to understand the knowledge and effect of this on participation.
WHAT WILL HAPPEN TO STUDY PARTICIPANTS: Children and their families will be informed verbally about the study at assessment by the specialist Bath CFS/ME team, given the patient information sheet and written consent will be obtained for contact from a research nurse and contact from a qualitative researcher. The qualitative researcher may contact the family and arrange to visit them at a convenient location to interview the parents and maybe the young person about their views of the Lightning Process and randomisation. The research nurse will contact the family and arrange to visit them at a convenient location (usually at home) to discuss the study and provide further information about the study. If the children and their family agree to take part in the study, they will be both asked to sign a consent form (16 and under) and the young person only will sign the consent form (17 & 18). The nurse will then telephone the Bristol Randomised Trials Collaboration (BRTC) for the intervention allocation which will be conveyed to the child and family.

INTERVENTIONS
Specialist medical care: children and their families are offered a variety of treatment options that are recommended in NICE guidelines. Typically this is centred around graded activity and involves a follow up phone call at 2 weeks followed by family based rehabilitation consultations at approximately 6 weeks (1 hour), 3 months (1 hour), and 4.5 months (1 hour). The number and timing of the sessions are agreed with the child and family and varies depending on the needs and goals of the child. Children who have high levels of anxiety are offered 3 individual sessions of CBT every 2 weeks over a 6 week period. Other interventions such as Graded Exercise Therapy (GET) are available for children and young people if needed.

Specialist medical care plus The Lightning Process: In addition to the specialist Medical Care detailed above, young people and their parents will be asked to read the information about the Lightning Process on the website or using information sheets. If the young person is able to, they will be asked to read a book about the Lightning Process. If they are unable to read the book, they will be asked to listen to an audio book. Children/young people and their parents will be asked to complete an assessment form (which will take about 10 minutes) where they are asked to identify their goals and describe what they learnt from reading the book. After this they will have a telephone call with a Lightning Process Practitioner (LPP) (usually approximately 20 minutes). This is used to check that the young person and their parents are happy about attending the course, checks the goals identified by the young person and is an opportunity for the young person and their parents to ask further questions. If the young person and their family are happy to continue, the young person will be given a date to attend a course.

The course is 3 sessions on 3 consecutive days. Each session is 3 hours 45 minutes long. Group sessions include 4 to 5 young people between 12 – 18 years of age who live within the region covered by the CFS/ME service. During the group, children and young people will have a theory session and a practical session.

The theory session will include taught elements on the stress response, how the mind-body interacts and how thought processes can be helpful and negative. The language used by young people will be discussed and in some cases challenged. Young people will be encouraged to think about what they may be able to take responsibility for and change. The taught sessions are followed by a group discussion.

The practical session is used to put some of the skills learnt into practise. Young people identify a goal they wish to achieve (such as standing for longer) and are then given alternative ways to think about and prepare for this. This involves using different cognitive (thinking) strategies before and whilst the goal is attempted. Young people are also asked to identify a goal in which they can practise the strategies in the afternoon or evening. This goal will usually be short but could be an activity that is up to 30 minutes long.

The LP Practitioner will then arrange two follow up phone calls with the young person and parents within 2 weeks of the course and then approximately 6 to 8 weeks later. These can be cancelled if the young person does not want or need them. These follow up phone calls will be in addition to specialist medical care follow up.

QUALITATIVE INTERVIEWS
In-depth interviews will be undertaken with some parents of children on several occasions to form "case studies". Parents will be interviewed at three time points: 1. After assessment and prior to randomisation; 2. After randomisation and before any intervention; and 3. After the intervention. Children will be interviewed once at one of these points for no more than 20 minutes. Purposive sampling will ensure that interviews include a range of informants, in terms of socio-economic circumstances, age, sex, ethnicity and families from both intervention arms (maximum variation sampling), with the potential to target people with characteristics of interest to follow-up and develop emerging findings (theoretical sampling). The sample size will be determined by data saturation, i.e. when no new themes are being uncovered.
It is anticipated that up to 30 interviews (10 case studies) will be conducted. Informants will be interviewed at a location of their choice. Interviews will be semi-structured in that they will follow a checklist of topics to ensure consistency (see topic guide), but parents and children will be able to raise issues of importance. Interviews will explore the recruitment process, including views and experiences of the initial assessment and recruitment to trial appointments, the written and verbal information provided to potential participants and its acceptability, and reasons for accepting or declining participation; beliefs, expectations and preferences about interventions in the early stages of the trial, and experiences of interventions and outcome later on; and prior exposure and external influences to the intervention that might impact upon its implementation and effectiveness.
Part of the interviews will include questions about the inventories used at assessment and follow up. In particular, parents and children will be asked to compare the HADS with the POMS and the SCAS. All interviews will be audio-recorded with consent, transcribed verbatim, and anonymised.

The qualitative component for this trial has been chosen to enable us to understand whether families have problems with the study design, recruitment or information given. If there are problems with recruitment we will have sufficient information to either change/adapt the methodology or improve recruitment methods.
JUSTIFICATION OF CONTROL ARM: Our control arm is specialist medical care alone as we feel it would be unethical to offer either placebo or waiting list.
BROAD TIMETABLE FOR STAGES OF RESEARCH:
Recruitment: Assessment in clinic September 2010 – December 2011; Consent to randomization September/October 2010 –January 2012; Interventions November 2010-February 2012; Qualitative interviews October 2010 – October 2011; Follow up December 2010 to May 2012; feasibility analysis January 2012 – May 2012; Health Economic Analysis February 2012 to July 2012
HOW WILL WE DEAL WITH RESEARCHER EFFECTS AND RESEARCHER BIAS? Previous research has shown that the interaction between the recruiter and potential participant during recruitment appointments can provide essential information about the way the study and its interventions are perceived, and optimum methods for recruitment and design11. All clinicians in the specialist CFS/ME team have equipoise for this study having experience of both success and failure in both interventions. As interviews will be recorded, clinicians who do not have equipoise will be identified and either offered retraining or will be able to leave the study. Researchers, clinicians (specialist medical care) and practitioners (the Lightning Process) will have interviews recorded.
OBSERVATIONAL COMPONENTS: 1. Recruitment encounters will be recorded, transcribed and analysed using content and conversation analytic methods 2. A small number of intervention and usual care sessions in different centres will be observed in the early, mid and late stages of implementation, to assess the implementation, acceptability and setting of treatment provision. Detailed notes will be taken at the sessions, including the context, intensity and variability of treatment delivery, to understand how treatment is delivered and received in practice and to help interpret outcome results (for example, variation of effects in subgroups). All treatment sessions will be routinely audio-recorded, with consent, for monitoring purposes. 3. Observations will also be made of people completing the outcome measures to observe for any difficulties or misunderstandings. Participants will be encouraged to describe what they are thinking of when they read each question and how they interpret it, with minimal prompting to allow as close to real life completion as possible. This will be followed by semi-structured interviews to ascertain their views on the measures and to explore areas of misunderstanding and misinterpretation to determine the most acceptable and sensitive outcome measures. The number of observations and interviews will be determined by data saturation, although up to 20 observations and interviews are anticipated.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [x] Management of the research
- [ ] Undertaking the research
- [ ] Analysis of results

☑ Dissemination of findings

☐ None of the above

Give details of involvement, or if none please justify the absence of involvement.
The need for doing a study properly evaluating the Lightning Process came from patients and service users. Representatives from the Association of Young people with ME (AYME) have read, and suggested changes to the protocol and methodology. Service users publicized the research project and are keen to disseminate the findings. Healthy teenagers have scrutinized the patient information sheets and consent forms. The Chief Executive of AYME will be on the External Advisory Group.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

1. Primary diagnosis of CFS/ME
2. Age 12 to 18
3. Able to attend hospital clinic (mild to moderately severe CFS/ME, not housebound). (Housebound patients are usually identified prior to assessment in the CFS/ME clinic)

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

1. Not CFS/ME as diagnosis for fatigue
2. Under 12 or over 18 years of age
3. Severely affected or housebound
4. Unable to speak sufficient English to take part in intervention arms (identified as difficulty reading patient information sheets).

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Completion of pre-assessment inventories (routine for clinic)	1	1	20mins	Participant at home
Consent at assessment to contact by research nurse and qualitative interview prior to randomization	1	0	20mins	Clinician providing CFS/ME assessment in outpatient clinic
Interview with some parents of child by qualitative researcher prior to randomization	1	0	20mins	Qualitative researcher in place of parents choice (usually home)
Consent to randomization and randomization by research nurse	1	0	20 mins	Research nurse
Interview with some parents by qualitative researcher after randomization	1	0	20 minutes	Qualitative researcher in place of parents choice (usually home)
INTERVENTION - Specialist Medical Care arm: Outpatient appointments	3	3	1 hour	Clinician in specialist CFS/ME service

INTERVENTION - additional interventions for those in SMC + LP arm: Read information about Lightning process (web and information sheets or book)	1	1	1 hour	Participants and their parents
INTERVENTION - LP arm: Complete application form for LP	1	1	20mins	Participants with parents
INTERVENTION - LP arm: phone call with Lightning Process Practioner	1	1	20 mins	Lightning practitioner
INTERVENTION - LP arm: Group sessions.	3	3	3.45 hrs	Lightning practitioner
Qualitative interview: With some parents after intervention	1	0	20 mins	Qualitative researcher in place of parents choice - usually at home
Qualitative interview with young person (at either time point)	1	0	20 mins	Qualitative researcher in place of young persons choice - usually at home
Outcome assessment questionnaires at 6 weeks, 3 months, 6 months and 12 months	4	3	20 minutes	Participant
Assessment questionnaires for parents	3	0	20 mins	Parents at home
Health resource and work productivity questionnaires for parents at 6 weeks, 3 months, 6 months and 12 months	4	0	20 mins	Parents at home

A21. How long do you expect each participant to be in the study in total?

Study participants will be followed up normally by the specialist medical team as part of service evaluation. However, they will continue to get additional inventories to self complete up to 12 months after the intervention. Therefore they will be involved in the study for a total of 15 months.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

We do not believe there are any risks of being part of this study. There is however a burden for study participants. Some parents will be interviewed on three occasions. Children and young people will be interviewed once. We have tried to reduce this by ensuring that interviews are conducted at a place and time that is convenient for parents and the young person (usually in the home). In addition, feedback from parents from a previous study suggested that interviews were welcome as parents are keen to discuss their experiences of this illness.
There is an additional burden of extra inventories for children (5 minutes more at each assessment) and one extra time point. We have tried hard to minimise the questions asked and included follow up at the time they normally receive follow up as part of service evaluation. Inventories are self completed at home and completion can therefore be spread out over several days if necessary.
We have excluded young people who are severely affected from this study as we feel the burden of this study would be excessive for them. We will only recruit young people who will be able to manage this extra burden.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

◉ Yes ○ No

If Yes, please give details of procedures in place to deal with these issues:

Although questionnaires or group discussions will not include topics that are sensitive, embarrassing or upsetting, it is always possible that disclosure may occur which will require action. The researchers will discuss issues of disclosure prior to interview with participants as part of the discussion on confidentiality. If disclosure occurs, the researchers will contact the clinical lead who is also the chief investigator and the appropriate action will be taken using clinical protocols.

A24. What is the potential for benefit to research participants?

There are no specific benefits for research participants apart from the benefit of taking part in research.

A26. What are the potential risks for the researchers themselves? *(if any)*

Researchers will visit homes alone to conduct interviews. At all times, researchers will use the Royal National Hospital for Rheumatic Diseases lone working policy and use strategies currently in use by the CFS/ME team for lone working.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used? *For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

Children and their families will be identified by clinicians conducting assessments for the Specialist Peadiatric CFS/ME team at the Royal National Hospital for Rheumatic Diseases. If CFS/ME is confirmed at assessment and if young people fulfil eligibility requirements, the clinician will inform young people and their families about the study.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

○ Yes ◉ No

Please give details below:

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

○ Yes ◉ No

A29. How and by whom will potential participants first be approached?

Participants will first be approached by the clinician conducting the assessment for the specialist paediatric CFS/ME team at the Royal National Hospital for Rheumatic Diseases.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

Because many of the participants will be young people, we have put in place rigorous procedures for informed consent from parents and guardians on behalf of their children.
At clinical assessment, consent will initially be obtained for further contact from a researcher to interview parents and possibly the young person about prior knowledge and for contact from a research nurse. Young people and their parents will each be given a patient information sheet, the study will be explained by the clinician and they will be encouraged to spend time reading the PIS. There will be time to ask questions and have further discussion with their clinician.

The research nurse will visit the young person and their family at home to discuss the study in more detail. This is to be sure that the young person and their family are fully informed about the trial and randomisation. The research nurse will ensure there is sufficient time for discussion of the study and will obtain consent for randomisation.

For those who are interviewed, qualitative researcher will consent participants before the interview including consent for audio-taping the interview. They will be reminded and consent will be checked for the use of anonymised quotes in reports.

In addition, all participants, clinicians and Practioners will be consented for audio-taping of interventions. Consent will be obtained by the researcher who is conducting the observations. Clinicians and practioners will be given the protocol and will have the opportunity to ask questions and discuss the study prior to consent being obtained.

If you are not obtaining consent, please explain why not.

n/a

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

◉ Yes ○ No

A31. How long will you allow potential participants to decide whether or not to take part?

Participants will have as long as they need to decide to take part within the confines of the study. They will be encouraged to take the PIS home and we have put in place sufficient opportunities to discuss the study in detail with both their clinician and with the research nurse.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? *(e.g. translation, use of interpreters)*

At the moment, the Specialist CFS/ME service in Bath does not need to use translation or interpreters for young people accessing the clinic. It will be assumed for the purpose of this study that patients or families who are able to read the patient information leaflet will have sufficient English to take part in either intervention arm.

As this is a feasibility study, if families are excluded because of the lack of translation or interpreters, we will incorporate this aspect into the full study.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

◉ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.

○ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.

○ The participant would continue to be included in the study.

○ Not applicable – informed consent will not be sought from any participants in this research.

Further details:

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential

participants)?*(Tick as appropriate)*

- ☐ Access to medical records by those outside the direct healthcare team
- ☐ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA
- ☑ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☑ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☑ Use of audio/visual recording devices
- ☐ Storage of personal data on any of the following:
  - ☑ Manual files including X-rays
  - ☑ NHS computers
  - ☐ Home or other personal computers
  - ☑ University computers
  - ☐ Private company computers
  - ☑ Laptop computers

Further details:
Use of personal addresses, postcodes and contact details will only be used on consent forms to allow the research team to contact participants. Copies of consent forms will be kept in a locked filing cabinet in a locked office within a locked department at the University of Bristol.

Children and young people are allocated a unique 13 digit identification number made up of the centre number, the team number, an individual patient number, first 4 digits of the postcode, and patient initials. This number is assigned to the patient and is used on assessment forms prior to transfer of data so they are anonymised at source. A list of names and corresponding identification numbers are kept separately and securely on a encrypted password protected NHS server at the Royal National Hospital for Rheumatic Diseases.
Audio-recordings will be encrypted, password protected and stored on a secure university server for five years. This is to enable us to check recordings if necessary while reports are being written. Transcripts will be anonymised and secure password protected university server.
Only university laptops are used. All are encrypted and password protected using high levels of security in accordance with the University of Bristol protocols. All memory sticks are encrypted and password protected.

A38. How will you ensure the confidentiality of personal data?*Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

Personal data is kept securely as above. All inventories are anonymised at source such that all self completed inventories only have the 13 digit ID number and no personal details to ensure confidentiality.
Audio-recordings will be encrypted, password protected and stored on a secure university server for five years.
Transcripts will have all personal details and any other identifiying characteristics removed before being stored on an encrypted password protected University Server.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

The researchers will only have access to personal data used on the consent forms in order to contact participants. They will not have access to other data.

Storage and use of data after the end of the study

A43. How long will personal data be stored or accessed after the study has ended?

- ○ Less than 3 months

- (●) 3 – 6 months
- ( ) 6 – 12 months
- ( ) 12 months – 3 years
- ( ) Over 3 years

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

( ) Yes (●) No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

( ) Yes (●) No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

( ) Yes (●) No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

(●) Yes ( ) No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

A49-2. Will you seek permission from the research participants to inform their GP or other health/ care professional?

(●) Yes ( ) No

It should be made clear in the participant's information sheet if the GP/health professional will be informed.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

( ) Yes (●) No

Please give details, or justify if not registering the research.
This is a feasibility study.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- [x] Peer reviewed scientific journals

- [x] Internal report
- [x] Conference presentation
- [x] Publication on website
- [x] Other publication
- [ ] Submission to regulatory authorities
- [ ] Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- [ ] No plans to report or disseminate the results
- [x] Other (please specify)

Through patient charities.

A53. Will you inform participants of the results?

○ Yes ◉ No

Please give details of how you will inform participants or justify if not doing so.
As this is only a feasibility study, participants will not be individually informed of the outcome. However, the results from the feasibility study will be disseminated through patient charities.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- [ ] Independent external review
- [ ] Review within a company
- [x] Review within a multi-centre research group
- [x] Review within the Chief Investigator's institution or host organisation
- [x] Review within the research team
- [x] Review by educational supervisor
- [ ] Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
The research methodology has been extensively reviewed by the research team, the co-applicants and the MRC ConDuCT (COllaboration and iNnovation in DifficUlt and complex randomised Controlled Trials) methodology hub.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

- [ ] Review by independent statistician commissioned by funder or sponsor
- [ ] Other review by independent statistician
- [ ] Review by company statistician
- [x] Review by a statistician within the Chief Investigator's institution
- [ ] Review by a statistician within the research team or multi-centre group
- [ ] Review by educational supervisor
- [ ] Other review by individual with relevant statistical expertise
- [ ] No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title	Forename/Initials	Surname
	Prof	Jonathan	Sterne
Department	Social Medicine		
Institution	University of Bristol		
Work Address	Canynge Hall		
	39 Whatley Road		
	Bristol		
Post Code	BS82PS		
Telephone	01179287396		
Fax			
Mobile			
E-mail	Jonathan.Sterne@bristol.ac.uk		

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

The feasibility and acceptability of doing an RCT will be assessed using the percentage recruited of those eligible for recruitment and the percentage who complete each intervention out of those randomised to each arm.

A58. What are the secondary outcome measures? *(if any)*

1. The primary outcome from the interventions will be school attendance at 6 months
2. Secondary outcome measures for the interventions will be school attendance at 6 weeks, 3 months and 12 months; the SF36 (physical function) at 6 weeks, 3 months, 6 months and 12 months and pain visual analogue scale at 6 months.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size: 96

Total international sample size (including UK):

Total in European Economic Area:

Further details:

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

This is a feasibility study. This is the estimated number of participants that we think it is feasible to recruit in the time frame available. It is sufficiently large for us to achieve our overall aim to investigate the feasibility and acceptability of conducting a Randomised Controlled Trial (RCT).

A61. Will participants be allocated to groups at random?

◉ Yes ○ No

If yes, please give details of the intended method of randomisation:
We will use computer generated randomisation from the Bristol Randomised Trials Collaboration (BRTC). The research nurse will telephone the BRTC for the intervention allocation, which will be conveyed to the participant. If for any reason the phone line is unobtainable, randomisation will be completed during the next working day and the participant will be told of the results by phone or in person.

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

The feasibility and acceptability of doing an RCT will be assessed using the percentage recruited of those eligible for recruitment and the percentage who complete each intervention out of those randomised to each arm.

Qualitative data analysis
Analysis will be an ongoing and iterative process commencing soon after data collection and will inform further sampling and data collection. Interview transcripts and observation notes will be imported into Atlas.ti where they will be systematically assigned codes and analysed thematically to identify themes using techniques of constant comparison. Individuals exhibiting contrasting attitudes ('negative cases') will be studied in detail to understand reasons underlying such contrasts and to gain a deeper understanding of the data and findings. Throughout analysis, the perspectives of the individuals will be paramount, with careful account taken of the context within which the discussion takes place. Descriptive accounts will be produced, and theoretical explanations for behaviours, opinions and decisions will be developed.
A sample of recruitment appointments will also be examined for common or divergent themes. It is likely that the appointments will follow similar basic patterns, and so the analysis will be structured around these patterns. Content analytic methods will be used to describe in a structured manner what was said by whom and how often. More flexible grounded theory methods (as in the interviews above) will be applied to identify common or divergent themes, particularly focusing on the impact of statements by the recruiter on patients. Conversation analysis will be used to focus in great detail on certain sections of the transcripts, for example the interactions during which randomisation is offered.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Dr	Alan	Montgomery
Post	Reader in Health Services Research		
Qualifications	BSc, MSc, PhD		
Employer	University of Bristol		
Work Address	Community Based Medicine 25/27 Belgrave Road Clifton, Bristol		
Post Code	BS8 2AA		
Telephone	01173313840		
Fax			
Mobile			
Work Email	Alan.A.Montgomery@bristol.ac.uk		

	Title	Forename/Initials	Surname
	Dr	Nicola	Mills
Post	Research Associate		
Qualifications	BSc, MSc, PhD		
Employer	University of Bristol		
Work Address	Canynge Hall 39 Whatley Road Bristol		
Post Code	BS8 2PS		
Telephone	01179287210		

Fax	
Mobile	
Work Email	Nicola.Mills@bristol.ac.uk

Title	Forename/Initials	Surname
Dr	William	Hollingworth

Post	Reader, Department of Social Medicine
Qualifications	MSc, PhD
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Title	Forename/Initials	Surname
Dr	Zuzana	Deans

Post	Research Associate, Community Based Medicine
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Work Address	Third Floor Hampton House Cotham Hill, Bristol
Post Code	BS6 6JS
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Title	Forename/Initials	Surname
Prof	Jonathan	Sterne

Post	Professor Medical Statistics and Epidemiology
Qualifications	MA, MSc, PhD
Employer	University of Bristol
Work Address	Canynge Hall 39 Whatley Road Bristol
Post Code	BS8 2PS
Telephone	01179287396
Fax	
Mobile	
Work Email	Jonathan.Sterne@bristol.ac.uk

Title	Forename/Initials	Surname
Mr	Alastair	Gibson

Post	Lightning Process Practitioner

Qualifications	ABNLP,BMHRD,EFT
Employer	Self Employed
Work Address	The Suncliff
	East Overcliff Drive
	Bournemouth
Post Code	BH9 3AG
Telephone	01202269972
Fax	
Mobile	
Work Email	alastair@withinspiration.co.uk

Title	Forename/Initials	Surname
Ms	Fiona	Finch

Post	Director
Qualifications	MSc, Dip COT
Employer	Phil Parker Group
Work Address	City Point, Room 1516
	1 Ropemaker Street
	London
Post Code	EC2Y 9HT
Telephone	02088954007
Fax	
Mobile	
Work Email	fiona@phil.parker.org

Title	Forename/Initials	Surname
Mr	Phil	Parker

Post	Designer and Developer of the Lightning Process
Qualifications	D.O,Dip E.Hyp.Pysc CMPNLP
Employer	Director
Work Address	City Point, Room 1516
	1 Ropemaker Street
	London
Post Code	EC2Y 9HT
Telephone	02088954007
Fax	
Mobile	
Work Email	info@phil.parker.org

Title	Forename/Initials	Surname
Prof	Jenny	Donovan

Post	Professor of Social Medicine
Qualifications	BA, PhD
Employer	University of Bristol
Work Address	Canynge Hall
	39 Whatley Road
	Bristol
Post Code	BS8 2PS
Telephone	01179287214
Fax	

Mobile	
Work Email	Jenny.Donovan@bristol.ac.uk

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- (●) NHS or HSC care organisation
- ( ) Academic
- ( ) Pharmaceutical industry
- ( ) Medical device industry
- ( ) Local Authority
- ( ) Other social care provider (including voluntary sector or private organisation)
- ( ) Other

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation	RNHRD
Given name	Jane
Family name	Carter
Address	Upper Borough Walls
Town/city	Bath
Post code	BA1 1RL
Country	UNITED KINGDOM
Telephone	01225465941
Fax	
E-mail	jane.carter@rnhrd.nhs.uk

Is the sponsor based outside the UK?

( ) Yes (●) No

Where the lead sponsor is not established within the UK, a legal representative in the UK may need to be appointed. Please consult the guidance notes.

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

( ) Yes (●) No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
	Dr	Jane	Carter
Organisation	RNHRD		
Address	Upper Borough Walls		
	BATH		
Post Code	BA1 1RL		
Work Email	jane.carter@rnhrd.nhs.uk		
Telephone	01225465941		
Fax			
Mobile			

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/09/2010
Planned end date: 27/07/2012
Total duration:
Years: 1 Months: 11 Days:

A71-1. Is this study?

- (●) Single centre
- ( ) Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

- [x] England
- [ ] Scotland
- [ ] Wales
- [ ] Northern Ireland
- [ ] Other countries in European Economic Area

Total UK sites in study

Does this trial involve countries outside the EU?
( ) Yes (●) No

A72. What host organisations (NHS or other) in the UK will be responsible for the research sites? *Please indicate the type of organisation by ticking the box and give approximate numbers of planned research sites:*

- [x] NHS organisations in England 1
- [ ] NHS organisations in Wales
- [ ] NHS organisations in Scotland
- [ ] HSC organisations in Northern Ireland
- [ ] GP practices in England
- [ ] GP practices in Wales
- [ ] GP practices in Scotland
- [ ] GP practices in Northern Ireland

- ☐ Social care organisations
- ☐ Phase 1 trial units
- ☐ Prison establishments
- ☐ Probation areas
- ☐ Independent hospitals
- ☐ Educational establishments
- ☐ Independent research units
- ☐ Other (give details)

Total UK sites in study: 1

A76. Insurance/ indemnity to meet potential legal liabilities

Note: in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

- ☑ NHS indemnity scheme will apply (NHS sponsors only)
- ☑ Other insurance or indemnity arrangements will apply (give details below)

Lightning Process Insurance: Towergate Professional Risks. Certificate number: CROU01AM01. Certificate attached.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

- ☑ NHS indemnity scheme will apply (protocol authors with NHS contracts only)
- ☐ Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

- ☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
- ☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

PART B: Section 7 - Children

1. Please specify the potential age range of children under 16 who will be included and give reasons for carrying out the research in this age group.

Children will be recruited between 12 and 18 years of age.

CFS/ME is different in children and adults with different risk factors, course and outcome. It is therefore not possible to complete a study in adults and extrapolate the results to children. At the moment, over 250 children currently use the Lightning Process as an intervention for CFS/ME. It is important to evaluate this intervention in children.

2. Indicate whether any children under 16 will be recruited as controls and give further details.

The two intervention arms are specialist medical care or specialist medical care plus the Lightning Process. There is no "control" arm in the sense of waiting list or placebo arm for this study.

3-2. Please describe the arrangements for seeking informed consent from a person with parental responsibility and/or from children able to give consent for themselves.

We will seek consent from all young people who are eligible to take part in this study at three stages: 1. For contact with the research nurse and possibly the researcher, 2. For randomization and to take part in the study and 3. prior to interview and 4. prior to interventions being recorded.

The information sheets and consent forms have been scrutinized by healthy teenagers (12 to 18) to ensure they are clear to read and have sufficient information.

In addition, informed consent will be sought from all parents of children between the age of 12 and 16 inclusive. Parental information sheets and consent forms have been prepared.

As parents are part of this study for young people of all ages, we will also be consenting parents for their part in the study at the same time points.

In each case, young people and parents will have ample opportunity to consider the information and ask questions either from their own clinician or from the research nurse who will visit them at home and will be available to answer questions by phone or in person if needed.

4. If you intend to provide children under 16 with information about the research and seek their consent or agreement, please outline how this process will vary according to their age and level of understanding.

Information sheets and consent forms have been prepared for young people aged 12 to 18 and have been scrutinised by young people to ensure they are readable and clear. The research nurse will be experienced in working with young people and will be able to provide ample time and opportunity to be sure that young people and their parents have been given sufficient and suitable information to reach informed consent.

Copies of written information sheet(s) for parents and children, consent/assent form(s) and any other explanatory material should be enclosed with the application.

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.*

Research site		Investigator/ Collaborator/ Contact	
Institution name	RNHRD	Title	Dr
Department name	Paediatric CFS/ME	First name/ Initials	Esther
Street address	Upper Borough Walls	Surname	Crawley
Town/city	Bath		
Post Code	BA1 1RL		

Participant Identification Centre(PIC)-Collaborator/ Contact

Dr Crawley

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.

9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:

    - Will be held by the main REC or the GTAC (as applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the main REC, in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs.
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.

10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.

11. I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

- [x] Chief Investigator
- [ ] Sponsor
- [ ] Study co-ordinator

☐ Student

☐ Other – please give details

☐ None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☐ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Dr Esther Crawley on 24/05/2010 01:37.

Job Title/Post:	Senior Lecturer
Organisation:	University of Bristol
Email:	esther.crawley@bristol.ac.uk
Signature:	.....
Print Name:	Esther Crawley
Date:	21/05/2010 *(dd/mm/yyyy)*

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.
7. I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

This section was signed electronically by MS Jane Carter on 24/05/2010 12:28.

Job Title/Post:	R&D manager
Organisation:	RNHRD
Email:	jane.carter@rnhrd.nhs.uk