

## STUDY NAME: Rare Kidney Disease (RKD) Registry and Biobank

### Information Leaflet and Consent Form for VASCULITIS PATIENTS <18 YEARS OLD

Site:	St Vincent's University Hospital
Principal Investigator (PI):	Dr John Holian
Contact Details (PI):	<a href="mailto:j.holian@svuh.ie">j.holian@svuh.ie</a>
Study Organiser:	Professor Mark Little, Trinity College Dublin
Contact Details:	<a href="mailto:mlittle@tcd.ie">mlittle@tcd.ie</a>
Data Controllers:	Trinity College Dublin (for Registry and Biobank data) St Vincent's University Hospital (for hospital medical records)

**Invitation to Parent(s)/ Guardian(s):** We invite you to provide consent for your child to take part in a national study called the Rare Kidney Disease ('RKD') Registry and Biobank. This study aims to set up a collection of samples and information that can be used to support future research into preventing, diagnosing and treating vasculitis. Your decision to allow your child to take part is entirely voluntary. Before you decide whether or not to allow your child to take part it is important that you understand why we are doing this research, what it will involve for your child and what the possible risks and benefits are. This process is known as 'informed consent'. Please take your time to read this leaflet and to ask questions about anything you are unsure about. Feel free to discuss this with others before deciding.

We will invite your child to read this information leaflet and to discuss the study with you and the study doctor. Please be aware that if your child declines to take part it will override your decision to allow your child to take part. References to 'you' and 'your' in the information leaflet refer to your child.

**Invitation to Participants (<18 Years):** We invite you to take part in a research study called the Rare Kidney Disease ('RKD') Registry and Biobank. This study aims to set up a resource of biological samples and information that can be used to support future studies into vasculitis and to help improve its diagnosis and treatment. This study is voluntary. You do not need to take part if you do not wish to. Your decision will in no way affect your treatment or care. Because you are under 18, your parent(s)/ guardian(s) will need to provide consent on our behalf. However, your decision to take part or not will be respected. Please take your time to read this information and to discuss your wishes with your parent(s)/ guardian(s). If you choose not to take part, your parent(s)/ guardian(s) will not be able to consent on your behalf.

**You will be contacted to provide consent to continue in this study when you are 18 years old.**

## PART 1 - THE STUDY

### What is the purpose of this study?

The purpose of this study is to create a large collection of biological samples (also known as a 'Biobank') and clinical data (also known as a 'Registry') donated by patients which can be used to carry out scientific research. We hope this research will help us to understand more about vasculitis and its causes, and will help develop new tests and treatments.

We will collect clinical information, biological samples and DNA from many people to build up as complete a picture as possible about vasculitis in Ireland.

We will:

1. Collect and store patient data, including medical history, in a database
2. Collect biological samples (blood, urine and DNA) and store these for a long time in a freezer (this sample collection is known as a 'Biobank')

The information and samples that we collect will be shared with researchers (both inside and outside Ireland) to carry out research in the area of vasculitis. This is an on-going study that will collect, store and study samples and data over a long period of time. We will collect samples and data from both people with vasculitis and those without vasculitis ('controls') so that we can look for differences that will tell us more about the condition.

### Why have I been invited to take part?

You have been invited because you have a type of vasculitis or related condition. We hope to understand the disease affecting you and others more clearly.

### Do I have to take part? What happens if I say No? Can I withdraw?

It is entirely up to you to decide whether or not to take part. Participation in this study is **voluntary**. If you take part, you are still free to withdraw at any time and without giving a reason. A decision not to take part or to withdraw at any time will in no way affect the standard of clinical care you receive.

You don't have to give a reason for not taking part or for opting out. If you wish to withdraw from the study, you can do so by contacting Prof Mark Little (details below).

### What will it involve if I decide to take part?

You will be asked to sign an Informed Consent Form. This will allow us to collect, store and study your samples and data. You will receive a copy of the completed Consent Form and this Patient Information Leaflet. Here is what will happen next:

1. **Blood sample:** We will need up to 40mls (equivalent to about two or three extra tubes) of blood from you at each visit. We are hoping to follow each participant over the lifetime of their disease and may need to take an additional research blood sample when you attend routine clinic

appointments during your time in the study. The research bloods will usually be collected at the same time as routine blood collection that you would otherwise have.

**2. Urine sample:** When you come to clinic you generally provide a urine sample. If you take part in this study, we will retain part of this urine sample for research.

**3. Healthcare Data:** We will collect information about your gender, date of birth, ethnicity, health, medical history and family history as part of this research. We will ask for your consent for your Doctor or a member of the study team to review your hospital medical record in the strictest confidence to collect information for this research. We will continue to update this information as new events happen during the course of your illness.

**4. DNA:** DNA samples will be extracted from blood and urine samples for research. DNA is the molecule that provides instructions for how cells in our body work. By looking at DNA from people with and without vasculitis we may see differences that are important for diagnosis, treatment or understanding the condition.

**Biopsy samples:** If you are having a biopsy procedure, the tissue will be stored in the hospital pathology department. We ask your permission to use some of this biopsy sample for research. We would access this by asking the hospital pathology department to give a section of the biopsy to us. You will not have to undergo any extra procedures or hospital visits.

### What will happen to my Samples and Data?

All samples and data will be given a random study ID number at your hospital in a process called pseudonymisation or “**coding**”. This process is intended to mask your identity. All samples and data will be transferred to and stored in the RKD Registry and Biobank using this code instead of your name or hospital number. The link between your study ID code and name will be kept securely by your hospital study Doctor and will not be shared outside of the study team.

Your **coded** samples will be stored in a secure freezer at the Trinity Translational Molecular Institute (TTMI) located at St James’s Hospital under the direction of Professor Mark Little. Samples will remain frozen for decades and potentially indefinitely, so that they can be used for future research studies into vasculitis or related diseases. We would like to keep them indefinitely because scientific research is changing and advancing all the time, and we do not yet know what kinds of research questions will arise in the future.

These samples will be used by us and will also be available to other researchers worldwide (including for-profit and industry researchers) to look for biomarkers such as proteins, DNA and RNA that will help us understand more about vasculitis. The only people who will have direct access to the RKD Biobank will be Professor Mark Little and his approved team. **Coded** samples may be sent to external laboratories (commercial and non-commercial laboratories, including laboratories located outside of the EU) for analysis and storage for approved studies.

Your data will be stored on a secure database managed by Trinity College Dublin. Your study team at the hospital and the team managing the RKD Registry and Biobank (under the direction of Professor Little) will have access to your **coded** data on the database.

**Sharing of data and samples:** External research organisations (with equivalent data protection standards) can apply to the RKD Registry and Database to use your **coded** samples and data for ethically approved research in the area of vasculitis. These may include national and international hospitals and academic research institutions, and for-profit research or biopharmaceutical companies. It is necessary to share **coded** samples and data in order to maximise the amount we can learn and increase the possibility of making meaningful discoveries.

We recognise the value of the samples and data that you are providing for vasculitis research. For this reason, we make careful decisions about who can receive and use the samples and data. Researchers must submit a detailed application describing the research project. The research must be in the area of vasculitis and of high standard. The RKD Registry and Biobank scientific committee (headed by Professor Little and including two patient representatives) and approving ethics committee will decide if researchers can receive samples and/or data. Researchers will be encouraged to publish their findings so that the wider research community can also benefit from what they have learned.

#### Are there any benefits to taking part in this research?

Taking part in this study will not directly benefit you. However, research performed with your '**coded**' samples and information may help us to better understand vasculitis, and may result in new tests, drugs or treatment approaches. This is a long-term research project, so the benefits of the research may not be seen for several years. By participating, you are helping to advance science and medicine for future generations.

#### Are there any risks with taking part?

- **Blood Sample:** The standard risk of providing a blood sample includes bruising and discomfort at the site of puncture. Patients may also, on rare occasions, feel faint. Care will be taken to avoid these risks and we will try to take research sample at the same time as routine blood samples so that no extra needle prick is needed.
- **Health Information (Data):** There is an extremely small risk that a connection to your identity could be made. Great care will be taken to ensure the confidentiality of all data as described in Part 2 and the risk to participants of a breach of confidentiality is considered very low.
- **Genetic Testing:** There are some risks to genetic testing. The greatest risk is that genetic testing may reveal that you are not related to one or more of your family members, for example we might discover that your father is not the person you expected him to be. There is also the possibility of social and economic disadvantages. Genetic information shared in the wrong way could affect you and your family, such as if an employer or insurance company was to obtain the information. This is termed 'genetic discrimination'. We will do our utmost to guarantee complete confidentiality, but there is a theoretical risk of this information becoming available to others.

Our genetic testing is focused entirely on the study of the genetics of vasculitis and we do not screen for all genetic disorders. Therefore, it is possible that even if you take part in this study you may still be diagnosed with a genetic disorder later. In addition, genetics is an evolving science and new genes that cause disease are being discovered all the time. Even if we do not discover a genetic cause for your

condition now, one may still be discovered in the future. It is common that we discover no genetic association with vasculitis or that it takes many years to do so.

#### What happens if something goes wrong when I'm taking part in the study?

In the unlikely event that you are harmed in any way, the researchers on this study are covered by insurance through the state claims agency clinical indemnity scheme. This insurance will cover you if you are injured as a result of taking part in this study.

#### Will I be told about the research results?

Unfortunately, it is not practical to notify each person of their individual research results. In addition, research results will not necessarily be approved for clinical use. Research may be carried out years after sample collection and researchers will receive **coded** samples and data that they will not be able to link back to you. However, research results will be published in scientific journals and presented at scientific meetings and conferences (national and international). You can also access information on research of the RKD Registry and Biobank on the following website: [www.tara.tcd.ie](http://www.tara.tcd.ie).

#### Genetic Testing Results

One goal of this study is to understand more about the genetic causes of vasculitis. It is possible that we could also find genetic changes that may cause different health problems unrelated to vasculitis. This information will not automatically be returned to you. Only individuals with vasculitis-associated gene problems will be informed of their genetic results in this study. Family members of affected individuals will not be informed.

As part of the consent process we will ask you to decide whether or not you wished to be informed of genetic results the RKD Registry and Biobank becomes aware of. If you do not wish to be informed of the results, we will not contact you.

If you do wish to be contacted, we will invite you back to a clinical genetics clinic if we find a result. Because we are a research, rather than a clinical lab, we will need to repeat the testing in an authorised clinical lab. No decisions on your clinical care will be made using results from this research study, but data from this study may be used, with your consent, to help guide labs performing your clinical genetic testing, to speed up the process. If your sample is going to be tested clinically you will be asked to consent separately to this, and another blood sample will be drawn. Only when we have the final result from the clinical lab will the result become part of your medical record.

#### What happens if I change my mind?

You can change your mind at any time by contacting your study Doctor (contact details below). If you choose not to continue to take part, this will not affect your medical care in any way.

If you choose not to take part any more, you will be asked to fill in a withdrawal form. If you wish, you can ask for your samples and/or data stored in the RKD Registry and Biobank to be destroyed. If you request this, we will destroy all samples and data that are still in our possession. We will no longer use or share your samples or data for research from this point onwards. However, it will not be possible to destroy samples and data already used in research studies prior to this time.

## PART 2 – DATA PROTECTION

### What information about me (personal data) will be used?

The research team at St Vincent's Hospital will collect information on your medical history and your health status from your medical records for this study. Throughout your time on this study, the research team at St Vincent's Hospital will continue to update the information in the RKD Registry as new events happen during the course of your illness.

### How will my privacy be protected?

Protecting your privacy is extremely important to us and to your hospital study team. Your data is stored and shared in two different ways:

**Coded data (without your name)** is stored as part of the Registry on a secure, encrypted, password-protected database managed by Trinity College Dublin. Only your study Doctor, their research team and approved members of the RKD Registry and Biobank research team have access to this database. **Coded** information from this database is shared with other researchers.

**Identifiable data (with your name)** is stored at the hospital site. Your study Doctor and the study team will have access to identifiable (named) data, your medical records and information that can link your name to your study code. It is important that the study team at the hospital can link your study code to your clinical records so that you can be followed up throughout the study. They will store these securely in a restricted access location. Access to your medical records is controlled by the hospital. Regulatory authorities and representatives of the RKD Registry and Biobank may require supervised access to your identifiable data at the hospital for the purposes of checking and confirming that the study has been carried out correctly.

### Sharing of coded data and samples

All research organisations that receive **coded** samples and data enter into a written agreement with Trinity College Dublin to only use samples and/or data for the approved research, and not to make any attempt to identify you from the information. This agreement is important because some of the research may include genetic analysis, which carries a small risk of being able to identify someone. External research organisations will only ever receive **coded** samples and data.

External research organisations receiving your **coded** samples and data may be located outside of the EEA in countries with less stringent data protection laws to Ireland. To protect your identity, researchers will need to complete an application process and sign a data sharing agreement to protect your privacy to the standards of the European General Data Protection Regulation.

Results of research using the **coded** samples and data will be published in journals and presented at scientific meetings. No identifiable data will be published.



## Information on Data Protection Laws

1. Under the European General Data Protection Regulation (GDPR), the lawful basis for processing your data in this study is for scientific research (Article 9(2) (j)) in the public interest (Article 6(1)(e)).
2. Under GDPR, you can exercise the following rights in relation to your personal data, unless the request would make it impossible or very difficult to conduct the research:
  - a. The right to access to your data and receive a copy of it.
  - b. The right to restrict or object to processing of your data
  - c. The right to object to any further processing of the information we hold about you (except where it is de-identified)
  - d. The right to have inaccurate information about you corrected or deleted
  - e. The right to receive your data in a portable format and to have it transferred to another data controller
  - f. The right to request deletion of your dataYou can exercise these rights by contacting your study Doctor.
3. A data protection risk assessment has been completed, taking into consideration the data security and data privacy measures (including use of **coded** data), and the study is considered low risk.
4. Under GDPR, if you are not satisfied with how your data is being used, you have the right to lodge a complaint with the Data Protection Commissioner of Ireland or the study Data Protection Officer (contact details below).

## PART 3 – COSTS, FUNDING and APPROVAL

### Who has reviewed this study?

The St Vincent's Hospital's Research Ethics Committee has reviewed and approved this study. Approval was granted on 13<sup>th</sup> July 2013.

### Who is organising and funding this study?

The research is being organised by Professor Mark Little of Trinity College Dublin, in collaboration with specialists with an interest in vasculitis in Ireland. No doctor taking part in this study is getting paid extra for including you in the study. Funding for the study comes from Science Foundation Ireland, Irish Kidney Association, Meath Foundation, Health Research Board and Trinity College Dublin.

In some cases, we will charge a small administration fee to external research organisations to cover costs of running the RKD Registry and Biobank.

### Is there any payment for taking part?

No, we are not paying patients to take part in the study. However, you may be reimbursed for travel expenses if you need to make any visits that you would not normally have made as part of your routine clinical care.

## PART 4 – FURTHER INFORMATION/ CONTACT DETAILS

For further information or queries, you can contact:

Study Doctor (Principal Investigator): Dr John Holian on +353-1-221-4493 or [j.holian@svuh.ie](mailto:j.holian@svuh.ie)

Study Organiser: Professor Mark Little on +353-1-896-2145 or [mlittle@tcd.ie](mailto:mlittle@tcd.ie)

**Data Protection Queries:** Data Protection Officer of Trinity College Dublin, [dataprotection@tcd.ie](mailto:dataprotection@tcd.ie) or Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland.

**If you would like to take part in this study, you will be asked to sign the consent form on the next page. You will be given a copy of this information leaflet and the signed consent form to keep.**



**STUDY NAME: Rare Kidney Disease (RKD) Registry and Biobank**

Centre ID: \_\_\_\_\_

Patient Identification Number for study: \_\_\_\_\_

**INFORMED CONSENT FORM for PARENT(S)/ GUARDIAN (S) of PATIENT <18 YEARS**

**Please initial the box if you agree with the statement. Please feel free to ask questions if there is something you do not understand.**

I have read and understood the <b>Information Leaflet</b> for this study. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.	
I understand that my child's <b>participation is voluntary</b> , and I can withdraw my child's biological material and data at any time without giving a reason. I understand that opting out will not affect mine or my child's future medical care or legal rights.	
I understand that sections of my child's <b>medical notes</b> may be looked at by my Study Doctor and his/ her study team at St Vincent's Hospital. I give permission for these individuals to have access to my child's records. All information will be kept private and confidential.	
I agree for the entry of my child's <b>clinical data</b> into the registry. I give <b>explicit</b> informed consent to have my child's data processed as part of this research study. I understand that my child's data will be securely <b>coded</b> and stored indefinitely.	
I agree to allow my child to provide <b>urine and blood</b> for use in this study as described in the information leaflet. I understand that my child's samples will be securely <b>coded</b> and stored indefinitely. The risk of taking samples has been explained to me.	
I agree to allow the RKD Registry and Biobank to access and use my child's previous <b>biopsy or tissue samples</b> (stored by St Vincent's Hospital) for this study.	
I give consent for my child's <b>coded biological samples</b> (including DNA samples) to be shared with authorised third parties including; national and international hospitals, academic research institutions and for-profit commercial research or biopharmaceutical companies for the purpose of vasculitis research, including genetic research, as described in this information leaflet.	
I give consent for my child's <b>coded data</b> to be shared with <b>academic</b> researchers for future research into vasculitis as described in this information leaflet. I understand that all future research performed on my child's coded data and samples will be approved by a research ethics committee.	
I give consent for my child's <b>coded data</b> to be shared with <b>industry</b> researchers for future research into vasculitis as described in this information leaflet. I understand that all future research performed on my child's coded data and samples will be approved by a research ethics committee.	
I understand that processing of my child's <b>personal data</b> , including any transfer of data outside of the EU, will be protected in accordance with the General Data Protection Regulation.	
I understand that results from the <b>analysis of my child's samples will not be given to me.</b>	

I understand that there are <b>no direct benefits to my child</b> from participating in this study. I understand that we will not benefit financially if this research leads to the development of a new treatment or medical test.		
I know how to contact the research team if I need to.		
I consent to my child taking part in this research study having been fully informed of the risks, benefits and alternatives.		
I have been given a copy of the Information Leaflet and this completed consent form for my records.		
I consent to my child's GP being informed of their participation in this study		
I understand that results related to disorders other than vasculitis will not be returned to me or my child.		
<i>The following relates to what you wish us to do if we discover a genetic disorder on genetic testing. If you do wish to be informed, you will need to attend a clinical genetics clinic and have a second blood sample taken to confirm the diagnosis.</i>		
<b>Optional:</b> I want to learn about results found about my child related to the vasculitis disorders studied as part of this project.	<b>Y</b> <input type="checkbox"/>	<b>N</b> <input type="checkbox"/>

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 Parent/ Guardian Name (printed)                      Signature    Date

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 Relationship to participant

## Rare Kidney Disease (RKD) Registry and Biobank

### PARTICIPANT ASSENT FORM (<18 YEARS)

Please <u>Initial</u> the box if you agree with the statement. Please feel free to ask questions if there is something you do not understand.	
I confirm I have read and understood the Information Leaflet for the above study. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction. I understand the risks and benefits.	
I understand that my participation is voluntary, and I can withdraw at any time without giving a reason. I understand that opting out will not affect my future medical care or legal rights.	
I agree to provide blood and urine samples as described in the information leaflet. I give permission for my biological samples to be used in research as described in this leaflet.	
I understand that sections of my medical notes may be looked at by the research team. I give permission for the research team to access my records. I agree for my data to be used in this research study as described in the leaflet.	
I have discussed this study with my parent(s)/guardian(s) and agree to take part in this study.	

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Participant Name (printed)	Signature	Date

#### To be completed by the Principal Investigator or nominee.

I, the undersigned, have taken the time to fully explain to the participant and their parent(s)/guardian(s) the nature and purpose of this study in a way that they could understand. I have explained the risks and possible benefits involved. I have invited them to ask questions on any aspect of the study that concerned them.

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Name (Block Capitals)	Qualifications	Signature	Date

**3 copies to be made: 1 for patient, 1 for PI and 1 for hospital records.**