THE CHILDHOOD CANCER DIAGNOSIS STUDY
Understanding the pathway to diagnosis

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We would like to invite you 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. One of our research team members 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 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 have I been invited to take part?**

You have been invited to take part because you 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 means we can start to understand what symptoms young people have, how they get their diagnosis (e.g. GP or A&E) and the time it takes from first symptoms to seeing the oncology team.

**Do I have to take part?**

It is completely up to you to decide whether or not to take part. If you do decide that you would like to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide you would like 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 by your doctor.

**What will happen if I choose to take part?**

You do not need to do anything if you decide to take part. The study involves us using the answers to questions you have already answered when you first met your oncology doctors. These questions are routinely asked to all young people at this time and your doctors have already noted down the answers on a form for us.

If you choose to take part in this study, the form will be passed on to us (the research team) and will be looked at by trained researchers to see 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.

What are the benefits of taking part?
There are no direct benefits for you 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. You 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 Belfast Health and Social Care Trust Complaints Department.

**Will me taking part in this study be kept confidential?**

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

If you decide to take part in the study, we will use information collected from your 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 information and using it properly. Your right to access, change or move your information is limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your 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](http://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 you as a research participant and we will do our best to meet this duty.

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

Your 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 you 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 feel puts you or anyone else at risk, we may feel it necessary to report this to the appropriate persons.

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

Your agreement to participate is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you decide you no longer want to take part in the study, we will no longer collect any information about you, from you or the medical records but we will keep the information about you 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 rights, we will use the minimum personally-identifiable information possible.

**Involvement of your General Practitioner (GP)**

The paediatric oncologist or haematologist involved in your care will be aware of your participation in the study. We will not routinely inform your general practitioner as this study only requires a collection of data from your 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 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:

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