UNIVERSITY OF LEEDS

smart

self management of analgesia and related treatments

Invitation Letter

We are writing to invite you to participate in a research study. The SMART study is aimed at reducing pain and the side-effects of pain medication experienced by patients with advanced disease living in the community. The Chief Investigator for this study is Professor Michael Bennett who is based at the University of Leeds.

Before you decided if you would like to take part in this study, please would you read the enclosed Information Sheet? With your permission, a member of the research team of the University of Leeds will contact you within the next few days to discuss the study and answer any questions you may have. This information will be kept strictly confidential.

If you would like more information about this study please do not hesitate to contact:
<<RESEARCHER CONTRACT DETAILS>>

Thank you very much for taking the time to read this information.

Yours Sincerely,

Mike Bennett

Michael Bennett
St Gemma's Professor of Palliative Medicine
Leeds Institute of Health Sciences
University of Leeds

UNIVERSITY OF LEEDS

This page is left blank of purpose

UNIVERSITY OF LEEDS

smart

self management of analgesia and related treatments

Patient Information Sheet

A large print version of this sheet is available on request

Invitation to participate in the study

We would like to invite you to take part in the SMART study, funded by the National Institute for Health Research (NIHR). This information sheet tells you the purpose of this study and what your participation would involve. Please take time to read it carefully and talk it over with another person if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Once you have read this information sheet, your Nurse or a member of the Research Team will talk to you about the study again and you can ask any question you like.

How to contact us

If you have any questions about this study, please talk to your Nurse at <<HOSPICE NAME>> (telephone xxxx) or contact a member of the Research Team at:

UNIVERSITY OF LEEDS

<<RESEACH TEAM CONTACT DETAILS>>

Thank you for taking time to read this information sheet.

What is the purpose of this study?

The SMART study is aimed at reducing pain and the side effects of pain medication experienced by patients with advanced disease living at home. To do this we are asking 30 patients to take part in a pain management educational programme for 6 weeks delivered by specialist palliative care nurses working in the community.

Why have I been invited to take part?

You have been given this information sheet as a person who is receiving hospice or specialist nursing services. Clinical staff providing your treatment and care have identified you as somebody who is living at home and may benefit from pain management support alongside the usual care you receive.

Do I have to take part?

It is up to you to decide to take part in the study. If you decide you do not wish to take part, it will not affect the care you receive in any way. If you do decide to take part, we will ask you to sign a consent form. Even if you sign the consent form, you are free to withdraw at any time without giving a reason.

What will happen to me if I agree to take part?

We have designed an educational programme (called the "SMART toolkit") for patients with pain to be used at home in partnership with their specialist nurse. It is designed to help patients increase their understanding of pain and provide skills to help manage pain and the side effects of pain medication more effectively. The SMART toolkit consists of four sections:

1. Identifying problems, fears or concerns about managing pain or opioid medicines
2. Providing information (fact sheets and/or podcast) about managing pain and opioid medicines
3. Setting weekly goals
4. Reviewing goals on a weekly basis

If you decide to take part you will be asked to meet with your specialist nurse once a week for six weeks to work through the SMART toolkit together.

The first time you use the SMART toolkit with your specialist nurse they will work with you to identify any problems or concerns you may have, or that you anticipate having, about managing your pain or about managing the opioid medicines you take. During this discussion your specialist may provide you with some information sheets (called fact sheets) or podcasts about managing your pain and/or opioid medicines. At the end of this first meeting your specialist nurse will work with you to set one or two goals for the week ahead related to managing your pain and/or opioid medicines. This first meeting should take about 30-60minutes, however you can take as much time as you need.

Following this, your specialist nurse will meet with you over the next 5 weeks to see how you are getting on with the goals you have set. These meetings can be done over the telephone if you prefer, although the majority are likely to be face-to-face. At these meetings your specialist nurse may provide you with additional fact sheets and set new goals with you for the week ahead. These meetings should take between 15-30 minutes, however you can take as much time as you need.

If you decide to take part in the study your specialist nurse may talk to you about whether you are happy to audio record your meetings when you use the SMART toolkit. Just under half of the people who are recruited to the study (about 12 people) will be asked to do this. If you are asked to do this, you can say no without giving a reason. This will not stop you from taking part in the rest of the study. The purpose of audio recording these meetings is so we can understand how people are using the SMART toolkit with their specialist nurse. This information will help us to train other nurses to use the SMART toolkit with their patients.

If you are asked about audio recording your meetings with your specialist nurse and you agree to it, the recordings will be typed up anonymously so you will not be identified.

If you agree to take part in this study, information about you will be collected from your medical records for the duration of the study by a local healthcare professional from the community palliative care team. You will also be asked to complete a questionnaire when you

enter the study, at 2 weeks, 4 weeks and 6 weeks after this date. These questionnaires can be completed at home with a Researcher from the University of Leeds or they can arrange to call you and complete them over the phone.

We would also like to invite you take part in an informal interview after you have been using the SMART toolkit for a few weeks to find out how you have found using the SMART toolkit. This interview is optional and you do not have to take part in this bit of the study if you prefer not to. It may be that a spouse/partner/other relative or friend is actively involved in helping you to manage your pain. If this is the case, with your permission we would like to approach that person as well, to ask them to take part in the interview also. This is up to you however; if you do not identify such a person or if you do not wish us to approach such a person for whatever reason, we will not do so and it will not affect your participation in the study. If you do agree for us to approach such a person and they do not wish to participate in the study this will not affect your involvement in the study in any way.

The interview will be more like a conversation than a set of questions with fixed responses. It will last for around 30 minutes to an hour and take place at a time and place that is convenient for you. With your permission, we would like to make an audio recording of the interview. This is because we want to get an accurate account of what is said and the researcher can concentrate on what you say without being distracted by having to take too many notes. The interview will then be typed up and you may have a copy of this if you wish by contacting the research team at the address at the end of this sheet – or directly after the interview. If you do not wish for the interview to be recorded in this way, we will of course respect your wishes and take written notes during the interview instead.

If at any point during the study you no longer wish to continue taking part you can withdraw. You don't have to give any explanation – just that you do not wish to continue participating. If during the interview you feel tired or uneasy in any way you can stop the interview at any time, just let the researcher know. If you wish, it will be possible to continue with the interview after a break, or at a later date.

If you do not wish to continue participating in all or any part of the study the information you have provided up to that point will still make a valuable contribution to the study. If you do decide to stop participating in the study at any point, this will not affect your treatment or support in any way.

How long is the study going on?

The study will last for 6 weeks. Once all our study participants have reached 6 weeks after they entered the study, final data will be collected from your medical records.

What are the disadvantages of taking part?

We do not foresee any disadvantages or risks to you taking part in this study. However you will be asked to give some of your time for taking part. Your routine care will remain the same whether or not you decide to take part.

What are the benefits of taking part?

We hope the information we collect from you will help us improve the care of patients living at home with pain from advanced disease in the future. We hope that patients who take part in this study will benefit from the educational resources that are provided as part of the study.

What happens when the research study stops?

When the study ends the usual care you receive from your specialist nurse will continue. You will be able to keep the SMART toolkit. At the end of the study your specialist nurse will not normally continue using the SMART toolkit with you.

Will my GP be informed of my involvement in the study?

With your permission, your GP, and the other doctors involved in your healthcare, will be kept informed of your participation in this study. Your GP may be contacted at the end of this study for a final collection of data from your medical records.

What will happen to the information we collect from you?

The information we collect from you will be kept confidential and will be handled strictly in accordance with the consent that you have given and also the 1998 Data Protection Act.

UNIVERSITY OF LEEDS

Personal information that contains your name, date of birth and contact details will be kept separate from any of the questionnaires or interview transcripts in a locked filing cabinet at the University of Leeds. Questionnaires, audio files and interview transcripts will have personal identifying information removed and you will be identified with a code number. This information will be kept in a locked filing cabinet and backed up on a password-protected encrypted hard drive. Questionnaires, audio files and transcripts will be seen and heard only by members of the research team.

What if there is a problem?

The Trial Management Group will closely monitor the study on an on-going basis. If there are any problems they will be detected as soon as possible so that the study can be changed or stopped if necessary. If you experience problems, you must report these to your study nurse or doctor.

If you have any concerns about this study, you should contact a member of the research team in the first instance. If you have a problem or concern about the study and you feel that it has not been responded to satisfactorily, you may at any point contact the Patient's Advisory Liaison Service (PALS) at The Patient Experience Team which is part of Harrogate and District NHS Foundation trust. This service is there for patients. You can either ring or email a member of staff at The Patient Experience Team office:

Telephone: [redacted], Email: [redacted]

What will happen if I don't want to carry on with the study?

If you withdraw consent from further study participation, information will still be collected about you and will be included in the final study analysis, unless you request otherwise. If you withdraw consent for further data collection your data collected up to that point will remain on file and will be included in the final study analysis. In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived for a minimum of 5 years. Arrangements for confidential destruction will then be made.

Who has reviewed this study?

UNIVERSITY OF LEEDS

This study has been reviewed by North West - Lancaster Ethics Committee and has been approved by them.

What will happen to the results of the research study?

When the study is complete the results will be published in a medical journal, but no individual participants will be identified. If you would like to obtain a copy of the published results, please contact a member of the research team (contact details and the end of this information sheet).

What happens now?

If there are questions you would like to ask about the study before deciding whether or not to take part please contact <<RESEARCHER NAME>> who is coordinating the study (contact details are below). If you decide you would like to take part in this study, please complete the consent form attached. A member of the research team will contact you by telephone in a few days. If you decide you would like to take part in this study, the researcher will arrange a convenient date and time at a place that suits you to meet with you and complete the first set of questionnaire data. You can keep this information sheet. You will be provided with a photocopy of the signed consent form (if you decide to take part).

Contact details of the research team

<<RESEARCH TEAM CONTACT DETAILS>>

Thank you for taking time to read this information sheet and consider this study. If you would like to discuss the study or require further information please contact me at the address below.

Yours Sincerely,

<< PRINCIPAL INVESTIGATORS NAME, SIGNATURE AND CONTACT ADDRESS>>

UNIVERSITY OF LEEDS

Self-Management of Analgesia and Related Treatments
SMART
Patient Consent Form

	Initial each box
1. I confirm that I have read and understand the information sheet for the above study and have been given a copy to keep. I have had the opportunity to consider the information and ask questions and had these answered satisfactorily. I understand why the research is being done and any risks involved.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without any consequences.	☐
3. I understand that my healthcare records may be looked at by authorised individuals from the study team, regulatory bodies or Sponsor in order to check that the study is being carried out correctly.	☐
4. I understand that all information collected from me for this study will be held securely and in confidence and that my personal details will not appear on any publication of results.	☐
5. I agree to my GP being informed of my participation in the study. I agree to a copy of this Consent Form being sent to my GP.	☐
6. I understand that data collected during the study may be looked at by individuals from regulatory authorities or from Leeds University (the study sponsor), where it is relevant to my taking part in this research. I give permission for these individuals to have access to my study records.	☐
7. I understand that if I decide to withdraw from the study, data already collected would be retained and used in the study.	☐
8. I agree to take part in this study	☐

Please turn over

UNIVERSITY OF LEEDS

The following is optional
If you agree to take part in this study, you do not have to agree to this section

9. I agree to being contact by a member of the study team to ask me if I would like to take part in an interview to tell them how useful I found the study	☐
10. I understand that this interview will be audio recorded and that all transcripts will be anonymised.	☐
11. I agree that the consultations with my specialist nurse will be audio-recorded and that these recordings will be typed up anonymously.	☐

Patient:
Name (in block letters) .....

Signature.....

Date: ...../...../.....

Investigator:
Name (in block letters).....

Signature.....

Date: ...../...../.....

For office use only	
Patient ID:	Initials:
Date of birth:	NHS/Hospital Number:
ISRCTN: 35327119	Principal Investigator:

The original copy of this Consent Form is to be stored in Investigator Site File.
One copy to be given to the patient.
One copy to be sent to the patient's GP.

UNIVERSITY OF LEEDS

smart

self management of analgesia and related treatments

Carer/Relative Information Sheet

A large-print version of this sheet is available on request

Invitation to participate in the study

We would like to invite you to take part in the SMART study, funded by the National Institute for Health Research (NIHR). This information sheet tells you the purpose of this study and what your participation would involve. Please take time to read it carefully and talk it over with another person if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Once you have read this information sheet, the Nurse looking after the person your care for or a member of the Research Team will talk to you about the study again and you can ask any questions you like.

How to contact us

If you have any questions about this study, please talk to the Nurse looking after the person your care for at <<HOSPICE NAME>> (telephone xxxx) or contact a member of the Research Team (contact details are on the next page).

UNIVERSITY OF LEEDS

<<RESEACH TEAM CONTACT DETAILS>>

Thank you for taking time to read this information sheet.

What is the purpose of this study?

The SMART study is aimed at reducing pain and the side effects of pain medication experienced by patients with advanced disease living at home. To do this we are asking 30 patients to take part in a pain management educational programme for 6 weeks delivered by specialists palliative care nurses working in the community. In addition, we also want to understand the views of people who care for someone managing pain from advanced disease at home who has used the SMART toolkit.

Why have I been invited to take part?

The person that you are caring for/close to has consented to take part in this study. We have asked their permission to approach you also to take part in the study.

Do I have to take part?

It is up to you to decide to take part in the study. If you decide you do not wish to take part, it will not affect the treatment the person you care for receives in any way. If you do decide to take part, we will ask you to sign a consent form. Even if you sign the consent form, you are free to withdraw at any time without giving a reason. It should be noted at this point that your participation is subject to the participation of the person you care for. If they decided not to take part this will prevent you from taking part.

What will happen to me if I agree to take part?

If you decide to take part you will be invited to take part in a face-to-face interview with the person you care for and a trained researcher from the University of Leeds. The interview will be more like a conversation than a set of questions with fixed responses. The purpose of the

UNIVERSITY OF LEEDS

interview is to allow you to talk in your own words about how you and the person you care for have found using the SMART toolkit to manage the pain that they experience. The interview will last for around 30 to 60 minutes. It will be arranged at a time and place that is convenient for you and the person you care for.

With your permission, we would like to make an audio recording of the interview with you and the person you care for. This is because we want to get an accurate account of what is said and the researcher can concentrate on what you say without being distracted by having to take too many notes. The interview will then be typed up and you may have a copy of this if you wish by contacting the research team at the address at the end of this sheet – or directly after the interview. If you do not wish for the interview to be recorded in this way, we will of course respect your wishes and take a written note of the interview instead.

If during the interview you or the person you care for feel tired, uneasy in any way or worried, you can stop the interview at any time – you don't have to give any explanation – just that you do not wish to go on. If you wish, it will be possible to continue with the interview after a rest, or at a later date. If you do not wish to continue with the interview the information you have provided up to that point will still make a valuable contribution to the study. If you do decide to stop the interview at any point, this will not affect your relative/friend's treatment or support in any way.

How long is the study going on?

The person you care for has consented to take part in a study lasting for 6 weeks. However, we are only asking you to take part in a one off face-to-face interview lasting approximately 30 to 60 minutes.

What are the disadvantages of taking part?

We do not foresee any disadvantages or risks to you taking part in this interview. However you will be asked to give some of your time for taking part.

UNIVERSITY OF LEEDS

What are the benefits of taking part?

We hope the information we collect from you will help us improve the care of patients living at home with pain from advanced disease in the future.

What happens when the research study stops?

When the study ends the usual care received by the person you care for will continue.

What will happen to the information we collect from you?

Everything that you say will be kept confidential and the information collected about you will be handled strictly in accordance with the consent that you have given and also the 1998 Data Protection Act. Personal information that contains your name and biographical details will be kept separate from interview transcripts in a locked filing cabinet at the University of Leeds. Audio files and interview transcripts will have personal identifying information removed and you will be identified with a code number. This information will be kept in a locked filing cabinet and backed up on a password-protected encrypted hard drive. Audio files and transcripts will be heard and seen only by members of the research team.

What if there is a problem?

The Trial Management Group will closely monitor the study on an on-going basis. If there are any problems they will be detected as soon as possible so that the study can be changed or stopped if necessary.

If you have any concerns about this study, you should contact a member of the research team in the first instance. If you have a problem or concern about the study and you feel that it has not been responded to satisfactorily, you may at any point contact the Patient's Advisory Liaison Service (PALS) at The Patient Experience Team. This service is there for patients. You can either ring or email a member of staff at The Patient Experience Team office:

Telephone: [redacted], Email: [redacted]

UNIVERSITY OF LEEDS

What will happen if I don't want to carry on with the study?

If you withdraw consent for further data collection your data collected up to that point will remain on file and will be included in the final study analysis. In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived for a minimum of 5 years. Arrangements for confidential destruction will then be made.

Who has reviewed this study?

This study has been reviewed by North West - Lancaster Ethics Committee and has been approved by them.

What will happen to the results of the research study?

When the study is complete the results will be published in a medical journal, but no individual participants will be identified. If you would like to obtain a copy of the published results, please ask your doctor or contact a member of the research team.

What happens now?

If there are questions you would like to ask about the study before deciding whether or not to take part please contact your specialists nurse who gave you this information sheet or <<RESEARCHER NAME>> who is coordinating the study (contact details are on the next page). If you decide you would like to take part in this study, please complete the consent form attached. A member of the research team will contact you by telephone in a few days. If you decide you would like to take part in this study, the researcher will arrange a convenient date and time for interview at a place that suits you. You can keep this information sheet. You will be provided with a photocopy of the signed consent form (if you decide to take part).

Contact details of the research team

<<RESEACH TEAM CONTACT DETAILS>>

UNIVERSITY OF LEEDS

Thank you for taking time to read this information sheet and consider this study. If you would like to discuss the study or require further information please contact me at the address below.

Yours Sincerely,

<< PRINCIPAL INVESTIGATORS NAME, SIGNATURE AND CONTACT ADDRESS>>

UNIVERSITY OF LEEDS

Self-Management of Analgesia and Related Treatments
SMART
Relative/Carer Interview Consent Form

	Initial each box
1. I confirm that I have read and understand the information sheet for the above study and have been given a copy to keep. I have had the opportunity to consider the information and ask questions and had these answered satisfactorily. I understand why the research is being done and any risks involved	☐
2. I understand that my participation is voluntary that that I am free to withdraw at any time, without giving any reason and without any consequences	☐
3. I understand that all information collected from me for this study will be held securely and in confidence and that my personal details will not appear on any publication of results	☐
4. I understand that data collected during the study may be looked at by individuals from regulatory authorities or from Leeds University (the study sponsor), where it is relevant to my taking part in this research. I give permission for these individuals to have access to my study records	☐
5. I understand that if I decide to withdraw from the study, identifiable data already collected would be retained and used in the study	☐
6. I understand that this interview will be audio recorded for purposes of data collection and all resulting transcripts will be anonymised	☐
7. I agree to take part in this study	☐

Please turn over

UNIVERSITY OF LEEDS

Carer:
Name (in block letters) .....

Signature.....

Date: ...../...../.....

Investigator:
Name (in block letters).....

Signature.....

Date: ...../...../.....

For office use	
Carer ID:	Initials:
ISRCTN: 35327119	Principal Investigator:

The original copy of this Consent Form is to be stored in Investigator Site File.
One copy to be given to the carer.

UNIVERSITY OF LEEDS

This page is left blank on purpose

UNIVERSITY OF LEEDS

This page is left blank on purpose

UNIVERSITY OF LEEDS

smart
self management of analgesia and related treatments

Health Professionals' Information Sheet

Invitation to participate in the study

We would like to invite you to take part in the SMART study, funded by the National Institute for Health Research (NIHR). This information sheet tells you the purpose of this study and what your participation would involve. Please take time to read it carefully and talk it over with another person if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Once you have read this information sheet, a member of the Research Team will talk to you about the study again and you can ask any questions you like.

How to contact us

If you have any questions about this study, please talk to a member of the Research Team at

<<RESEACH TEAM CONTACT DETAILS>>

Thank you for taking time to read this information sheet.

UNIVERSITY OF LEEDS

What is the purpose of this study?

The SMART study is aimed at reducing pain and the side effects of pain medication experienced by patients with advanced disease living at home. To do this we are asking 30 patients to take part in a pain management educational programme for 6 weeks delivered by specialists palliative care nurses working in the community. We want to understand how useful the specialists nurses delivering the education programme found it. Also, we want to understand if specialists nurses working in research active teams but not themselves delivering the educational programme were aware of it and if this influenced their practice in any way

Why have I been invited to take part?

You have been identified as a healthcare professional (clinical nurse specialist, district nurse, community matron, community nurse specialist) who provides care for patients with advanced disease in the community. You have been involved with delivering the SMART study or are working in a team where your colleagues have.

Do I have to take part?

No. It is up to you to decide. If you do decide to take part, we will ask you to sign a consent form. Even if you sign the consent form, you are free to withdraw at any time without giving a reason.

What will happen to me if I agree to take part?

If you decide to take part a member of the research team will contact you to arrange a time and a place convenient to you to conduct an interview lasting approximately 30 to 60 minutes. With your permission, the interview will be audio-recorded. This is because we want to get an accurate account of what is said and the researcher can concentrate on what is being said without being distracted by having to take too many notes. The interview will then be typed

up and you may have a copy of this if you wish by contacting the research team at the address at the end of this sheet – or directly after the interview. If you do not wish for the interview to be recorded in this way, we will of course respect your wishes and take a written note of the interview instead.

If you agree to take part but during the interview you feel tired, uneasy in any way or concerned, you can choose to stop the interview at any time – you don't have to give any explanation – just that you do not wish to go on.

We would also like to ask for your permission to audio record the consultations you have with one of your patients with whom you use the SMART toolkit. The purpose of this is so we can see how specialist nurses and patients use the SMART toolkit and how this develops over the course of the study. We will use this information to design a training package to coach other non-specialist nurses to use the SMART toolkit with their patients. These recordings will be typed up anonymously so neither you or your patient will be identified from the transcripts. The audio recording and transcripts will only be review by members of the research team.

How long is the study going on?

The study is open from November 2015 to March 2016.

What are the disadvantages of taking part?

We do not foresee any disadvantages or risks to you taking part in this interview. However you will be asked to give some of your time for taking part.

What are the benefits of taking part?

The insight you can provide will help us to evaluate our educational programme and assess the feasibility of conducting a future definitive study. Both of these will help to enhance the

management of pain from advanced disease for patients living in the community. By participating you therefore have the opportunity to potentially help shape the future direction of this area of your professional practice.

What will happen to the information we collect from you?

Everything that you say in either a patient consultation or one-to-one interview with a researcher will be kept confidential. The information collected about you will be handled strictly in accordance with the consent that you have given and also the 1998 Data Protection Act. Personal information that contains your name and biographical details will be kept separate from interview transcripts in a locked filing cabinet at the University of Leeds. Audio files and interview transcripts will have personal identifying information removed and you will be identified with a code number. This information will be kept in a locked filing cabinet and backed up on a password-protected encrypted hard drive. Audio files and transcripts will be heard and seen only by members of the research team.

What if there is a problem?

If you have any concerns about this study, you should contact a member of the research team in the first instance. If you remain unhappy about any part of this project or any activity of a member of the research team and wish to complain formally, you can do this by contacting

<<RESEACH TEAM CONTACT DETAILS>>

Who has reviewed this study?

This study has been reviewed by North West - Lancaster Ethics Committee Ethics Committee and has been approved by them.

UNIVERSITY OF LEEDS

What will happen to the results of the research study?

When the study is complete the results will be published in a medical journal, but no individual participants will be identified. If you would like to obtain a copy of the published results, please contact a member of the research team.

What happens now?

If there are questions you would like to ask about the study before deciding whether or not to take part please contact Dr Matt Mulvey who is coordinating the study (contact details are on the next page). If you decide you would like to take part in this study, please complete the consent form attached. A member of the research team will contact you by telephone in a few days. If you decide you would like to take part in this study, the researcher will arrange a convenient date and time for interview at a place that suits you. You can keep this information sheet. You will be provided with a photocopy of the signed consent form (if you decide to take part).

Thank you for taking time to read this information sheet and consider this study. If you would like to discuss the study or require further information please contact Dr Matthew Mulvey.

Contact details of the research team

<<RESEACH TEAM CONTACT DETAILS>>

Thank you for taking time to read this information sheet and consider this study. If you would like to discuss the study or require further information please contact me at the address below.

Yours Sincerely,

<< PRINCIPAL INVESTIGATORS NAME, SIGNATURE AND CONTACT ADDRESS>>

UNIVERSITY OF LEEDS

Self-Management of Analgesia and Related Treatments
SMART
Health Professional Interview Consent Form

	Initial each box
1. I confirm that I have read and understand the information sheet for the above study and have been given a copy to keep. I have had the opportunity to consider the information and ask questions and had these answered satisfactorily. I understand why the research is being done and any risks involved	☐
2. I understand that my participation is voluntary that that I am free to withdraw at any time, without giving any reason and without any consequences	☐
3. I understand that all information collected from me for this study will be held securely in confidence and that my personal details will not appear on any publication of results	☐
4. I understand that data collected during the study may be looked at by individuals from regulatory authorities or from Leeds University (the study sponsor), where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records	☐
5. I understand that if I decide to withdraw from the study, identifiable data already collected would be retained and used in the study	☐
6. I understand that this interview will be audio recorded for purposes of data collection and all resulting transcripts will be anonymised	☐
7. I agree to take part in this study	☐

The following is optional
If you agree to take part in this study, you do not have to agree to this section

8. I agree to audio recording the consultations with one patient with whom I use the SMART toolkit and that these audio recordings will be anonymously transcribed.	☐

Please turn over

UNIVERSITY OF LEEDS

Health Professional
Name (in block letters) .....

Signature.....

Date: ...../...../.....

Investigator
Name (in block letters).....

Signature.....

Date: ...../...../.....

For office use	
Healthcare Professional ID:	Initials:
ISRCTN: 35327119	Principal Investigator:

The original copy of this Consent Form is to be stored in Investigator Site File.
One copy to be given to the Healthcare Professional.

UNIVERSITY OF LEEDS

This page is left blank of purpose

UNIVERSITY OF LEEDS

This page is left blank of purpose