We would like to invite your child to take part in the ‘Childhood cancer diagnosis’ study. Before you decide, we would like you to understand why the research is being done and what it would involve for you and your child. One of our research team will go through the information sheet with you and answer any questions you have. Please take time to read the following information carefully and discuss it with family members, friends or health professionals if you wish to.

We encourage you to 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 for your child to take part. You are welcome to keep this leaflet. Thank you for reading this.
What is the purpose of the study?

We would like to understand the journey that children and young people experience, from the start of their symptoms until they receive their diagnosis of cancer.

In order to do this, we want to know what symptoms they experience, who they go to see with these symptoms initially and how long it takes before the diagnosis is reached.

Why has my child been invited to take part?

Your child has been invited to take part because they have a new diagnosis of a childhood cancer. We are inviting all children and young people in the United Kingdom with a new diagnosis of cancer to take part. This provides an opportunity for us to understand which symptoms children experience, what are the most common routes to get to their diagnosis (e.g. A&E or GP) and the time it takes from first symptoms to being seen by the oncology team.

Does my child have to take part?

It is up to you and your child to decide whether or not to take part. If you do decide that your child can take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide for your child to take part you can still change your mind at any time and without giving a reason, if you wish. Whatever you decide, it will not affect the course of treatment recommended for your child by their doctor.

What will happen if I choose for my child to take part?

Neither you nor your child need to do anything. The study involves us using the answers to questions you have already answered when you first
met your child’s oncology team. These questions are routinely asked to all children and families at this time and your team have already noted down the answers on a form for us.

If you choose to take part in this study, the form will passed on to the research team and will be looked at by researchers trained in statistics to understand if there are any patterns in the symptoms, the routes and lengths to diagnosis. We will also compare the data across different cancer types, age groups and geographical region.

Your child’s clinical care will not be affected by taking part in this study.

What are the benefits of taking part?

There are no direct benefits for you or your child in taking part in the study. However, the information we get from this study will help us to identify any areas where the pathway to diagnosis of cancer can be improved. Any change made as a result of this information will hopefully improve other children and young peoples’ experiences of diagnosis in the future.

What are the possible disadvantages and risks of taking part?

There are no specific risks or disadvantages from taking part in this study.

What happens when the research study stops?

The results of this study will be written up as a part of one of the researchers’ PhD and submitted for publication in peer reviewed scientific journals to form an evidence base for healthcare professionals nationally and internationally. Your child will not be identified in any report or publication. It is hoped that the results will be used to guide further research and policies to improve the journey to diagnosis for children.
and young people with cancer in the future. All published results of this study will be available for you to view on the Children’s Cancer and Leukaemia Group (CCLG) website (www.cclg.org.uk).

What if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions. The research team’s contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting the hospital PALS team.

Will my child’s taking part in this study be kept confidential?

Yes. We will follow ethical and legal practice and all information about your child will be handled in confidence.

If you decide to take part in the study, we will use information collected from your child’s medical records during the course of the research. This information will be kept strictly confidential stored in a secure and locked office and on a password protected database.

Under UK Data Protection laws, the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of the study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your child’s information and using it properly. Your right to access, change or move your child’s information is limited as we need to manage your child’s information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your child’s rights, we will use the minimum personally-identifiable information possible.
You can find out more about how we use your information and read our privacy notice at www.nottingham.ac.uk/utilities/privacy.aspx

The data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty to confidentiality to your child as a research participant and we will do our best to meet this duty.

Where possible, information about your child which leaves the hospital will have your child’s name and address removed (anonymised) and a unique code will be used so that your child cannot be recognised from it, however sometimes we need to ensure that we can recognise you to link the research data with your child’s medical records so in these instances we will need to know your name and date of birth.

Your child’s personal data (address, telephone number) will be kept for 5 years after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies (unless you advise us that you do not want to be contacted). All research data will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain confidentiality, only members of the research team will have access to your personal data.

In accordance with the University of Nottingham’s, the Government’s and our funders’ policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to

allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that your child could not be identified) but if we need to share identifiable information we will seek your consent and ensure it is secure.

Although what you say to us is confidential, should you disclose anything to us which we feels puts you, your child or anyone else at risk, we may feel it necessary to report this to the appropriate persons.

**What will happen if my child does not want to carry on with the study, or if I want my child not to carry on with the study?**

Your agreement for your child to participate is voluntary and you are free to withdraw your child at any time, without giving any reason, and without your legal rights being affected. If you decide you no longer want your child to take part in the study, we will no longer collect any information about your child from you or the medical records but we will keep the information about your child that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your child’s rights, we will use the minimum personally-identifiable information possible.

**Involvement of your child’s General Practitioner (GP)**

The paediatric oncologist or haematologist involved in your child’s care will be aware of your child’s participation in the study. We will not routinely inform your general practitioner as this study only requires collection of data from your child’s consultation with the paediatric oncology team.
Who is organising and funding the research?

The study is being organised by researchers at the University of Nottingham, together with the Children’s Cancer and Leukaemia Group (CCLG). The study is funded by The National Institute of Health Research (NIHR).

Who has reviewed the study?

This study has been reviewed and given favourable opinion by Yorkshire & The Humber - Leeds West Research Ethics Committee.

Contact for Further Information

If you would like to discuss the study further or would like more information, please feel free to contact us by email:

Dr Shaarna Shanmugavadivel
Children’s Brain Tumour Research Centre, University of Nottingham, Queen’s Medical Centre, Nottingham NG7 2UH
Email: CCDstudy@nottingham.ac.uk

General information and useful links regarding participation in clinical research is provided by the People in Research website: www.peopleinresearch.org/?o=1192