Application 2: Please Stop Informing Me: Enabling people to use internet information to self-manage musculoskeletal pain

Important note: This is a real application which has been doctored for the purposes of training. Information has been removed from the application and the application has been anonymised. The UREC does not endorse this application as a model.

The application, shown on the following pages, was discussed at the workshop. A summary of the key points raised by the participants, the UREC and the original ethics reviewers follows (this is not an exhaustive list):

- There was a query regarding whether the application should have been reviewed by the NHS ethics review procedure, depending on the way that participants are identified (i.e. if they are identified from, or because of, their past or present use of NHS services, then the ethics application should be submitted for NHS approval via NRES); it was noted that this can be difficult to interpret and there are grey areas for which it is not clear who should review the project;
- It was noted that there was a governance issue relating to the plan to visit some participants in their homes (specific permissions may required for this, particularly if children may be present, and risk assessments may be required);
- More information was required concerning the potential participant group (e.g. could it include children or vulnerable adults?);
- The application did not provide sufficient detail, particularly in relation to when the researcher would be following up with participants;
- Greater clarity was required concerning whether participants were already using the website. If not, it needed to be clearer that some of the referral organisations are private services and that there may be a cost implication;
- Greater clarity was required concerning whether there is a face to face questionnaire which is being administered by the health professional, and if so, is this part of the research?
- Greater clarity was required about the interviews, and an information sheet and consent form should be provided for them. The application states that interviews won’t be recorded, so how will data be recorded?
- There were concerns around the idea of texting or emailing participants contact details to other members of the team, and how secure these data will be (i.e. only on password protected phones);
- It is unclear whether participants have to take part in both the questionnaire and the interview;
- There is a potential issue regarding the boundary between research (which requires ethics approval) and service evaluation (which does not require ethics approval).
This form has been approved by the University Research Ethics Committee (UREC)

<table>
<thead>
<tr>
<th>Date:</th>
<th>XXXX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of applicant:</td>
<td>XXXX</td>
</tr>
<tr>
<td>Research project title:</td>
<td>Please Stop Informing Me: Enabling people to use internet information to self-manage musculoskeletal pain</td>
</tr>
</tbody>
</table>

**Complete this form if** you are a **member of staff or a postgraduate research student** who plans to undertake a research project which requires ethics approval via the University Ethics Review Procedure.  

**or**

**Complete this form if** you plan to submit a ‘**generic** research ethics application (i.e. an application that will cover several sufficiently similar research projects). Information on the ‘generic’ route is at: [www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy/approval-procedure/review-procedure/generic-research-projects](http://www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy/approval-procedure/review-procedure/generic-research-projects)

If you are an undergraduate or a postgraduate-taught student, this is the wrong form.

This form should be accompanied, where appropriate, by all Information Sheets/Covering Letters/Written Scripts which you propose to use to inform the prospective participants about the proposed research, and/or by a Consent Form where you need to use one.

Further guidance on how to apply is at: [www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/approval-procedure/review-procedure](http://www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/approval-procedure/review-procedure)

Guidance on the possible routes for obtaining ethics approval (i.e. on the University Ethics Review Procedure, the NHS procedure and the Social Care Research Ethics Committee, and the Alternative procedure) is at: [www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/approval-procedure/ethics-approval](http://www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/approval-procedure/ethics-approval)

Once you have completed this research ethics application form in full, and other documents where appropriate, check that your name, the title of your research project and the date is contained in the footer of each page and email, as a word document, to the Ethics Administrator. Please note that the original signed and dated version of ‘Part B’ of the application form should be provided to the Ethics Administrator in hard copy.

**I confirm that I have read the current version of the University of Sheffield ‘Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue’, as shown on the University’s research ethics website at: [www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy](http://www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy)**
### Part A

#### A1. Title of Research Project: Please Stop Informing Me: Enabling people to use internet information to self-manage musculoskeletal pain

#### A2. Contact person (normally the Principal Investigator, in the case of staff-led research projects, or the student in the case of supervised-postgraduate researcher projects):

<table>
<thead>
<tr>
<th>Title:</th>
<th>Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>XXXX</td>
<td>XXXX</td>
</tr>
<tr>
<td>Post:</td>
<td>Department:</td>
</tr>
<tr>
<td>XXXX</td>
<td>XXXX</td>
</tr>
<tr>
<td>Email:</td>
<td>Telephone:</td>
</tr>
<tr>
<td>XXXX</td>
<td>XXXX</td>
</tr>
</tbody>
</table>

#### A2.1. Is this a postgraduate researcher project? If yes, please provide the Supervisor’s contact details:

<table>
<thead>
<tr>
<th>Title:</th>
<th>Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Post:</td>
<td>Department:</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Email:</td>
<td>Telephone:</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### A2.2. Other key investigators/co-applicants (within/outside University), where applicable. Please list all (add more if necessary):

<table>
<thead>
<tr>
<th>Title:</th>
<th>Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>XXXX</td>
<td>XXXX</td>
</tr>
<tr>
<td>Post:</td>
<td>Department:</td>
</tr>
<tr>
<td>XXXX</td>
<td>XXXX</td>
</tr>
<tr>
<td>Email:</td>
<td>Telephone:</td>
</tr>
<tr>
<td>XXXX</td>
<td>XXXX</td>
</tr>
</tbody>
</table>

#### A3. Proposed Project Duration:

<table>
<thead>
<tr>
<th>Start date:</th>
<th>End date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>XXXX</td>
<td>XXXX</td>
</tr>
</tbody>
</table>

#### A4. Mark ‘X’ in one or more of the following boxes if your research:

- [ ] involves adults with mental incapacity or mental illness
- [ ] involves prisoners or others in custodial care (e.g. young offenders)
- [ ] involves children or young people aged under 18 years
- [ ] involves using samples of human biological material collected before for another purpose
- [ ] involves taking new samples of human biological material (e.g. blood, tissue) *
- [ ] involves testing a medicinal product *
- [ ] involves taking new samples of human biological material (e.g. blood, tissue) *
- [ ] involves additional radiation above that required for clinical care *
- [ ] involves investigating a medical device *
- [ ] is social care research
- [ ] is ESRC funded
- [x] Is taking place in the health service but does not require NHS ethical approval**
Participant Information Sheet

URMS number if required (please see below)

* If you have marked boxes marked * then you also need to obtain confirmation that appropriate University insurance is in place. The procedure for doing so is entirely by email. Please send an email addressed to insurance@shef.ac.uk and request a copy of the ‘Clinical Trial Insurance Application Form’.

- If you have marked the box** your supervisor, needs to obtain an URMS number

It is recommended that you familiarise yourself with the University’s Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue before completing the following questions. Please note that if you provide sufficient information about the research (what you intend to do, how it will be carried out and how you intend to minimise any risks), this will help the ethics reviewers to make an informed judgement quickly without having to ask for further details.

A5. Briefly summarise:

i. The project’s aims and objectives:
   (this must be in language comprehensible to a lay person)

The aim of this project is to develop methods for evaluating whether web-based information on self-management increases the health literacy of people suffering from chronic pain.

Our evaluation question is: Can use of a web-based resource help people with chronic pain to self-manage their condition?

The objectives of the project are to:

1) Ensure that people with chronic pain are routinely referred to the NHS Sheffield website sheffieldpersistentpain.com by participating physiotherapists and general practices
2) Explore the feasibility of obtaining baseline information on health literacy levels
3) Explore the feasibility and utility of obtaining information on changes in health literacy after using the website, to determine whether people can:
   - Access information that is relevant to their pain-related concerns
   - Understand written, visual and audio information on the website
   - Evaluate whether the information is applicable to their particular situation
   - Apply the information to self-manage their condition

ii. The project’s methodology:
   (this must be in language comprehensible to a lay person)

The project will

1. Monitor referrals to the website by
   a. counting the number of referrals made by physiotherapists and general practitioners; and
   b. counting the number of people referred who access the site
2. Obtain baseline health literacy information by asking people to complete the European Health Literacy Questionnaire (EU-HL-Q) when they are ready to use the website
3. Obtain information on experiences of using the site
   a. from clients who use the Health Trainer Community Chronic Pain Programme, through routine service data
   b. from users of the web site via web-based questionnaires
   c. a subset of clients and users will be interviewed to explore their experiences of using the website
4. Obtain information on changes to health literacy by asking people to complete a follow up EU-HL-Q questionnaire
Participant Information Sheet

A6. What is the potential for physical and/or psychological harm/distress to participants?

There is little potential for physical or psychological harm or distress. Participants are (1) clients who have been referred to a Health Trainer by their GP to obtain support in managing chronic pain; and (2) patients who are receiving treatment for chronic pain from a physiotherapist or GP, but are not referred to the Health Trainer. Information containing the web link will be included in the package of information and resources that is routinely given to clients and patients to promote self-management. We will ask clients and patients to complete the Health Literacy questionnaire, which is not currently used in the service. They may decline to complete the questionnaire. The EU-HL asks participants for the following demographic data: age band; educational level; economic status; social status. We will add a question on computer use (frequent/infrequent). The questionnaire itself asks whether people know how to find health information, and whether they can understand it and use it. There are no questions about personal circumstances on the questionnaire. The questions in the interviews will mirror those that are asked on the questionnaire.

A7. Does your research raise any issues of personal safety for you or other researchers involved in the project? (especially if taking place outside working hours or off University premises)

Chronic pain makes it difficult for people to predict when they will be well enough to participate, or whether they will be mobile enough to get out for an interview. Some participants may therefore wish to be interviewed in their homes, outside working hours, because they suffer from chronic pain.

If yes, explain how these issues will be managed.

The contact details of the participant will be sent to another member of the evaluation team one hour before the interview via email and text. The interviewer will contact the team member when the evaluation is completed and/or within 1.5 hours after the start of the interview. If contact is not made, the team member will try to contact the interviewer’s mobile. If there is no response, the participant will be contacted.

A8. How will the potential participants in the project be:

i. Identified? (please ensure that all practical issues about contacting individuals are covered and that you are not requesting the personal details of individuals be given over without their consent)

Chronic pain patients will be identified by their physiotherapist and/or their general practitioner.

ii. Approached?

Patients will be given the web link for the sheffieldpersistentpain.com site and an information sheet that explains why we want to collect information on Health Literacy. They will be given a copy of the questionnaire to look at. The information sheet will also ask them if they are willing to participate in an interview.

iii. Recruited?

Patients who are referred to the CCPP will be reminded at their first session that they were given an information sheet and a copy of the EU-HL questionnaire. The Health Trainer will explain that we would like to evaluate whether the CCPP service helps people to find and use information to manage their condition. People will be asked if they would like assistance to complete the questionnaire.
Participants who are not referred to the CCPP may choose to access the web site. When they access the site, they will be asked if they would like to complete an online version of the EU-HL questionnaire. If patients decline, they can still access the site.

In the CCPP, Health Trainers will ask clients if they are interested in participating in an interview. The topics that will be covered in the interview will be described on the information sheet. Patients who access the website independently will find a window on the website that asks them if they are interested in participating in an interview. When they click on the window, they will see a copy of the information sheet. Both clients and patients can choose a face to face or telephone interview. GPs and physiotherapists may also ask patients when they next see them if they had a chance to look at the website, and if they are willing to be interviewed.

**A9. Will informed consent be obtained from the participants?**

Yes [x] No [ ]

*If informed consent or consent is NOT to be obtained please explain why.* Further guidance is at: www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/policy-notes/consent

Informed consent will be obtained for the interviews. Consent is not needed, however, for the HL-EU-Q. This is an additional questionnaire that we would like to add to routine service evaluation. We do not ask for informed consent for the other forms that are currently used to evaluate the service.

**A9.1. This question is only applicable if you are planning to obtain informed consent:**

**How do you plan to obtain informed consent? (i.e. the proposed process?):**

The information sheet will ask clients and patients if they are interested in participating. The contact details of the researchers will be on the sheet and they will be invited to make contact if they have questions. Interested participants will sign the consent and give their contact details. The details will be passed by the Health Trainer, GP or physiotherapist to the researchers. The researchers will contact interested people and explain the project in further detail. The participants will then be asked again if they are still interested in participating. Patients who indicate interest after visiting the website will receive the same information online. They will be given an email address to contact if they are interested in receiving more information about the project. The researchers will contact them and ask if they can telephone them to describe the project. The participants will then be asked again if they are still interested in participating.

**A10. What measures will be put in place to ensure confidentiality of personal data, where appropriate?**

(As a minimum please ensure details are included of: how long data will be kept; when and how it will be destroyed; that PCs and other devices are password protected; that personal details are encrypted. This information should also be included on your information sheet).

Names and contact details of interested people will be kept in a secure file on an encrypted computer. Only the research team will have access to the file. After data is collected, each participant will be given an ID number and their personal details will be separated from the ID numbers. As this evaluation aims to assess the feasibility of incorporating web-based resources into self-management, we do not aim to link patient of client data with the HL-EU-Q or interview data. NHS patient data will not be shared with the research team. Personal data for clients is kept by the
Health Trainers on the Department of Health Data Collection and Reporting System. The DCRS is a password protected system, and any data that is extracted from the system is automatically compiled in the form of anonymised reports. Patients who are not referred to the CCPP, and access the website independently, will complete anonymous EU-HL questionnaires. There will be a question at the beginning of the questionnaire asking them if they were referred to the website by their doctor or physiotherapist. No other personal information will be collected.

A11. **Will financial/in kind payments (other than reasonable expenses and compensation for time) be offered to participants?** (Indicate how much and on what basis this has been decided)

No

A12. **Will the research involve the production of recorded media such as audio and/or video recordings?**

NO [x]

A12.1. This question is only applicable if you are planning to produce recorded media:

How will you ensure that there is a clear agreement with participants as to how these recorded media may be stored, used and (if appropriate) destroyed?

Guidance on a range of ethical issues, including safety and well-being, consent and anonymity, confidentiality and data protection are available at:

[www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/policy-notes](http://www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/policy-notes)
Title of Research Project:

Please Stop Informing Me: Enabling people to use internet information to self-manage musculoskeletal pain

I confirm my responsibility to deliver the research project in accordance with the University of Sheffield’s policies and procedures, which include the University’s ‘Financial Regulations’, ‘Good Research Practice Standards’ and the ‘Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue’ (Ethics Policy) and, where externally funded, with the terms and conditions of the research funder.

In signing this research ethics application form I am also confirming that:

- The form is accurate to the best of my knowledge and belief.
- The project will abide by the University’s Ethics Policy.
- There is no potential material interest that may, or may appear to, impair the independence and objectivity of researchers conducting this project.
- Subject to the research being approved, I undertake to adhere to the project protocol without unagreed deviation and to comply with any conditions set out in the letter from the University ethics reviewers notifying me of this.
- I undertake to inform the ethics reviewers of significant changes to the protocol (by contacting my academic department’s Ethics Administrator in the first instance).
- 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 personal data, including the need to register when necessary with the appropriate Data Protection Officer (within the University the Data Protection Officer is based in CiCS).
- I understand that the project, including research records and data, may be subject to inspection for audit purposes, if required in future.
- I understand that personal data about me as a researcher in this form will be held by those involved in the ethics review procedure (e.g. the Ethics Administrator and/or ethics reviewers) and that this will be managed according to Data Protection Act principles.
- If this is an application for a ‘generic’ project, all the individual projects that fit under the generic project are compatible with this application.
- I understand that this project cannot be submitted for ethics approval in more than one department, and that if I wish to appeal against the decision made, this must be done through the original department.

Name of the Supervisor:

Name of the student:

Signature of the Supervisor:

Date:

Email the completed application form and provide a signed, hard copy of ‘Part B’ to the Ethics Administrator (also enclose, if relevant, other documents).
Please Stop Informing Me: Enabling people to use internet information to self-manage musculoskeletal pain

Persistent musculoskeletal pain is pain in the back, shoulders, neck, knees, hips, hands or elbows that lasts longer than 3 months. Nearly 1 in 7 people suffer from persistent pain, and 20% have suffered for more than 20 years.

We have created a website for patients in Sheffield that aims to help you understand what persistent pain is. It offers tips, advice and information to help you self-manage your condition and enjoy a better quality of life. It has been created by people who successfully live with persistent pain, working with healthcare professionals such as physiotherapists, doctors, psychologists and pain specialists.

Now that the website is up and running, we would like to find out whether it helps you to manage your pain. Our evaluation question is: Can use of a web-based resource help people with chronic pain to self-manage their condition?

You are being invited to take part in this evaluation because your GP, your physiotherapist, or your Health Trainer has given you information about how to access the website. In this evaluation, we are asking people to:

1. Complete a questionnaire that gives us information on how much you know about how to manage your overall health
2. Participate in an interview to discuss
   - Whether it is easy or difficult to find information on the website about your pain-related concerns
   - Whether the website has helped you in any way to
     o Learn more about persistent pain
     o Get tips on how to manage your pain
     o Discuss your situation with your Doctor, Physiotherapist, Health Trainer or other people

The information that you give us will be confidential, and your details will not be shared with anyone. You are free to decide whether you wish to participate. Your decision will not affect your care in any way.

The evaluation is funded by The Health Foundation and sponsored by Sloane Medical Centre, Sheffield. If you are interested in participating in an interview, please complete the form and give us your contact details. Your contact details will be passed on to the researcher who is managing the evaluation:

XXXX, University of Sheffield XXX

She will call you to give you more information on the project and answer any questions that you might have. If you are still interested after discussing the project, a time can be set up that is convenient for you to discuss your experiences with the website. This can be done over the telephone, or at a place that is convenient for you – either the general practice or your home. The discussion can take as little as ten minutes or up to an hour – it is up to you.
Participant Information Sheet

We will use the information that you give us to make improvements to the website. Your information will also help us to decide how to use the website as part of routine care in the NHS.

I am interested in finding out more about the evaluation.
Name: __________________________________________________________
Telephone: __________________________ email: __________________________