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 complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
SMART Feasibility Study

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 to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
( ) Basic science study involving procedures with human participants
( ) 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 (or other human biological samples) and data (specific project only)
( ) Study limited to working with 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. Will the study involve the use of any medical device without a CE Mark, or a CE marked device which has been modified or will be used outside its intended purposes?

( ) Yes (●) No

2b. 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?

- [ ] HRA Approval
- [x] NHS/HSC Research and Development offices
- [ ] Social Care Research Ethics Committee
- [x] Research Ethics Committee
- [ ] Confidentiality Advisory Group (CAG)
- [ ] National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

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

(•) Yes ( ) No

5a. Are all the research costs and infrastructure costs for this study provided by an NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC) or NIHR Research Centre for Patient Safety & Service Quality in all study sites?

( ) Yes (•) No

If yes and you have selected HRA Approval in question 4 above, your study will be processed through HRA Approval.

If yes, and you have not selected HRA Approval in question 4 above, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio? Please see information button for further details.

(•) Yes ( ) No

If yes, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form immediately after completing this project filter and before submitting other applications. If you have selected HRA Approval in question 4 above your study will be processed through HRA Approval. If not, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

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

( ) Yes (•) No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

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

○ Yes ◉ No

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

○ Yes ◉ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

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

○ Yes ◉ No

NOTICE OF SUBSTANTIAL AMENDMENT

Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs).
The form should be completed by the Chief Investigator using language comprehensible to a lay person.

Details of Chief Investigator:

	Title	Forename/Initials	Surname
	Professor	Michael	Bennett
Work Address	[redacted]		
PostCode			
Email			
Telephone			
Fax			

Full title of study:	Self-Management of Analgesia and Related Treatments in palliative care - Feasibility Study
Lead sponsor:	University of Leeds
Name of REC:	North West - Lancaster
REC reference number:	15/NW/0797
Name of lead R&D office:	University Hospital Southampton NHS Foundation Trust
Date study commenced:	23 November 2015
Protocol reference (if applicable), current version and date:	SMART phase 3 protocol version 1 21 September 2015
Amendment number and date:	Amendment number 1 05 November 2015

Type of amendment

(a) Amendment to information previously given in IRAS

○ Yes ◉ No

If yes, please refer to relevant sections of IRAS in the "summary of changes" below.

(b) Amendment to the protocol

◉ Yes ○ No

If yes, please submit <u>either</u> the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

Revised protocol attached. Version 2, date 05 November 2015. All changes to the protocol have been tracked

using track-changes

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

(●) Yes ( ) No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

The information sheets and consent forms listed in section "List of enclosed documents" have been amended with new version numbers, dates and changes tracked using track-changes.

Is this a modified version of an amendment previously notified and not approved?

( ) Yes (●) No

Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study.
If this is a modified amendment, please explain how the modifications address the concerns raised previously by the ethics committee.
If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

The changes outlined below were made following consultation with patient and carer representatives and the study steering committee at the recent SMART project meeting in October 2015. These changes do not significantly alter the research design or methodology, rather they are intended to (1) reduce the burden for patients of completing fortnightly questionnaires and (2) improve the assessment of the fidelity of intervention delivery in clinical practice and (3) ensure our patient review procedure more closely reflect usual clinical nurse specialist practice.

1. Changes to patient reported outcome measures:
After consultation with patients, carers and the study steering committee it was felt that the 'Self-management ability scale' (SMAS) was too burdensome for an end of life patient group. It was decided to replace the SMAS with the 'self-efficacy for managing chronic disease scale' which is a short 6 item scale which can be adapted to an end of life context and is therefore more closly aligned to the aims and objectives of the study.

In addition, it was also felt that the Beliefs about Medicines (BMQ) questionnaire was felt to be too burdensome and some questions were inappropriate for patients at the end of life. It was therefore decided to remove the BMQ from the study as it was not direcrlty related to the objectives of the study and many of the domains were already address in the patient interview topic guide.

2. Changes to assessing fidelity of delivering the SMART intervention:
The study steering committee advised the study team that audio recording nurse-patient consultations when the SMART intervention is used is the most appropriate way of assessing the fidelity of delivering the intervention. This data can be used to develop a coding framework which in a definitive trail can be used to evaluate the delivery of the intervention.

Audio recording nurse-patient consultations has been written into the protocol under section 10.7 'Intervention adherence' (page 20). It is intended that each specialist nurse will be asked to audio record their consultation with one patient with whom they use the SMART toolkit intervenor.

The information sheets and consent forms for patients and health professionals have been amended to include audio-recording the consultations during which the SMART toolkit is used. It has been made clear that consenting to audio recording consultations is be voluntary and if either the nurse or patient dose not consent to it, it will not prevent them from taking part in the rest of the study.

3. Change to wording of "weekly" review of patient's progress with goal setting.
Following feedback from specialists palliative care nurses on the protocol it was decided to modify the description of the "weekly nurse-patient review" to "regular nurse-patient review". This has been changed throughout the protocol, as well as the patient and health professional information sheets.

The reason for this change is because it will allow are study protocol to reflect more closely usual specialist nurse care. Nurse feedback indicated that they often review their patient's progress more or less frequently than once a week. Therefore, so that our protocol reflects this usual practice and to ensure we capture all nurse-patient consultations where the SMART toolkit is used we have modified our protocol accordingly to accommodate this.

Any other relevant information

Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.

List of enclosed documents

Document	*Version*	*Date*
SMART Protocol phase 3	2	05/11/2015
SMART Health Professional Consent Form	2	05/11/2015
SMART Patient Consent Form	2	05/11/2015
SMART Health professional information sheet	2	05/11/2015
SMART Patient Information Sheet	2	05/11/2015

Declaration by Chief Investigator

1. *I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.*
2. *I consider that it would be reasonable for the proposed amendment to be implemented.*

This section was signed electronically by Professor Mike Bennett on 17/11/2015 16:24.

Job Title/Post: Professor of Palliative Medicine

Organisation: University of Leeds

Email: [redacted]

Declaration by the sponsor's representative

I confirm the sponsor's support for this substantial amendment.

This section was signed electronically by Mrs Clare Skinner on 17/11/2015 13:24.

Job Title/Post: Sponsors Representative

Organisation: Leeds University

Email: [redacted]

NHS
Health Research Authority
National Research Ethics Service

North West - Lancaster Research Ethics Committee

[redacted]

23 November 2015

Professor Michael Bennett
St Gemma's Professor of Palliative Medicine
University of Leeds
[redacted]

Dear Professor Bennett

Study title:	**Self-Management of Analgesia and Related Treatments in palliative care - Feasibility Study**
REC reference:	**15/NW/0797**
Amendment number:	**1**
Amendment date:	**17 November 2015**
IRAS project ID:	**188663**

Changes to reported outcome measures, assessing fidelity, change to patient review

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The members had no ethical issues with this amendment.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Notice of Substantial Amendment (non-CTIMP)	1	17 November 2015

Participant consent form [health professional]	2	05 November 2015
Participant consent form [patient]	2	05 November 2015
Participant information sheet (PIS) [Health professsional]	2	04 November 2015
Participant information sheet (PIS) [patient]	2	05 November 2015
Research protocol or project proposal [phase 3]	2	05 November 2015

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

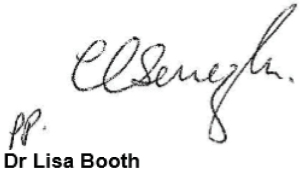
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

15/NW/0797:	**Please quote this number on all correspondence**

Yours sincerely



pp.

Dr Lisa Booth
Chair

E-mail: [redacted]

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Mrs Sharon Davies-Dear, University Hospital Southampton NHS Foundation Trust*
Research Ethics and Governance Admin

North West - Lancaster Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 23 November 2015

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Lisa Booth	Senior Lecturer / Chair	Yes	
Professor Jois Stansfield	Professor of Speech Pathology	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Carol Ebenezer	REC Manager