**LSIP [Lynch Syndrome Identification Project] Patient Information Leaflet**

**Study Title: Primary Care Lynch Syndrome Patient Identification Project**

I would like to invite you to take part in a research study. Before you decide if you would like to take part, please take time to read the information, and discuss it with others if you wish, to enable you to understand why this research is being done and what it will involve for you. This should take about 5 minutes. Talk to others about the study if you wish. Please ask if there is anything that is not clear. This project is being undertaken as part of an educational project.

1. What is the purpose of the study?

The purpose of this project is to identify patients who have Lynch Syndrome but are undiagnosed. Lynch syndrome is an inherited condition which significantly increases the chances of developing a cancer.

The condition runs in families and so we can look for people who may be at higher risk of having this by finding out about their family history, and investigating further if appropriate.

Patients with Lynch syndrome can be prescribed medications to reduce their risk of getting cancer and they can have regular checks to look for early cancers that may not have caused any symptoms. Through these measures we can reduce the chance of developing a cancer and improve cancer survival by diagnosing cancers at an earlier stage.

1. Why have I been invited

You have self identified as having a history which would put you in the higher risk category for having Lynch Syndrome and so we are offering you investigations to look at this further.

3. What will happen to me if I take part?

We will have a short conversation to take a more detailed family history, if we think you are at high risk we will refer you to the specialist Genetics team in Newcastle for further investigations. From this point you will be in the normal care system for patients who are being tested for genetic conditions. You will be contacted thereafter by the genetic clinic and we will follow-up the outcomes.

We will also screen you for any current symptoms which may warrant investigation, and refer you to a GP working in the study to discuss these further.

4. Do I have to take part?

It is up to you to decide to join the study. You do not have to take part. If you agree to take part, I will ask you to sign a consent form, a copy of which you will be given to keep. You are free to change your mind and withdraw from the study at any time and do not have to give a reason. Deciding not to take part, or withdrawing from the study, will not affect your current or future medical care in any way. If you decide to withdraw, we will use the data we have collected up to the point of withdrawal.

5. What are the potential disadvantages and risks of taking part in this study?

There are no anticipated physical risks or side effects from the project however there could be potential anxiety associated with a project which increases awareness of an illness which affects yourself or your family. Any anxiety will be reviewed on discussion and follow-up in primary care or with genetic counselling can be made as appropriate.

6. What are the possible benefits of taking part?

*For you*

The diagnosis of previously undiagnosed Lynch Syndrome will mean you are eligible for treatment which will significantly lower the chance of subsequently developing colon cancer, it will also mean you are enrolled in a colonoscopy surveillance program aimed at diagnosing colon cancers at an early curable stage. Additionally we hope that the diagnosis will result in you presenting to the GP at an earlier stage after the onset of any concerning features.

*For your family*

Aware of an index case of Lynch Syndrome within the family will allow other members to be offered testing .

7. What if there is a problem?

If you have any concern or complaint about any aspect of this study you should contact us by phone and ask to speak to the researcher who will do their best to answer your questions. The researcher can be contacted on 01912418607 (office hours). For further independent advice you can contact the patient advice and liaison service on 08000320202.

8. 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. All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you will have your name and contact details removed so that you cannot be recognised. The researche team may contact your direct care team should any issues be identified that are important for your wellbeing and safety. In the event of disclosure of confidential information, confidentiality will be broken if any of the following are identified; malpractice of staff, evidence of harm to participants/service users, incidents relevant to the criminal justice system, adverse effects on wellbeing and health. We will inform your general practitioner that you are taking part in this research.

9. What will happen to the results of the research study?

We will publish the results of the study in scientific journals and present the findings at meetings. No personal information will be identifiable in any report, paper or presentation.

10. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC). This study has been reviewed and approved by Wales REC7, who ensure that you are protected in terms of your health and your rights. This study has also been reviewed by the Health Research Authority and Northumbria Healthcare NHS Foundation Trust is the sponsor for this study.

11. How will we use information about you?

We will need to use information from you and your medical records for this research project. This information will include your name, NHS number and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. All the information that you provide during this research will be securely stored in locked files and a secure computer database. The answers you provide will be kept separate from your personal information (such as your name and contact details) and will only be identified by a unique code number. No individually identifiable information will be stored outside the main research team. No individual will be identified or identifiable in any publication arising from the research. We will keep all information about you safe and secure. Identifiable research data generated as part of the study will be stored securely for 5 years following conclusion of the study. The rest of this section gives more detail on how your information will be used during the study.

Your rights to access change or move your information are limited, as we need to manage the information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we already have obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Northumbria Healthcare NHS Foundation Trust will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Northumbria Healthcare NHS Foundation Trust may look at your medical and research records to check the accuracy of the research study. The only people in Northumbria Healthcare NHS Foundation Trust who will have access to information that identifies you will be people who need to contact you about taking part in the study to or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

12. What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.

13. Where can you find out more about how your information is used?

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/ or by asking one of the research team whose details are located below. For further independent information about being involved in a research study, please contact the Patient Advice and Liaison Service on telephone number 0800 032 02 02. You may also contact our data protection officer Tracey Best 0344 811 8111.

Contact for Further Information

Researcher: Donna Job: 0191 2418607