**PARTICIPANT INFORMATION LEAFLET FOR PARENTS/GUARDIANS**

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| **Study Title:** | “Molecular and Genomic Interrogation of Childhood Cancer – Ireland “ (MAGIC-I)  |
| **Participant Name:** |  |

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 Children’s Health Ireland at Crumlin

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 National Children’s Research Centre

1. **Introductory statement:**

Your child is being invited to take part in a research study. Please read this information carefully. It describes the purpose, procedures, benefits and risks of the study. It also describes your child’s right to withdraw from the study at any time. If this form contains any words that you do not understand, you should ask your study doctor or a member of the study team to explain it to you.

You can take this information sheet home with you to review the information with others before coming to a decision. If, after all your questions have been answered, you decide to take part in the study, you will need to sign a consent form (or sign on behalf of your child).

You will receive a copy of this information sheet and a copy of the signed consent form. If you have any questions or would like more information about the research study, please ask the research coordinator/team at Children’s Health Ireland (CHI), Crumlin.

1. **What is purpose of this study?**

This research is about improving the diagnosis and treatment of cancers in children and adolescents. For the purposes of this information leaflet, the term ‘childhood cancer’ will be used to describe cancers affecting infants, children and adolescents. Childhood cancers can occur anywhere in the body and include haematological cancers (e.g., leukaemias, lymphomas), cancers affecting solid organs, and cancers affecting the central nervous system. All cancers have genetic changes (known as variants) that help cancer cells grow. Alterations in genes can affect the function of proteins and metabolites in cells. We do not fully understand whether and how all these changes contribute to the unrestricted growth of cancer cells.

**2.1** The purpose of this study is twofold. It has a clinical diagnostic purpose, which is to try to identify genetic change(s) in your child’s cancer that may help the cancer grow. This information may be used by your child’s clinical team to adjust the treatment for your child’s cancer, where they believe it would be appropriate.

**2.2** As a second purpose, and on a research basis, we want to measure and study genetic changes and changes in proteins and metabolites in cancer cells. We will then try to combine and understand all this information using computer models that we hope will eventually simulate the behaviour of cancers in individual patients. This part of the study is very unlikely to have any direct impact on your child’s treatment.

1. **How will the study work?**

In order to obtain this detailed information about your child’s cancer, we will need to analyse cancer tissue and compare the cancer tissue with normal tissue. Dependent on the type of cancer your child has, these tissue samples may comprise blood samples, bone marrow samples, and/or tumour samples. We will analyse portions of blood samples and/or bone marrow samples and/or tumour tissue samples taken during routine diagnostic testing. No extra procedures are required. Because these samples are precious, we have combined these two purposes into one study, so that we can utilise the same samples to support both clinical improvements and research into novel ways for diagnosing, classifying, and treating childhood cancers.

**3.1. Who is conducting the study?**

The study is being organised by your child’s clinical team at Children’s Health Ireland (CHI) in conjunction with researchers based at University College Dublin (UCD). Because of the novel technologies and specialist expertise required, the study will be carried out by a multi-disciplinary team.

All clinical care and all treatment decisions will be carried out by the clinical team at CHI. A team of experts will be assembled at CHI to discuss all diagnostic findings and to advise on any additional analyses that may inform and/or complement treatment options available to your child.

As genetic analysis of biological samples is complex, the research team will hire a company who specialise in handling biological samples for genetic analysis to assist with this study. Analysis of all genetic data generated will be carried out at UCD. The analysis of proteins (proteomics) and metabolites (metabolomics), and the construction of computational models will also be carried out at UCD.

**3.2. What will the study look at?**

This study will look at your child’s cancer samples (blood and/or bone marrow and/or tumour tissue) which contain genetic material (DNA and RNA), proteins and metabolites. In order to decide what is normal and what is cancer-specific, we typically will need to compare cancer samples to samples from normal tissues. The normal tissue can be obtained from blood samples, taken alongside routine blood samples needed as part of your child’s care so that no extra procedures will be required.

**3.3. What types of analysis will be performed?**

This study will involve genomic analysis of your child’s cancer and normal biological samples. In simple terms, genomic analysis aims to understand how genes function and interact with each other and with the environment, and how changes in genes influence health and wellbeing and contribute to the development of disease.

Genomic analysis is complex and can involve many different scientific techniques. This study will analyse genetic material known as DNA and another type of genetic material called RNA – this type of testing is often referred to as “genetic sequencing”. Genetic sequencing can identify changes or variants within genes that mean that the gene doesn’t work normally, contributing to cancer development. The identification of certain gene variants may allow your clinical team to refine your child’s diagnosis and/or may provide your clinical team with additional information in relation to potential therapeutic options that may complement your child’s cancer treatment.

This study will also analyse proteins and metabolites (building blocks within cells) to try to understand how cancers grow and develop – this type of testing is known as ‘proteomics’ and ‘metabolomics’. Computer models will then be utilised to analyse and interpret the complex data generated from this type of testing. These computer models will also aim to simulate each individual cancer, its biological behaviour and to analyse why and how each cancer responds to or becomes resistant to treatment over time – this testing is referred to as ‘digital twin’ technology.

1. **Why are we doing this research?**

**4.1** We hope to explore the genetic changes that contribute to the development and growth of childhood cancers. Any new information generated could potentially help us to refine the classification of cancer and provide a better understanding of the genetic drivers of disease, thereby adding to the diagnostic tools the clinical team has to thoroughly evaluate your child’s cancer.

**4.2** For some of these genetic changes there may be specific therapies available, that may be considered for use by your clinical team to complement standard of care therapies. In the clinical, diagnostic part of the study we will evaluate whether and how this genetic information improves the diagnosis and treatment of childhood cancers.

**4.3** In the research part of the study, we will test whether adding information about proteins and metabolites and using computational ‘digital twin’ models of the cancer will further enhance diagnosis and treatment of childhood cancers. The results of this research are experimental in nature and are highly unlikely to change your child’s treatment, but they may change the diagnosis and treatment of childhood cancers in the future.

1. **Who is being invited to take part in this study?**

All children and teenagers who are suspected or are known to have cancer based on their symptoms and test results to date are being invited to take part in this study.

1. **What will happen if I /my child takes part in this research study?**

All children and teenagers attending CHI who are suspected of having cancer, those newly diagnosed with cancer, or those with a new relapse of their existing cancer will be invited to take part in this study. You will be given time to think this over and to ask questions.

**6.1** If you agree to take part, you will be asked to sign a consent form for your child to allow your clinical team to:

* + 1. Take a portion of the diagnostic sample of tumour tissue and/or blood and/or bone marrow from your child at the time of standard diagnostic clinical tests and procedures and facilitate transfer of these samples for additional genomic analysis.
		2. Allow a member of the clinical research team at CHI to review your child’s clinical records, in the strictest confidence, to collect relevant information for the study.

**6.2.** Important information for study participants:

**6.2.1.** Your child does not have to take part in this study, and it is up to you to decide whether or not your child wants to participate.

**6.2.2.** Your child will receive exactly the same standard treatment whether you participate in this study or not. Some study participants may have additional treatment options available to them, where deemed appropriate by their clinical team, if a particular genetic change is detected for which a specific treatment is available.

**6.2.3.** This study **WILL NOT** require your child to have any additional procedures or visits to hospital other than those that are normally required for diagnostic purposes or as part of routine care and follow-up. We hope to achieve our aims by analysing portions of blood samples and/or bone marrow samples and/or tumour tissue samples (taken during routine diagnostic testing) and by reviewing the clinical notes.

**6.2.4.** During the study, your child’s clinical data will be stored securely at CHI, and genomic data will be stored securely at University College Dublin.

**6.2.5.** Biological samples will be labelled only with you/your child’s study ID number. No personal information will accompany biological samples such that individuals external to CHI will not be able to identify your child.

**6.2.6.** Your child’s personal health information will be pseudonymised. A unique study number or ‘code’ will be used for all study-related samples. Thus, the researchers analysing biological samples and producing the computational models will not know your child’s identity. However, your doctor will have the ability to link your child’s medical record to the study number, allowing them to contact you if required.

1. **How will biological samples and data be used?**

If you agree to participate in this study, the study team will access you/your child’s medical records at CHI. They will also collect and be responsible for you/your child’s study data and for coordinating the analysis of all biological samples. They will control access to any study records at the study site, including consent forms and documentation, generated from this study. If you have any questions about how the hospital keeps data safe and confidential, please ask your study doctor or his/her team.

1. **Protecting your child’s data and clinical samples**

During the study, your child’s pseudonymised biological samples will be safely stored and pseudonymised at CHI.

* + 1. The pseudonymisation is intended to protect your child’s identity by assigning random study ID numbers to biological samples.
		2. Personal identifiers, (e.g. name, date of birth, address) are never used to label samples.
		3. Only your child’s doctor and the study team have access to personal identifiers such as name and date of birth, and the ‘code’ to match the pseudonymised samples back to a patient. They keep this information so they can let you know the results of the research or to facilitate a request from you to withdraw your child from the study. These personal identifiers will never leave the study site at CHI.
		4. All data handled by and stored by UCD are pseudonymised. After pseudonymisation at CHI, the biological samples are shipped to UCD for analysis.
		5. The genomic analysis will be performed by a third-party company that will be employed to do the work. A legal agreement will be put in place between CHI-UCD and this company before they are sent any samples belonging to your child. This agreement will ensure that once the work is done the company will destroy all data/leftover samples belonging to your child.
		6. UCD will perform the analysis of the proteins and metabolites using the Core Technologies of the UCD Conway Institute of Biomolecular and Biomedical Research in Dublin. These data will only be used for research purposes and therefore do not require to be analysed in an accredited laboratory.
		7. UCD will also perform a detailed analysis of the results of the genomic sequencing data, the integration of the genomic data with the protein and metabolite data, and will construct the Digital Twin computer models.
		8. Any samples remaining after analysis must be stored to allow confirmation of any research results. Biological samples will be stored for 10 years, and then destroyed. This is in line with UCD policy and with international guidelines pertaining to biomedical research.
		9. CHI will receive the results from UCD so that they can be matched to the clinical history and treatment response. This matching is done using pseudonymised data for research purposes.
		10. If the genomic data reveals a change that can potentially lead to a change in diagnosis or treatment, your doctor will match the data to your child in order to enable clinical consideration of the findings.

**9. Sharing of data and results**

An important part of medical research is to share data and results so that other researchers, clinicians and their patients can benefit from new findings. The international medical research and clinical communities share such data according to long- and well-established rules that protect the personal information of the patient and communicate important findings to colleagues.

The main forums for sharing such data and findings are:

* scientific articles published in peer reviewed scientific/medical journals and books
* presentations at scientific/medical conferences
* scientific/medical databases that allow other qualified researchers and clinicians to examine the data on which findings are based, and also use the data to derive new findings. This is especially important for understanding genomics data.

**9.1 European Genome-Phenome Archive (EGA)**

The following section of the study is entirely optional. Your child can still be involved in the rest of this research study even if you decide you would prefer not to be involved in the following section.

The EGA is a European Union infrastructure service for the permanent archiving and sharing of data that have resulted from biomedical research projects where data are involved which potentially could lead to the identification of a person. The EGA accepts pseudonymised data only and never holds personal data that are directly identifiable. The EGA also allows the controlled sharing of data, so that other researchers can re-analyse and re-use the data. The EGA has no commercial interests and is a not-for-profit service. Data will never be shared without permission.

To ensure that data sharing through this research initiative is in keeping with EU standards, and with patient consent, we will deposit pseudonymized genomic data in the European Genome-Phenome Archive (EGA, <https://ega-archive.org/>). Specifically, we will deposit the following pseudonymised data: age, sex, diagnosis, treatment, response to treatment, side effects from therapy, and molecular data.

To ensure access control to data deposited in the EGA, the data submitters, in this case the study leaders CHI and UCD, will set up a Data Access Committee (DAC). DAC members will comprise authorized members of the CHI and UCD study teams and/or experts nominated by them in case a study team member becomes unavailable. The EGA is merely a secure repository and has no say of what happens to the data. Once the data are deposited at the EGA, all local copies of the deposited data will be destroyed.

The research team in University College Dublin are also creating a website that will be updated regularly with information about all of the research projects that will access this data. The website can be found here: www.ucd.ie/sbi/magic-i

If you decide that you would prefer that your child does not participate in this section, genomics data will not be submitted to the EGA but stored by UCD instead for 10 years. This storage is necessary to comply with UCD research data policy which requires that raw data are stored for 10 years in case that there are any queries about findings that need re-confirmation.

**9.2 Receiving information on potential underlying cancer predisposition variants**

Genome sequencing performed through this research initiative will generates lots of genetic data. It is possible that through this initiative, a genetic change in a cancer predisposing gene may be detected that explains why your child has developed cancer. If a genetic change in a cancer predisposing gene is detected, it may have additional implications for you / your family. In this case, your child’s clinical team may wish to discuss this finding with you and proceed to further investigate the finding in collaboration with the clinical genetics team at CHI. This would likely involve genetic evaluation/genetic counselling and confirming the genetic finding in an accredited testing laboratory. If a cancer predisposing variant were to be confirmed, your child/additional family members may be eligible for additional health surveillance.

As this is an important situation to consider, we want to give you the option of deciding whether you would like to be informed about results of this nature. Some families may wish to opt out of this section, thereby choosing to decline receiving such genetic information, while other families may wish to receive any/all information pertaining to genetic findings that may be relevant for them.

Genetic information related to non-cancer related health conditions will not be analysed in this study.

**10. Do we have to take part in this study?**

No. It is up to you to decide whether or not your child wishes to take part.

Your child’s current medical treatment will not be affected, whether you decide to take part or not, and participation in this study is voluntary.

**11. What if I/we want to withdraw from this study?**

**Your child’s participation in this study is completely voluntary.**

**Your child’s current medical treatment will not be affected if you decide not to participate.**

**If you choose not to participate, you have no obligation to justify why you have made this decision.**

Your child can withdraw from this study at any time, on your request, or at the request of your child, if they have capacity to make this decision. If your child turns 18 during the study (including the period of data retention afterwards), the research team will contact him/her/them to ask if they wish to continue in the study and we will need to complete the consent process with them again. They may also choose to withdraw at any time in the future.

If your child withdraws from the study, their biological samples will be destroyed, and their genomic and clinical data will be deleted from all databases. Please note that data cannot be withdrawn from research already completed, or from published results and findings. Your child’s consent form will be retained for legal, regulatory and audit purposes. If your child chooses to withdraw from the study, you can request that all data we have collected to that point is deleted, and their samples destroyed. Please note that if data has been anonymised or combined will other people’s data it will not be possible to fully delete it from the study, as we will have no way to trace all the information directly back to your child.

Should you wish to raise a query or make a complaint about compliance, please contact the CHI study team.

Participants have the right to contact Ireland’s data protection authority, the Data Protection Commission, if you have any concerns about the use of personal data by CHI at Crumlin or University College Dublin. Please consult www.dataprotection.ie for appropriate contact details.

The CHI and UCD ethical review boards have reviewed this study and can be contacted if there are any concerns.

**12. What happens if we do not agree to take part?**

Nothing. Your child’s standard of care treatments will not be affected if you decide not to take part.

1. **What are the benefits of taking part in this research study?**

The purpose of this study is twofold. It has a clinical diagnostic purpose, which is to identify the genetic change(s) in your child’s cancer, that may help the cancer grow. This information may be used by the clinical care team to adjust the treatment for your child’s cancer, where appropriate. There is no guarantee that treatment will be adjusted – this may only be possible in a minority of patients. There is also no guarantee that if treatment is adjusted that your child will benefit from this. Studies in adult cancers have shown that application of genomics data improves outcomes, but we do not have enough data on childhood cancers to ascertain a benefit. This is one of the reasons we are doing this study.

In the research arm, we will construct Digital Twins, which are computer models that allow us to simulate your child’s cancer on the computer, predict its development and test different treatments on the computer model. This is an experimental and ambitious undertaking that is unlikely to benefit your child directly. However, developing the Digital Twins models alongside a real world treatment situation will give researchers a unique opportunity to make these models fit for eventual clinical use.

1. **What are the risks of taking part in this research study?**

Your child will receive standard of care treatment, and no additional interventions or procedures are necessary for study participants. Therefore, no additional harms will arise through participation in this study.

Study samples will be taken at the same time as other diagnostic samples – tumour tissue, blood and/or bone marrow. Samples will only be taken by trained staff such as a doctor or nurse who are experienced in drawing blood or aspirating bone marrow. Tumour tissue will be removed during planned surgeries or diagnostic biopsies.

To minimise any risk of patient identification from the data collected from your child in this study, biological samples, health and clinical data will be pseudonymized, i.e. coded, before it leaves CHI. This means that your child’s data will be assigned a random study number that can only be associated with your child’s name by your study doctor and the research team at CHI. Your child’s name, address and date of birth are stored at the CHI study site and will never be made available to anyone accessing the data through UCD or EGA.

The findings from this research may appear in published scientific articles. For very rare diseases, it may be possible to identify your child by their diagnosis. The study team will make every reasonable effort to ensure that your child are not identifiable from any research reports or publications arising from this study. To minimise this risk, your child’s name, date of birth, address will never be included in these publications.

Finally, as your child’s genetic information is unique to your child, and rare genetic variants may be uncovered, there is a small risk that an individual may be re-identified by their genetic data. To minimise any risks of this happening, final genome sequences will only be available to the research team, and therefore will not be known to anyone outside of the research team.

1. **How will you find out what happens with this project?**

Your child’s clinical team will tell you about any findings that may refine your child’s diagnosis or inform treatment options for your child’s cancer. The findings from this research may appear in published scientific papers, poster or slide presentations at scientific conferences, scientific books. Occasionally, we may inform the public about findings from this study via press releases, social media or blogs. These communications will only provide general updates of the study and will never mention names of patients or any specifics that may lead to the identification of individual patients.

1. **How long will the study last?**

This study will recruit patients for 5 years, but the analysis of research data may continue for up to 2 years after that.

1. **What happens if my child turns 18 during the period where their personal data is retained?**

If your child turns 18 during the course of this study, then they will be legally able to sign their own consent form. The research time will get in touch to give your child the opportunity to decide for themselves if they would like to continue to be involved in this study. If they decide that they no longer want to be involved in the study, they can also request that we delete all of their stored data and not use it in any future reports or publications. However, if the data has been anonymised or combined with other patient data as part of a scientific publication/report it will not be possible to have the data removed as we would not be able to trace the data back to them.

1. **Is my child’s doctor being paid for this study?**

No. Your child’s doctor is not being paid for this study. Neither your child’s doctors nor the researchers involved in this study will receive any remuneration or private benefits from this study.

1. **Has this study been reviewed by an ethics committee?**

All research involving human participants is reviewed by an independent group of people, called a research ethics committee to protect participants’ interests. This study has been reviewed and has been approved by the research ethics committees at CHI at Crumlin, and at UCD.

**20. How do I initiate a query or complaint?**

Should you wish to raise a query or make a complaint about compliance with the personal data processing practices of CHI at Crumlin or University College Dublin, please contact as follows:

CHI at Crumlin: By email DPO@childrenshealthireland.ie or via post: Data Protection Officer, Children’s Health Ireland at Crumlin, Cooley Road, Dublin 12, Ireland.

University College Dublin: By email at gdpr@ucd.ie or via post: Office of the DPO, Roebuck Castle, University College Dublin, Belfield, Dublin 4, Ireland.

**21 Study contact details**

Thank you for taking the time to read this information leaflet.

If you wish to take part in this study, please read and sign the consent form on behalf of your child with your study team.

If you would like any further information, please contact: The research team at CHI (Prof Owen Smith, Dr Cormac Owens, Dr Noelle Cullinan at 01-4096714 or the research nurses at 01-4282327).

**Appendix – DATA PROTECTION INFORMATION**

**1a. This section provides further information about how your child’s** **samples and data will be protected**

To ensure that your child’s data and samples are always optimally protected, the following measures have been put in place by the study team.

**At Children’s Health Ireland:**

Samples for genomic profiling will be taken at CHI or affiliated hospitals, pseudonymised, and shipped to UCD for extraction of DNA, RNA, proteins and metabolites. Investigators at UCD will only have access to pseudonymised patient data. As the data controller, CHI will receive all study data during and at the completion of the study. During the study, patient clinical information will be stored on the hospital’s secure internal network. Access is limited to registered users, who require a personal password to access the network. Regular back-ups of the data are performed and stored in a separate secure area of the hospital. All patient samples taken by CHI will be pseudonymised at site. A random participant number (PN) and sample number (SN) are assigned to key participant data and samples. Participant’s names, addresses, date of birth are never used. The PN is only recorded against the participant’s name in documents held by the study team in CHI.

If results of genomic data are being using for diagnostic purposes or clinical decision-making, CHI will re-identify the patient, and will discuss the patient in molecular tumour board meetings. Doctor-patient confidentiality rules apply to these discussions.

**At University College Dublin**

Investigators at UCD will receive blood, bone marrow, and tissue samples from CHI for extraction of DNA, RNA, proteins, and metabolites. Depending on the amount of tissue available, only selected types of molecules may be extracted. Leftovers of samples (DNA, RNA, tissue, bone marrow, blood) will be stored at UCD in case the analysis has to be repeated or extended, e.g. because of a technical failure, the need to reconfirm a finding, or the availability of a better method and/or instrument for sample analysis. Leftover samples will be stored in locked freezers in UCD. They will be destroyed by disposal into biomedical waste and autoclaving, which destroys genetic material. The 10 year storage duration is based on UCD's policy for retention of raw data for research, so that they are available for re-examination should any queries about the data arise.

Investigators at UCD will receive only pseudonymized data. The raw data from genomic profiling will be stored at secure servers in UCD/SBI. SBI has a dedicated data manager, who administers these servers and performs regular backups to ensure that data is protected appropriately. Access to data at UCD is limited to registered users, who require a personal password to access the data. Access will be determined by the UCD study leader. UCD receives only pseudonymised data and has no access to the code/key list that can identify patients. The pseudonymized participant numbers will be stored on a secure, encrypted, access-controlled server located in UCD.

UCD/SBI will perform the analysis and integration of the molecular data. This includes the analysis of full genome information, transcriptional data, proteomics data, metabolomics data, multiomics data integration and integration with clinical and imaging data. The analysed and integrated molecular data will be shared with CHI. With patient consent, UCD/SBI will also upload the molecular data to the EGA, https://ega-archive.org/), which is the EU infrastructure service for the permanent archiving and sharing of all types of personally identifiable genetic and phenotypic data resulting from biomedical research projects (see below).

**At the European Genome-Phenome Archive (EGA):**

The EGA is an EU service for permanent archiving and sharing of all types of personally identifiable genetic and phenotypic data resulting from biomedical research projects. The EGA is merely a secure repository and has no say of what happens to the data. Access to data deposited into the EGA is via a Data Access Committee, which is set up by the depositor. See https://ega-archive.org/access/data-access for detailed information about accessing data in the EGA. For EGA, the data controller is ultimately the data producer and the submitter(s) who submit the data to EGA. The data controller also creates a Data Access Committee (DAC) who will decide on data access permissions at EGA. Data processors are the persons or entities which process the data on behalf of a data controller. With regard to GDPR, EGA is a data processor as it processes data as instructed by the data controller. without any access rights to the data, except storage and distribution to users who have obtained access permission from the DAC. EGA does not accept personally identifiable data except genetic and phenotypic data, so all other data submitted to EGA, such as names and addresses, must be pseudonymized. As a data processor, EGA has a set of security policies that are followed to minimize the risk of unauthorized data access or data loss. For more details see https://ega-archive.org/privacy-notice

**2a. Who controls access to your child’s data and biological samples?**

If you agree to participate in this study, the study team will access your child’s medical records at CHI. They will also collect and be responsible for your child’s study data and for coordinating the transfer of your child’s biological materials to UCD for analysis. They will control access to any study records at the study site, including consent forms and documentation, generated from this study. If you have any questions regarding how your child’s data is kept safe and confidential, please ask your Study Doctor or research team whose contact details are set out in this leaflet.

University College Dublin controls access to all data stored by University College Dublin.

Access to data deposited at the European Genome – phenome Archive (EGA) are controlled by a Data Access Committee that is appointed by CHI and UCD.

**3a. How long will your child’s data be accessed and studied and how long will it be stored for?**

Clinical and genomic data from your child will be studied by a team of doctors, clinical researchers and computer scientists/bioinformaticians at CHI and UCD to examine the contribution of genetic changes to your child’s cancer. The data will be used for clinical diagnostic purposes and medical research purposes. The duration of access and storage depends on the purpose.

Data will be retained and accessed as follows:

(a) for the diagnostic arm of the studies, CHI will store the data in accordance with HSE guidelines until a patient’s 25th birthday, or 26th if the young person was 17 at the conclusion of treatment, or eight years after the patient’s death. CHI will store all the clinical information, the key for patient pseudonymization, and the results of the genomic analyses that were used for clinical diagnostic purposes. These data will be accessed by the clinical study team as needed during the course of your child’s treatment. The genomics company who will help with the genetic sequencing aspect of this study will need to store pseudonymised data during the time required for sequence analysis only and will delete the data once it has been transferred onwards to UCD.

(b) for the research arm of the studies, pseudonymised data will be retained no longer than 10 years after study completion, or until the data have been deposited in the EGA, whichever occurs first. The data storage duration of 10 years is based on UCD’s policy for the retention of research data. It is required to allow for confirmation or refinement of any study findings. Sometimes questions arise about research findings that need to be re-evaluated in light of new knowledge and/or new technologies. These data will be accessed by the research team of the study and data may be shared with the clinical team. For long term storage, pseudonymised data will be deposited at the EGA. The EGA is an EU infrastructure resource that will store the data without time limit. Data in the EGA can only be accessed with permission by the Data Access Committee set up by CHI and UCD. Data that have been deposited at the EGA will be deleted from UCD’s storage.

All persons carrying out this research or otherwise having access to personal data are bound by a professional code of secrecy (such as doctors) or a contractual code of secrecy or other legal arrangements, such as Data Processing Contracts, that ensure confidentiality and compliance with the General Data Protection Regulation (GDPR).

**4a. What type of data is collected for the study and who is the data controller?**

We will collect the following data from your child:

1) Name, date of birth, gender, physical description (CHI will collect and process these data only)

2) Age, sex, ethnicity/race (as some cancers show preference for different ethnic groups), health information, disabilities (CHI will collect these data and make them available in pseudonymised form to UCD for use in the research study)

3) Human biological samples (blood, bone marrow, tumour tissue), genetic information (CHI will collect these samples and pseudonymise them before providing them to UCD for processing)

The information or data that we collect for this study is known as “special categories of personal data” under Irish Data Protection Laws, as it relates to personal health data. Your child’s personal health data will be processed with the following lawful bases (1) public interest (Art 6.1.e, GDPR), and (2) scientific research (Art 9.2.j, GDPR), in accordance with Section 6 of the Children’s Health Act 2018. In addition,

UCD and CHI are the joint data controllers of these data. The third-party genomics company employed by the research team and the EGA are data processors, i.e. they have no right to the data and can only process them as instructed by the controllers.