**Participant Information Sheet for Children and Adolescents (11-15 years) (Version no: Two, date: 16.09.2014)**

Study Title: How does period pain affect children and their families?

Researcher: Polly Langdon.

ERGO and RGO reference number: 12099 (12871 after amendments)

(To be read with a parent/guardian/the study researcher)

Note: Make sure you read this with your parent/ guardian or the researcher for this study.

We are asking whether you would join in a research project to find out the answer to these questions:

1. How does period pain affect a child’s life?

2. How does period pain affect a child’s family?

If you decide to, you can help us to answer question 1 and your mother can help us answer question 2.

Before you decide if you want to join in, it‘s important to understand why the research is being done and what it will involve for you. So please consider this leaflet carefully. Talk to your family, friends, teacher, doctor or nurse if you want to.

There are 2 parts to this information sheet:

**Part 1:** We will describe our research; tell you why it is being done, and what you would do if you decide to join in.

**Part 2:** Go into a little bit more detail about the research

**Part One:**

Why are we doing this research?

We would like to understand how period pain affects children and their families. We would like to know this so that more people can learn about it. This might help doctors and professionals take care of young people with pelvic pain in the future.

Why have I been invited to take part?

You have been invited because you are a young person who experiences period pain. Because you are living with this pain, you (and other girls with period pain) will be able to tell us about it and help us to answer our research question.

Do I have to take part?

 No! It is up to you. We will ask you for your assent (permission) and then ask if you would sign a form. We will give you a copy of this information sheet and your signed form to keep. You are free to stop taking part at any time during the research without giving a reason. If you decide to stop, this will not affect the care you receive.

What will happen to me if I take part?

 If you would like to take part in this study then we would like to arrange one interview with you. The interview will be audio-recorded and transcribed word-for-word by the researcher.

Your interview will last for around 30-60 minutes and will be similar to a conversation. The researcher will ask you some questions about your pain, experiences and how it affects your life.

You and your mum can decide whether you would like the interview to take place at home or the University of Southampton Pain Research Laboratory. The Pain Research Laboratory has a sound proof room where the interviews will take place. Your mum or dad must come with you to the interview but you will be asked if you would like your parent/ guardian to wait in the waiting area which is separated from the interview room by a door with a glass panel, so that you can see your parent/guardian at all times. Travel expenses, of up to £20 per participant, will be compensated. If you decide to do the interview at home, you will be asked where you would like your mum or dad to wait during the interview. Doors of the interview rooms in participants own homes will remain open at all times.

What will I have to do?

 You will be asked to answer as honestly as possible about your experiences and feelings. You will not have to discuss anything that you do not want to.

Also, you won’t have to miss any school because we can conduct the interview outside of school hours.

Is there anything to be worried about if I take part?

 If you feel upset at all during the interview, you can let the researcher know. The researcher will be understanding and ask if you would like to take a break from the interview. If you feel distressed at all or say that you would like to stop, the researcher will stop the recording and the interview. If this happens, your travel expenses will still be compensated and your standard of care will not be affected. The researchers will understand if you would like to stop taking part at any time.

What are the possible benefits to taking part?

We cannot promise that there will be benefits to taking part. We hope that our findings will improve understanding and help to improve care for children with period pain in the future. If you participate, you will be entered into a raffle where the winner will receive a prize worth £20-£30.

 Contact Details:

If you have any questions and would like to contact one of the researchers:

Name of researcher: Polly Langdon

Telephone: 02380 594719

Email: plhj1e12@soton.ac.uk

Thank you for reading this so far, if you are still interested, please go to **part 2**:

**Part 2:**

What if there is a problem?

 If you do not feel comfortable with the way you have been treated in the study, please tell your parent/ guardian or one of the research team. We will try to solve the problem immediately, listen to any complaints and try to resolve it as best we can.

If you would not like to discuss the complaint with a researcher and would like to make a formal complaint then please contact the Chair of the Ethics Committee, Psychology, University of Southampton, Southampton, SO17 1BJ. Phone: +44 (0)23 8059 4663, email slb1n10@soton.ac.uk.

Will anyone else know I’m doing this?

 We will keep your information in confidence. This means we will only tell those who

have a need or right to know. Wherever possible, we will only send out information that

has your name and address removed.

The only time that we won’t be able to keep your information in confidence is if you tell us that you or another child is at risk of harm. If this happens then the appropriate authorities will be contacted (i.e. ChildLine or the NSPCC).

What will happen to the results of the research study?

 If you would like to find out about the findings of our research, you will be able to contact any member of the research team who will be happy to provide you that information or links to the published report. Your parent/guardian will also be able to help you with this.

Who has reviewed the study?

 Before any research goes ahead it has to be checked by a Research Ethics Committee.

They make sure that the research is fair. Your project has been checked by the University of Southampton Research Ethics Committee.

Thank you for reading this – please ask any questions if you need to.

Contact Details:

If you have any questions and would like to contact one of the researchers:

Name of researcher: Polly Langdon

Telephone: 02380 594719

Email: plhj1e12@soton.ac.uk

**Participant Information Sheet for Adolescents (16-18 years) (Version no: Two, date: 16.09.2014)**

Study Title: An Exploration of the Impact of Period-Related Pelvic Pain on the Lives of Young Females and their Families

Researcher: Polly Langdon.

ERGO Study ID and RGO reference number: 12099 (12871 after amendments)

Please read this information carefully before deciding to take part in this research. If you are happy to participate you will be asked to sign a consent form.

Invitation:

We would like to invite you to take part in our research. Before you decide whether you would like to take part or not, we would like you to understand why we are carrying out this research and what your help would involve. A member of our research team is going to go through this information with you and will be happy to answer any questions you might have. Please make sure you take as much time as you need to go through this information and talk to others about it (i.e. your clinician, family, teachers, or peers) if you would like.

In our research, we are interviewing young girls who are experiencing chronic pelvic pain and their mothers.

The first part of this information sheet will explain why we are carrying out this research and what your participation would involve. The second part will go into some more details about the conduct of the study. Please ask us if any of the information is not clear or if you have any other questions.

**Part One**

What is the purpose of the study?

 This study is being conducted to help researchers and health care professionals to better understand how your pain affects your life and your family’s life. We would like to find this out because so far, there is very little understanding about this. By improving how much people know about it, we may, in the future, be able to help improve the quality of care and management for girls who experience this pain and their families.

Why have I been invited?

 You have been invited to help with our research because you experience period pain.

Do I have to take part?

 It is up to you whether or not you take part in this study. Once we have described the study and you have understood all of the information in this sheet, you can tell us whether you would like to take part or not. If you would then we will ask you to sign a consent form. You are free to change your mind at any time in the study, even if you have signed the form. If you do decided that you would not like to take part, or you withdraw your consent, you do not have to give a reason and this will not affect any care you receive for your pain.

What will happen to me if I take part?

 If you consent to take part in this study then we would like to arrange one interview with you. The interview will be audio-recorded and transcribed word-for-word by the researcher.

Your interview will last for around 30-60 minutes and will be similar to a conversation. The researcher will ask you some questions about your pain, experiences and how it affects your life.

You and your mother can decide whether you would like the interview to take place at home or the University of Southampton Pain Research Laboratory. The Pain Research Laboratory has a sound proof room where the interviews will take place. Travel expenses, of up to £20 per participant, will be compensated. You can either come to the interview on your own or with a parent/ guardian.

What will I have to do?

 You will be asked to answer as honestly as possible about your experiences and feelings. If you do not wish to answer anything just let the researcher know. You will not have to discuss anything that you do not want to.

You can decide to have your interview outside of school/work/college hours.

What are the possible disadvantages to taking part?

 If you feel upset at all during the interview, you can let the researcher know. The researcher will be understanding and ask if you would like to take a break from the interview. If you feel distressed at all or say that you would like to stop, the researcher will stop the recording and the interview. If this happens there will be no penalty or consequences to you or your mother. Your travel expenses will still be compensated and your standard of care will not be affected.

What are the possible advantages to taking part?

 We cannot promise that there will be any advantages to taking part in this research. We hope that our findings will improve understanding about paediatric chronic pelvic pain and help to improve management and care in the future. All participants will be entered into a raffle where the winner will receive a prize worth £20-£30.

What if there is a problem?

 Any complaint that you may have about the way that you have been dealt with in the study will be addressed. Detailed information about this is presented in part two.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. Details will be provided in part two.

This completes part one. If the information in part one has interested you and you are considering participation in this research, please read part two before making a decision.

**Part Two:**

What will happen if I do not want to carry on with the study?

 If you decide to withdraw from the study then all of the information that you have provided up until that point will be destroyed.

What if there is a problem?

 If you have any complaints about the study or the way that you have been treated in the study, then you can contact any members of the research team (details at the end of the information sheet) to let them know. The researcher you contact will try to solve the problem immediately. If you would not like to discuss the complaint with a researcher and would like to make a formal complaint then please contact the Chair of the Ethics Committee, Psychology, University of Southampton, Southampton, SO17 1BJ. Phone: +44 (0)23 8059 4663, email slb1n10@soton.ac.uk.

Will my taking part in the study be kept confidential?

 Yes, all information about you will be kept confidential. The information you provide will be safeguarded. The recordings and transcripts will be kept safe on a pass-worded computer. Any names or places (or any other identifying information) will be deleted or replaced with pseudonyms (fake names).

No identifying information will be used in the report.

The only time that confidentiality will be breached is if you tell us that you or another child is at risk of harm. If this happens then the appropriate authorities will be contacted (i.e. ChildLine or the NSPCC).

What will happen to the results of the research study?

 It is possible that the final report will be published. If you would like to be informed of the findings you will be able to contact any member of the research team who will be happy to provide you that information or links to the published report.

Who is funding the research?

 The Economic and Social Research Council (ESRC) are funding this research.

Who has reviewed this study?

 All research in the NHS is looked at by independent group of people, called a

Research Ethics Committee, to protect your interests. This study has been reviewed

and given favourable opinion by University of Southampton Research Ethics Committee.

Further information and contact details:

 If you have any further questions or would like any further details, please contact the primary researcher, Polly Langdon.

Telephone: 02380 594719

Email: plhj1e12@soton.ac.uk

**Participant Information Sheet for Mothers Providing Consent for their Daughter’s Participation (Version no: Two, date: 16.09.2014)**

Study Title: An Exploration of the Impact of Period-Related Pelvic Pain on the Lives of Young Females and their Families

Researcher: Polly Langdon

ERGO Study ID and RGO reference number: 12099 (12871 after amendments)

Please read this information carefully before deciding for your daughter to take part in this research. If you are happy for her to participate, you will be asked to sign a consent form, and your daughter will be asked to sign an assent form.

Invitation:

We would like to invite your daughter to take part in our research. Before you decide whether you would like your daughter to take part or not, we would like you to understand why we are carrying out this research and what her participation would involve. A member of our research team is going to go through this information with you and will be happy to go answer any questions you might have. Please make sure you take as much time as you need to go through this information and talk to others about it (i.e. your family or peers) if you would like.

In our research, we are interviewing children and adolescent girls experiencing chronic pelvic pain and their mothers. We will require your consent for your own participation as well as your daughter’s participation if she is less than 16 years old. This information sheet is relevant to your child’s participation in the research. You will be provided with a separate information sheet that will provide details about your participation.

The first part of this information sheet will explain why we are carrying out this research and what her participation would involve. The second part will go into some more details about the conduct of the study. Please ask us if any of the information is not clear or if you have any other questions.

**Part One**

What is the purpose of the study?

 This study is being conducted to help researchers and health care professionals to better understand how your child’s pain affects yours, your child’s and your family’s lives. We would like to find this out because so far, there is very little understanding about this. By improving how much people know about it, we may, in the future, be able to help improve the quality of care and management for girls experiencing period pain and their families.

Why has my daughter been invited?

 Your child has been invited to help with our research because she is currently experiencing period-related pain.

Does she have to take part?

 It is up to you and your daughter to decide whether or not you would like to take part in this study. Once we have described the study and you have understood all of the information in this sheet, you can tell us whether you would like your child to take part or not. If you would like her to take part, then we will ask you to sign a consent form. You are free to change your mind at any time in the study, even if you have signed the form. If you do decide that you would not like your child to take part, or you withdraw your consent, you do not have to give a reason and this will not affect any standard of care your daughter receives. We will also provide your child with an information sheet for you to read with her, and will ask for her to provide assent. This means that your child can say whether or not she would like to take part in this study.

What will happen to my daughter if she takes part?

 If you consent for your child to take part in this study then we would like to arrange one interview with her. You or another parent/ guardian must accompany your daughter to the interview. The interview will be audio-recorded and transcribed word-for-word by the researcher.

Her interview will last for around 30-60 minutes and will be similar to a conversation. The researcher will ask your daughter questions about her pain, her experiences related to her pain and how it affects her life. If your daughter is under the age of 10, we will begin the interview by asking her is she would like to draw her pain. This will be used as an ice-breaker to start up conversation about her experiences.

You and your daughter can decide whether you would like the interview to take place at home or the University of Southampton Pain Research Laboratory. The Pain Research Laboratory has a sound proof room where the interviews will take place. Your daughter will be asked if she would like her parent/ guardian to wait in the waiting area which is separated from the interview room by a door with a glass panel, so that your child can see her parent/guardian at all times. Younger children will be asked if they would like to have their parent/ guardian present in the interview room for the interview. Travel expenses, of up to £20 per participant, will be compensated for your daughter and yourself. If you decide to have the interview take place in your own home, your daughter will be asked where she would like her parent(s) to wait during the interview. Doors of the interview rooms in participants own homes will remain open at all times.

What will she have to do?

 She will be asked to answer as honestly as possible about her experiences and feelings. If she does not wish to answer anything, she can let the researcher know. She will not have to discuss anything that she does not want to.

What are the possible disadvantages to taking part?

 If your daughter feels upset at all during the interview, she will be informed that she can let the researcher know who will respond sensitively by reassuring the child that their parent or guardian are nearby, reassuring the child that it is OK to feel upset, and by asking if she would like to take a break from the interview. Your daughter will also be reminded that she can withdraw from the research at any time. If she feels distressed at all and indicates that she would like to stop then the researcher will stop the recording and the interview. If this happens there will be no penalty or consequences to you or your child. Your travel expenses will still be compensated and your child’s standard of care will not be affected. You or another parent/ guardian will also be nearby at all times to comfort your child if they feel upset at all.

What are the possible advantages to taking part?

 We cannot promise that there will be any advantages to taking part in this research. We hope that our findings will improve understanding about adolescent period pain and help to improve management and care in the future. All participants will be entered into a raffle where the winner will receive a prize worth approximately £20-£30.

What if there is a problem?

 Any complaint that you may have about the way that your child has been dealt with in the study will be addressed. Detailed information about this is presented in part two.

Will her taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about your daughter will be handled in confidence. Details will be provided in part two.

This completes part one. If the information in part one has interested you and you are considering participation in this research, please read part two before making a decision.

**Part Two:**

What will happen if she doesn’t want to carry on with the study?

 If she decides to withdraw from the study then all of the information that she has provided up until that point will be destroyed.

What if there is a problem?

 If you or your daughter have any complaints about the study or the way that she has been treated in the study, then you can contact any members of the research team (details at the end of the information sheet) to let them know. The researcher you contact will try to solve the problem immediately. If you would not like to discuss the complaint with a researcher and would like to make a formal complaint then please contact the Chair of the Ethics Committee, Psychology, University of Southampton, Southampton, SO17 1BJ. Phone: +44 (0)23 8059 4663, email slb1n10@soton.ac.uk. Your complaint will be taken seriously and addressed accordingly depending on the nature of the complaint.

Will her taking part in the study be kept confidential?

 Yes, all information about your daughter will be kept confidential. The information you provide will be safeguarded. The recordings and transcripts will be kept safe on a pass-worded computer. Any names or places (or any other identifying information) will be deleted or replaced with pseudonyms (fake names).

No identifying information will be used in the report.

The only time that confidentiality will be breached is if your child tells us that she, or another child is at risk of harm. If this happens then the appropriate authorities will be contacted (i.e. ChildLine or the NSPCC).

What will happen to the results of the research study?

 It is possible that the final report will be published. If you or your daughter would like to be informed of the findings you will be able to contact any member of the research team who will be happy to provide you that information or links to the published report.

Who is funding the research?

 The Economic and Social Research Council (ESRC) are funding this research.

Who has reviewed this study?

 All research is looked at by independent group of people, called a

Research Ethics Committee, to protect your interests. This study has been reviewed

and given favourable opinion by the University of Southampton Research Ethics Committee.

Further information and contact details:

 If you have any further questions or would like any further details, please contact the primary researcher, Polly Langdon.

Telephone: 02380 594719

Email: plhj1e12@soton.ac.uk

**CONSENT FORM for Adolescents (16-18 years)(Version no: TWO, date: 16. 09. 2014)**

Study title: Title of Project: An Exploration of the Impact of Period-Related Pelvic Pain on the Lives of Young Females and their Families

Researcher name: Polly Langdon

ERGO and RGO reference number: 12099 (12871 for amendments)

Please initial the box (es) if you agree with the statement(s):

I have read and understood the information sheet (date: 16.09.2014/version no: TWO.) and have had the opportunity to ask questions about the study

I agree to take part in this research project and agree for my data to be used for the purpose of this study

I understand my participation is voluntary and I may withdraw at any time without my legal rights being affected

Name of participant (print name)……………………………………………………

Signature of participant……………………………………………………………..

Date…………………………………………………………………………………

**Assent Form for Children (aged 11-15 years)**

(To be completed by the child and their parent/guardian)

Version: Two, Date: 16.09.2014

Project title: How Does Period Pain Affect Children and their Families?

Name of researcher: Polly Langdon

ERGO and RGO reference number: 12099 (12871 after amendments)

Child (or if unable, parent on their behalf) /young person to circle all they agree with:

Has somebody else explained this project to you? Yes/No

Do you understand what this project is about? Yes/No

Have you asked all the questions you want? Yes/No

Have you had your questions answered in a way you understand? Yes/No

Do you understand it’s OK to stop taking part at any time? Yes/No

Are you happy to take part? Yes/No

If any answers are “no” or you do not want to take part, don’t sign your name!

If you do want to take part, you can write your name below

Your name ……………………………………………………………………………………………………

Date ………………………………………………………………………………………………………………

The adult who explained this project to you needs to sign too:

Print Name …………………………………………………………………………………………………….

Sign ………………………………………………………………………………………………………………...

Date ……………………………………………………………………………………………………………….,,

Thank you for your help!

**CONSENT FORM for Mother’s Providing Consent for their Daughters Participation (Version no: Two, date: 16.09.2014)**

Study title: Title of Project: An Exploration of the Impact of Period-Related Pelvic Pain on the Lives of Young Females and their Families

Researcher name: Polly Langdon

ERGO and RGO reference number: 12099 (12871 after amendments)

Please initial the box (es) if you agree with the statement(s):

I have read and understood the information sheet (Date: 16.09.2014/version no: TWO) and have had the opportunity to ask questions about the study

I agree that my daughter can take part in this research project and agree for my daughter’s data to be used for the purpose of this study

I understand my daughter’s participation is voluntary and she may withdraw at any time without her legal rights being affected

Name of child/ adolescent participant (print name)……………………………………………………

Name of parent/guardian providing consent (print name)……………………………………………

Signature ……………………………………………………………..

Date……………………………………………………………………