## 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)*

☑ 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

## Site-Specific Information Form

**Is the site hosting this research a NHS site or a non-NHS site?** *NHS sites include Health and Social Care organisations in Northern Ireland. The sites hosting the research are the sites in which or through which research procedures are conducted. For NHS sites, this includes sites where NHS staff are participants.*

- (●) NHS site
- ( ) Non-NHS site

*This question must be completed before proceeding. The filter will customise the form, disabling questions which are not relevant to this application.*

*One Site-Specific Information Form should be completed for each research site and submitted to the relevant R&D office with the documents in the checklist. See guidance notes.*

*The data in this box is populated from Part A:*

Title of 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.

Short title: SMILE – Specialist Medical Intervention & Lightning Evaluation

Chief Investigator:

| Title | Forename/Initials | Surname |
|---|---|---|
| Dr | Esther | Crawley |

Name of NHS Research Ethics Committee to which application for ethical review is being made:
South West 2 Research Ethics Committee

Project reference number from above REC: 10/H0206/32

**1-1. Give the name of the NHS organisation responsible for this research site**

Royal National Hospital for Rheumatic Diseases NHS Foundation Trust, Bath

**1-2. In which country is the research site located?**

- (●) England
- ( ) Wales
- ( ) Scotland
- ( ) Northern Ireland

**1-3. Is the research site a GP practice or other Primary Care Organisation?**

( ) Yes (●) No

**2. Who is the Principal Investigator or Local Collaborator for this research at this site?**

Select the appropriate title: ◉ Principal Investigator
○ Local Collaborator

| | Title | Forename/Initials | Surname |
|---|---|---|---|
| | Dr | Esther | Crawley |
| Post | Honorary Consultant Paediatrician | | |
| Qualifications | BA(Hons), BM BCh, FRCPH, PhD | | |
| Organisation | RNHRD and University of Bristol | | |
| Work Address | CCCAH | | |
| | Hamptom House | | |
| | Bristol | | |
| PostCode | BS6 6JS | | |
| Work E-mail | esther.crawley@bristol.ac.uk | | |
| Work Telephone | 01225465941 | | |
| Mobile | | | |
| Fax | | | |

a) Approximately how much time will this person allocate to conducting this research? *Please provide your response in terms of Whole Time Equivalents (WTE).*
10% WTE (4 hours a week)

b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation? ◉ Yes ○ No

*A copy of a current CV for the Principal Investigator (maximum 2 pages of A4) must be submitted with this form.*

**3. Please give details of all locations, departments, groups or units at which or through which research procedures will be conducted at this site and describe the activity that will take place.**

*Please list all locations/departments etc where research procedures will be conducted within the NHS organisation, describing the involvement in a few words. Where access to specific facilities will be required these should also be listed for each location.*

*Name the main location/department first. Give details of any research procedures to be carried out off site, for example in participants' homes.*

| | Location | Activity/facilities |
|---|---|---|
| 1 | RNHRD outpatient area | Patients will be identified during assessment by the clinician; given a patient information sheet (PIS) and consented to a visit by the research nurses and the qualitative researcher |
| 2 | Participants home | Consent to study by research nurse and interviews by qualitative researcher. |

**4. Please give details of all centres where potential participants for this research site will be identified.**

| Participant Identification Centre | Name(s) of individuals involved in identifying potential participants |
|---|---|
| Cadbury Heath PCT NHS clinic | Avril Missen (CFS/ME Consultant Psychologist)<br>Andy Haig Ferguson (CFS/ME Health psychologist) |
| Great Western Hospital, Paediatric OPD, Swindon | Jackie Christie-Collins (CFS/ME Physiotherapist) |
| Stonehouse NHS clinic Gloucester | Beverly Knops, (CFS/ME specialist OT) |

**5. Please give details of all other members of the research team at this site.**

1

| | Title | Forename/Initials | Surname |
|---|---|---|---|
| | Ms | Lucy | Beasant |
| Work E-mail | Lucy.Beasant@bristol.ac.uk | | |
| Employing organisation | University of Bristol | | |
| Post | Qualitative Researcher | | |
| Qualifications | BSc, MSc | | |
| Role in research team: | researcher | | |

a) Approximately how much time (approximately) will this person allocate to conducting this research? *Please provide your response in terms of Whole Time Equivalents (WTE).*
0.8 - 1.0

b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation? ◉ Yes ○ No

*A copy of a current CV for the research team member (maximum 2 pages of A4) must be submitted to the R&D office.*

2

| | Title | Forename/Initials | Surname |
|---|---|---|---|
| | Ms | Debbie | Johnson |
| Work E-mail | d.johnson@bristol.ac.uk | | |
| Employing organisation | University of Bristol | | |
| Post | Research Nurse | | |
| Qualifications | Nursing qualification | | |
| Role in research team: | research nurse | | |

a) Approximately how much time (approximately) will this person allocate to conducting this research? *Please provide your response in terms of Whole Time Equivalents (WTE).*
0.5 - 0.8

b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation? ◉ Yes ○ No

*A copy of a current CV for the research team member (maximum 2 pages of A4) must be submitted to the R&D office.*

3

| | Title | Forename/Initials | Surname |
|---|---|---|---|
| Work E-mail | | | |
| Employing organisation | University of Bristol | | |
| Post | Project Manager | | |
| Qualifications | First degree | | |

| | | |
|---|---|---|
| Role in research team: | other (please specify) | Project Manager |

a) Approximately how much time (approximately) will this person allocate to conducting this research? *Please provide your response in terms of Whole Time Equivalents (WTE).*
0.4 - 0.6 NOT YET APPOINTED

b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation? ◉ Yes ○ No

**6. Does the Principal Investigator or any other member of the site research team have any direct personal involvement (e.g. financial, share-holding, personal relationship etc) in the organisation sponsoring or funding the research that may give rise to a possible conflict of interest?**

○ Yes ◉ No

**7. What is the proposed local start and end date for the research at this site?**

| | |
|---|---|
| Start date: | 01/09/2010 |
| End date: | 30/12/2011 |
| Duration (Months): | 15 |

**8-1. 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.)*

*Columns 1-4 have been completed with information from A18 as below:*

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

*Please complete Column 5 with details of the names of individuals or names of staff groups who will conduct the procedure at this site.*

| Intervention or procedure | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| Completion of pre-assessment inventories (routine for clinic) | 1 | 1 | 20mins | Participant at home | Participants |
| 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 | Members of the paediatric CFS/ME clinical team: Esther Crawley (PI and Consultant Paediatrician); Avril Missen (Consultant psychologist); Jackie Christie-Collins (Consultant physiotherapist); Beverly Knops (Consultant OT) |
| Interview with some parents of child by qualitative researcher prior to randomization | 1 | 0 | 20mins | Qualitative researcher in place of parents choice (usually home) | Qualitative Researcher |
| Consent to randomization and randomization by research nurse | 1 | 0 | 20 mins | Research nurse | Research Nurse |
| Interview with some parents by | 1 | 0 | 20 | Qualitative | Qualitative Researcher |

| | | | | | |
|---|---|---|---|---|---|
| qualitative researcher after randomization | | | minutes | 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 | Paediatric CFS/ME clinical team |
| 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 | Participants |
| INTERVENTION - LP arm: Complete application form for LP | 1 | 1 | 20mins | Participants with parents | Participants with parents |
| INTERVENTION - LP arm: phone call with Lightning Process Practioner | 1 | 1 | 20 mins | Lightning practitioner | Lightning Process Practioner |
| INTERVENTION - LP arm: Group sessions. | 3 | 3 | 3.45 hrs | Lightning practitioner | Lightning Process Practioner |
| Qualitative interview: With some parents after intervention | 1 | 0 | 20 mins | Qualitative researcher in place of parents choice - usually at home | Qualitative Researcher |
| Qualitative interview with young person (at either time point) | 1 | 0 | 20 mins | Qualitative researcher in place of young persons choice - usually at home | Qualitative Researcher |
| Outcome assessment questionnaires at 6 weeks, 3 months, 6 months and 12 months | 4 | 3 | 20 minutes | Participant | Participants |
| Assessment questionnaires for parents | 3 | 0 | 20 mins | Parents at home | Participants parents |
| 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 | Participants parents |

**8-2. Will any aspects of the research at this site be conducted in a different way to that described in Part A or the protocol?**

○ Yes ◉ No

*If Yes, please note any relevant changes to the information in the above table.*

*Are there any changes other than those noted in the table?*

**10. How many research participants/samples is it expected will be recruited/obtained from this site?**

96 young people

**11. Give details of how potential participants will be identified locally and who will be making the first approach to them to take part in the study.**

Participants will be identified by paediatric CFS/ME clinicians in clinic. If they are eligible, the clinician providing the assessment will discuss the study and give them a patient information sheet.

**12. Who will be responsible for obtaining informed consent at this site? What expertise and training do these persons have in obtaining consent for research purposes?**

| Name | Expertise/training |
|---|---|
| Esther Crawley | Consultant Paediatrician. Extensive experience of obtaining consent for studies and for treatment. She will only be involved in obtaining consent for further contact by researcher and research nurse |
| Avril Missen | Consultant psychologist. Extensive experience of obtaining consent for studies and for treatment. She will only be involved in obtaining consent for further contact by researcher and research nurse |
| Jackie Christie-Collins | Consultant physiotherapist. Extensive experience of obtaining consent for studies and for treatment. She will only be involved in obtaining consent for further contact by researcher and research nurse |

**15-1. Is there an independent contact point where potential participants can seek general advice about taking part in research?**

Yes - through Jane Carter, R & D Manager at the RNHRD.

**15-2. Is there a contact point where potential participants can seek further details about this specific research project?**

Yes - through Jane Carter, R & D Manager at the RNHRD.

**16. Are there any changes that should be made to the generic content of the information sheet to reflect site-specific issues in the conduct of the study?** *A substantial amendment may need to be discussed with the Chief Investigator and submitted to the main REC.*

No

*Please provide a copy on headed paper of the participant information sheet and consent form that will be used locally. Unless indicated above, this must be the same generic version submitted to/approved by the main REC for the study while including relevant local information about the site, investigator and contact points for participants (see guidance notes).*

**17. What local arrangements have been made for participants 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 etc.)*

Children and young people will be excluded if they or their parents have insufficient English to either understand the Patient Information Sheet (PIS) and consent form to take part in the Lightning Process or take part in the interviews. As the overall aim of this study is to investigate the feasibility and acceptability of conducting a Randomised Controlled Trial (RCT) we will use this study to determine the measures we need to take to include all participants for the full study. We do not believe families will be excluded from this study because the CFS/ME clinical service does not currently need to use translators for families referred into the service.

**18. What local arrangements will be made to inform the GP or other health care professionals responsible for the care of the participants?**

Consent will be obtained to inform the young person's GP that they have been recruited into the study.

**19. What arrangements (e.g. facilities, staffing, psychosocial support, emergency procedures) will be in place at the site, where appropriate, to minimise the risks to participants and staff and deal with the consequences of any harm?**

The clinical team is very experienced with this group of patients and will liaise closely with the research team when necessary throughout the trial to provide the appropriate support. There is extensive psychological support available within the clinical team if this should be necessary. The research team are also very experienced with children and

families, and will be able to both provide support and signposting if necessary for support (including emergency support) if the need should arise. The research team will use the lone working policy used by the paediatric CSF/ME team to reduce the risks of domiciliary interviews.

**21. What external funding will be provided for the research at this site?**

- ○ Funded by commercial sponsor
- ◉ Other funding
- ○ No external funding

Please give details of the funding:

| Type of funding | Details (including breakdown over years if appropriate) |
|---|---|
| (i) Block grant | A total of £164,000 has been awarded by the Linbury Trust and the Ashden Trust. |
| (ii) Per participant | |
| (iii) Other (give details) | |

Which organisation will receive and manage this funding?
The University of Bristol

**23. Authorisations required prior to R&D approval**

This section deals with authorisations by managers within the NHS organisation. It should be signed in accordance with the guidance provided by the NHS organisation. This may include authorisation by clinical supervisors, line managers, service managers, support department managers, pharmacy, data protection officers or finance managers, depending on the nature of the research. Managers completing this section should confirm in the text what the authorisation means, in accordance with the guidance provided by the NHS organisation.

This section may also be used by university employers or research support staff to provide authorisation to NHS organisations, in accordance with guidance from the university.

1. Type of authorisation:
Data Protection

| | Title | Forename/Initials | Surname |
|---|---|---|---|
| | Ms | Hayley | Sewell |
| Post | Director of Governance and Performance | | |
| Qualifications | | | |
| Organisation | RNHRD | | |
| Work Address | Upper Borough Walls<br>Bath | | |
| PostCode | BA1 1RL | | |
| Work E-mail | Hayley.sewell@rnhrd.nhs.uk | | |
| Work Telephone | 01225465941 | | |
| Mobile | | | |
| Fax | | | |

Signature: .....

Date: .....

2. Type of authorisation:
Head of Department

| | Title | Forename/Initials | Surname |
|---|---|---|---|
| | Dr | Tim | Jenkinson |
| Post | Medical Director | | |
| Qualifications | FRCP | | |
| Organisation | RNHRD | | |
| Work Address | Upper Borough Walls | | |
| | Bath | | |
| PostCode | BA1 1RL | | |
| Work E-mail | rachel.edwards@rnhrd.nhs.uk | | |
| Work Telephone | 01225465941 | | |
| Mobile | | | |
| Fax | | | |

Signature: .....

Date: .....

**Declaration by Principal Investigator or Local Collaborator**

1. The information in this form is accurate to the best of my knowledge and I take full responsibility for it.
2. I undertake to abide by the ethical principles underpinning the World Medical Association's Declaration of Helsinki and relevant good practice guidelines in the conduct of research.
3. If the research is approved by the main REC and NHS organisation, I undertake to adhere to the study protocol, the terms of the application of which the main REC has given a favourable opinion and the conditions requested by the NHS organisation, and to inform the NHS organisation within local timelines of any subsequent amendments to the protocol.
4. If the research is approved, I undertake to abide by the principles of the Research Governance Framework for Health and Social Care.
5. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to the conduct of research.
6. I undertake to disclose any conflicts of interest that may arise during the course of this research, and take responsibility for ensuring that all staff involved in the research are aware of their responsibilities to disclose conflicts of interest.
7. I understand and agree that study files, documents, research records and data may be subject to inspection by the NHS organisation, the sponsor or an independent body for monitoring, audit and inspection purposes.
8. I take responsibility for ensuring that staff involved in the research at this site hold appropriate contracts for the duration of the research, are familiar with the Research Governance Framework, the NHS organisation's Data Protection Policy and all other relevant policies and guidelines, and are appropriately trained and experienced.
9. I undertake to complete any progress and/or final reports as requested by the NHS organisation and understand that continuation of permission to conduct research within the NHS organisation is dependent on satisfactory

completion of such reports.

10. I undertake to maintain a project file for this research in accordance with the NHS organisation's policy.

11. I take responsibility for ensuring that all serious adverse events are handled within the NHS organisation's policy for reporting and handling of adverse events.

12. I understand that information relating to this research, including the contact details on this application, will be held by the R&D office and 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.

13. I understand that the information contained in this application, any supporting documentation and all correspondence with the R&D office and/or the REC system relating to the application 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.

This section was signed electronically by Dr Esther Crawley on 26/05/2010 12:48.

| | |
|---|---|
| Job Title/Post: | Senior Lecturer |
| Organisation: | University of Bristol |
| Email: | esther.crawley@bristol.ac.uk |