RARE TUMOR DATABASE

Next of Kin Participant Information and Consent Form for participants who are alive and older than 16 years of age

Version #11, Date: 20th February 2017

Full Project Title: Collection of data from patients with rare tumor types or inherited rare tumor predisposition for the establishment of a Rare Tumor Database for ethically approved research projects.

Principal Researchers: Dr Clare Scott, Dr Jayesh Desai, Associate Professor Peter Gibbs

---

1. Your Consent

You are invited to take part in this project as the next of kin of the person who is alive and 16 years or older, who has a rare tumor or inherited rare tumor predisposition and whose data you are submitting to the project.

This Participant Information contains detailed information about the project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project before you decide whether or not to take part in it by providing the data of the person for whom you are the next of kin.

Please read this Participant Information carefully. Feel free to ask questions about any information in the document. You may also wish to discuss the project with a relative or friend or your local health worker. Feel free to do this.

Once you understand what the project is about and if you agree to take part in it, you will be asked to provide your consent by completing the Consent Form. By completing and submitting the Consent Form, you indicate that you understand the information and that you give your consent to participate in the project by providing the data of the person for whom you are the next of kin.

The Consent Form can be completed and submitted electronically via the online consent facility or it can be printed, completed and returned to the CART-Wheel office.

If printing a Consent Form, the completed form can be scanned (or photographed) and emailed to contact@cart-wheel.org. Alternatively, you may prefer to post the Consent Form to:

CART-WHEEL BioGrid Australia

PO Box 2138

Royal Melbourne Hospital VIC 3050 Australia

If submitting by post, please keep a copy of the Consent Form for your records.

After submitting the Consent Form, you will receive an email to acknowledge that your consent has been received and recorded in the CART-Wheel database.

2. Background

It is often difficult to study tumors that are rare due to the small number of reported cases at any given hospital. This includes rare tumor types of the brain, eye, thyroid, blood system, bones, joints, liver, reproductive organs, small intestine, gallbladder and ureter. In order to effectively research into rare tumors to improve diagnosis, prognosis, treatment outcome and tumor predisposition, it is necessary to have access to large amounts of information about these

tumors. As a group, rare cancers can have a large impact, and the total incidence from all rare tumors is substantial.

Therefore it is necessary to collect as much information as possible from people diagnosed with such rare tumors or the increased likelihood of developing such tumors (inherited rare tumor predisposition), to allow more effective clinical research and providing a greater chance of a useful outcome than would currently be possible.

3. What is BioGrid Australia and the Rare Tumor Database

For many years, doctors and hospitals have collected information on the way people's health alters over the years, the disease and other test results, and a patient's response to treatment. Much of this information is now stored on computer databases. By combining information on these computer databases from a number of hospitals, disease patterns in large numbers of patients over time can be studied. The more patients involved, the more information is collected and the more powerful the research can be.

BioGrid Australia is a data sharing technology company providing a secure infrastructure that advances health research by linking privacy-protected and ethically approved data among a wide network of health organisations. BioGrid Australia links real-time health data across institutions, jurisdictions and diseases to assist researchers and clinicians improve their research and clinical outcomes. The web-based infrastructure provides ethical access while protecting both privacy and intellectual property.

We have established a Rare Tumor Database through BioGrid Australia that enables identification of people with rare tumor types or inherited rare tumor predisposition and storage of their information. Participants in this project can access the Database via the website (www.biogrid.org.au) and contribute electronically, or if they are patients of the Royal Melbourne Hospital, will be approached by their doctor or a research nurse to discuss it. By having this Database available over the internet, it allows participation from a much larger number of people with similar diseases. When a researcher decides to study certain type of rare cancers, they apply to BioGrid Australia to obtain the information. BioGrid Australia will permit the researcher access to the information if the research project meets the required ethical and scientific standards.

4. What do you want from me?

The person for whom you are the next of kin has been diagnosed with a rare tumor or a rare subtype of a tumor or inherited rare tumor predisposition and we would like you to complete a questionnaire on the Rare Tumor Database. It will take you about 30 to 60 minutes to complete, depending on how much information you choose to include, and many of the questions will ask you about the medical history and disease of the person for whom you are the next of kin. If preferred, the questions can be answered during a number of sessions and all the data will be saved. On the Consent Form we will ask you if you would like to be approached again by BioGrid Australia. There are 5 options for you to consider: you may choose yes or no for each consent option depending on what you think is best for you.

If we have not received your consent within 4 weeks for Australian and 8 weeks for internationally registered participants, you will receive several reminder emails to your nominated email address.

If you agree to consent, you will receive a link to a 6 monthly newsletter about the Rare Tumor Database to your nominated email address.

Consent Option 1: you will be asked if you give permission for BioGrid Australia to store medical information of the person for whom you are the next of kin as data in the Rare Tumor Database and for it to be used in a re-identifiable (coded) way, for example looking at how many patients with a particular tumor type or inherited rare tumor predisposition we have information for and what are the basic characteristics of those patients.

Consent Option 2: you will be asked if you give permission for the clinician treating the person for whom you are the next of kin to enter, view, or edit their data. You may still edit the data but if you consent for this option, the nominated clinician will also have access to the data. The data may help the clinician.

Consent Option 3: you will be asked if you give permission for BioGrid Australia to contact you for an update of personal information of the person for whom you are the next of kin. This is to find out what has happened to that person since you last gave us their information. Again, this information would be stored and used in a re-identifiable (coded) way as in Option 1.

Consent Option 4: you will be asked if you give permission for BioGrid Australia to contact the doctor of the person for whom you are the next of kin to obtain their tumor pathology (histologic) report(s) or inherited rare tumor predisposition report and other medical details to confirm tumor type or inherited rare tumor predisposition type. This is so that the information we store is as accurate as possible.

Consent Option 5: you will be asked if you give permission for BioGrid Australia to contact you about the possibility of the person for whom you are the next of kin participating in other ethically approved research projects studying their type of disease.

Such a study may collect more detailed information from you about their case; may inform you about a clinical trial that may be relevant to the person; may request a blood sample from the person for whom you are the next of kin if that is convenient (such a sample may have already been stored in one of the Victorian Tissue Banks); and may request permission to use a small part of any tumor tissue that has been removed in the past and has been examined by a pathologist for the presence of cancer (the tissue samples will only be used by researchers for ethically approved projects, and will be in excess of that required by the pathologist).

The researchers may extract genetic material (DNA and RNA), from the tumor tissue. The cells in our bodies all contain genes. Genes are made up of DNA and RNA. These are molecules that carry the genetic information in our cells. Genes are inherited from our parents. Genes provide the information that determines our physical features such as hair and eye colour. Differences in our genes help explain why we are all different. Sometimes genes can be altered. This is called genetic mutation. The alterations to these genes can sometimes cause a specific disease or make a person more likely to develop a specific disease. In some cases cells will be grown and reproduced from the tumor cells, indefinitely. These are called long living cell lines. The genetic material will be used to study how rare tumors develop.

Please feel free to decline to answer any questions or approaches.

5. Isn't all of the tissue needed to make a diagnosis?

Generally, no. If there is a tumor present, the surgeon removes it and some of the surrounding normal tissue to ensure that all of the diseased tissue is removed. The specimen is sent to the pathology laboratory where a doctor examines it. This doctor selects areas of tissue that will be processed into paraffin (wax) tissue blocks. These blocks are cut into very thin slices, mounted on microscope slides and then stained. The pathologist views the slide under a microscope, makes a diagnosis and then sends a report to your doctor. After the diagnosis has been made, there is usually tissue remaining in the wax blocks, which are stored or 'archived' indefinitely in the laboratory. With your consent, tissue will be taken from the left-over tissue sample of the person for whom you are the next of kin, for future research projects, after the necessary diagnostic tests are completed.

6. Who will use the tissue?

Only researchers who have approval from a Human Research Ethics Committee (HREC) and BioGrid Australia can request samples. HRECs, which are made up of doctors, lawyers, research scientists, community members and ethicists, ensure that projects are scientifically sound and are conducted according to the National Statement on Ethical Conduct in Human Research (2007) as issued by the National Health and Medical Research Council of Australia.

7. For what purpose will tissue be used?

Tissue samples may be requested by scientists who are involved in various aspects of cancer research, so we cannot say exactly what projects your samples may be used for. The tissue may be helpful for research into understanding the causes and processes that lead to the disease, and/or to develop improved methods for the detection, diagnosis, monitoring and/or treatment of the disease. This might include looking for common changes in how cells function or how genes work. Researchers may want to look at differences in the tumor tissue and how they relate to different treatment results; ways to better predict the effects of treatment on the cancer cells in your disease or processes leading normal cells to become malignant cells, etc. Other researchers may want to study how diseases are passed on in families by comparing the genetic material (proteins and genes) present in both normal and affected cells; this is called genetic research.

Cells obtained from the blood or tissue of the person for whom you are the next of kin may also be used to establish cell lines. A cell line consists of cells that are grown and kept for a very long time in the laboratory. Cell lines, therefore, allow the creation of a large supply of material for research. This allows material to be shared with other research groups and enables researchers to compare each other's results. Only researchers who have obtained special approval can establish cell lines or perform genetic research.

8. What information will be on the Rare Tumor Database?

There are two sorts of information that will be on the Rare Tumor Database.

Identifying information
If you agree to participate in this study on behalf of the person for whom you are the next of kin, we will record their name, date of birth, address and, if they reside in Australia, part of their Medicare number on the Rare Tumor Database. We will create a unique code for that person. Only this unique code will be attached to their clinical information.

Clinical information
In keeping with the philosophy of BioGrid Australia, the details of what data are collected will vary from tumor type to tumor type or according to type of inherited rare tumor predisposition. This will include clinical data such as age and main presenting symptom when first diagnosed with the tumor, how the diagnosis was made (eg what type of biopsy was performed, what scans were undertaken), who the patient's doctors were at the time, general details about treatment the patient might have had, whether anyone in the patient's family has had a cancer (as sometimes, but not always, this information is helpful for rare tumors). This information will be kept on a different computer database and identified only by the patient's unique code. The type of information will include things like diagnosis and treatment details.

9. How will privacy be protected?

BioGrid Australia is structured so that participant identifying and clinical information are always kept separate. Researchers never receive information that would enable the researchers to know the identity of the people involved in the research. Thus researchers can conduct research while participant privacy is fully protected.

The data will only be available in coded form, the name and other identifying information of the person for whom you are the next of kin will not be available to researchers. All data will be stored in a password protected secure computer facility at Melbourne Health. The only people who have access to the codes are two database administrators who do not have access to the health data of the person for whom you are the next of kin.

Any information obtained in connection with this project and that can identify the person for whom you are the next of kin will remain confidential. It will only be disclosed with your permission, except as required by law.

For a researcher applying to gain access to the Database, the following requirements will be essential:

- The researcher must demonstrate that there are adequate resources, including funding, to complete the project satisfactorily. That will usually mean that there is a research grant, which means in turn that the project has been subject to strict scientific scrutiny. The project must have been examined by appropriately qualified scientists and judged to be of good scientific merit.
- The Human Research Ethics Committee of the researcher's hospital, university or institution must have approved the project.
- When these requirements are satisfied, a decision whether to grant access to the Rare Tumor Database will be made by BioGrid Australia, which is ultimately responsible for the proper maintenance and use of the Database.

It is possible that information about the study might be published. However, no information that might identify the person for whom you are the next of kin will appear in these publications.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws you have the right to access the information collected and stored by the researchers about the person for whom you are the next of kin. You also have the right to request that any information with which you disagree be corrected. Please contact one of the researchers named below if you would like to access the information about the person for whom you are the next of kin.

Since this project will be set up to promote research, which by its very nature, is experimental and can take many years the data about the person for whom you are the next of kin will be kept indefinitely unless you choose to notify the researchers that you wish to withdraw their data from the project.

10. Are there any benefits or risks?

There may be no direct benefit to the person for whom you are the next of kin. However, their information will be used to produce clinical research studies and reports that may improve treatments in the future.

There is always a risk of maintaining privacy of personal information; however, we have paid a lot of attention to this and have a number of strategies to ensure that this risk is minimal.

11. Will I find out the results of the research using my information and tissue?

You will not be informed of the results of any research that is undertaken using information or tissue of the person for whom you are the next of kin. This is because research, by its very nature, is experimental, can take many years, and is highly unlikely to be of relevance to an individual patient.

12. Further Information or Any Problems

If you require further information or if you have any problems concerning this project, you can contact the BioGrid Australia office or the principal researchers:

BioGrid Australia Office	Telephone: +61-3-9342 2690 contact@cart-wheel.org
Dr Clare Scott	Telephone: +61-3-9345 2498
Dr Jayesh Desai	Telephone: +61-3-9342 7695

13. Other Issues

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about the rights of the person for whom you are the next of kin as a research participant, then you may contact

Name: ***Ms Jessica Turner***
Position: ***Manager, Human Research Ethics Committee***
Telephone: ***+61-3-9342 7602***

You will need to tell ***Ms Jessica Turner*** the name of one of the researchers given in section 12 above.

14. Participation is Voluntary

Participation in any research project is voluntary. If you do not wish to take part you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If the person for whom you are the next of kin is a patient of the Royal Melbourne Hospital, your decision whether to take part or not to take part, or to take part and then withdraw, will not affect their routine treatment, relationship with those treating the patient or their relationship with the Royal Melbourne Hospital.

Before you make your decision, a member of the research team or the BioGrid Australia office will be available so that you can ask any questions you have about the research project. You can ask for any information you want. Complete and submit the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers.

If you decide to withdraw the person for whom you are the next of kin from this project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to inform you if there are any health risks or special requirements linked to withdrawing.

15. Ethical Guidelines

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research* (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The ethical aspects of this research project have been approved by the ***Melbourne Health Human Research Ethics Committee***.

NEXT OF KIN ACKNOWLEDGEMENT FORM

Version #11, Date: 20th February 2017

Full Project Title: Collection of data from patients with rare tumor types or inherited rare tumor predisposition for the establishment of a Rare Tumor Database for ethically approved research projects.

Principal Researchers: Dr Clare Scott, Dr Jayesh Desai, A/Prof Peter Gibbs

---

I have read, and I understand the Participant Information Version #11, Date: 20th February 2017.

I acknowledge that the researchers would like to enrol _____ (participant's name) the person for whom I am the next of kin in the research project named above, according to the conditions in the Participant Information.

The researcher has agreed not to reveal _____'s identity and personal details if information about this project is published or presented in any public form.

Please read carefully and tick either YES or NO

1. I give my permission for the data of the person for whom I am the next of kin to be stored in the Rare Tumor Database and to be used in a re-identifiable (coded) way ☐ Yes ☐ No
2. I give my permission to the clinician of the person for whom I am the next of kin (full name of clinician) _____ to enter, view and edit their data in the Rare Tumor Database ☐ Yes ☐ No
3. I give my permission for BioGrid Australia to contact me for updates of the personal information of the person for whom I am the next of kin ☐ Yes ☐ No
4. I give my permission for BioGrid Australia to contact the doctor to obtain histologic report(s) and medical details to confirm tumor type or inherited rare tumor predisposition type of the person for whom I am the next of kin ☐ Yes ☐ No
5. I give permission for BioGrid Australia to contact me regarding participation of the person for whom I am the next of kin in an ethically-approved research project ☐ Yes ☐ No

Participant's Name (printed) _____

Name of Person providing Next of Kin Acknowledgement (printed)

_____

Relationship to Participant: _____

Signature ……..…… Date ……..…

Name of Witness to Signature (printed) _____

Signature ……..…… Date ……..…

PARTICIPATION IN A RESEARCH PROJECT other than CART-WHEEL

The person for whom I am the next of kin has enrolled to participate in the following research project and I give permission for CART-WHEEL study investigators to access their data:

Name of Project: _____

Located at (Research Organisation, Hospital or University):_____

_____

Research Project ID (optional, if known to you):_____

Participant's Name (printed) _____

Name of person providing Next of Kin Acknowledgement (printed)

_____

Relationship to Participant _____

Signature …..…… Date ……..……

Name of Witness to Signature (printed) _____

Signature …..…… Date ……..……

REVOCATION OF CONSENT FORM

Full Project Title: Collection of data from patients with rare tumor types or inherited rare tumor predisposition for the establishment of a Rare Tumor Database for ethically approved research projects.

I hereby wish to WITHDRAW my consent for the person for whom I am the next of kin to participate in the research proposal described above and understand that such withdrawal WILL NOT jeopardise any treatment of the person for whom I am the next of kin or their relationship with the Royal Melbourne Hospital.

Participant's Name (printed) _____

Next of Kin Name _____

Signature …..…… Date …….