Granulomatous Hypophysitis Disease Registry

Participant Information and Consent Form

This Participant Information and Consent Form is 4 pages long. Ensure you have all the pages.

1. Your Consent

You are invited to participate in an international study of patients with granulomatous hypophysitis. This Participant Information contains detailed information about the research project, to enable you to make an informed decision about whether or not you wish to participate in the research project.

Please read this Participant Information carefully. Feel free to discuss your potential participation with family and friends, and ask questions about any information in the document.

If you agree to take part in this research project, you will be asked to sign a Consent Form. By signing the Consent Form, you agree that you understand that your information will be entered into the Granulomatous Hypophysitis Disease Registry.

You will be provided with a copy of the Participant Information and Consent Form.

2. About Granulomatous Hypophysitis.

Hypophysitis (or inflammation of the pituitary gland, also called the hypophysis) is a relatively rare disorder, with an estimated incidence of one case per ten million people each year.

We are particularly interested in one form of the disease, Granulomatous Hypophysitis (GH), which accounts for around 25% of cases. Because the disease is so rare, little is known about the causes of the disease, or about how to best treat it.

GH is usually diagnosed by your doctor taking a history and performing an examination, along with blood tests and brain scans. The most common symptoms include headache and visual changes.

We expect that you are reading this because you doctor has informed you that you, or a close relative or friend, has been diagnosed with this condition, and she/he is asking you to provide consent for us to collect some information about your case.

Collection of case information is very important to help us compare the outcomes from different cases, and determine the best way to treat cases like yours.

The information that we would like includes the symptoms that you had, the results of any tests performed, your treatment and how you recovered from the treatment. All of this information is "de-identified," which means that it is made anonymous, and nobody can link this information back to you except your doctor.

We ask that your doctor fill in and submit the form, but the full questionnaire is available for you to see on the website.

While we would appreciate your consent to collect this information, it is entirely voluntary, and if you decide not to allow us to enter your information, it will in no way affect your medical care.

Any information collected is entirely confidential, and once your information is entered it is de-identified, so no-one else (apart from your doctor) can relate the information back to you personally.

You can ask you doctor any questions about your disease or about the registry.

3. Privacy, Confidentiality and Disclosure of Information

Information for this study will be kept locally on an electronic database which is stored on a secure, encrypted computer system. This database is only accessible by the GH Disease registry research team. Once your anonymised information reaches the Registry it may be used for studies of GH by participating GH researchers. Researchers participating will therefore only see coded information which does not identify you.

Any information obtained in connection with this project and that can identify you will remain confidential. It will only be disclosed with your permission, except as required by law. If you give us permission to use your anonymised information by signing the Consent Form, we plan to include it in the large international database (Registry) and use results related to the large groups of people in this Registry, for presentations at meetings or in publications.

The following information is **not** transmitted to the GH Disease Registry:

- Your name
- Your day of birth (month and year of birth is transmitted)
- Your address (the hospital or clinic you attended is transmitted)
- Any personal information which may identify you

4. Results

Outcomes of the studies conducted using information from the GH Disease Registry may be presented at scientific meetings and published in medical journals.

5. Other issues

If you have any questions about any aspect of the project then you may contact:

Name: Dr. Ben Hunn

Position: Chief Investigator, Granulomatous Hypophysitis Disease Registry

Telephone: +61 439 853 491

Email: Ben.Hunn@utas.edu.au

If you wish to make a complaint, please see the details provided in Section 7, Ethics.

6. 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.

7. Ethical Guidelines

This study has been approved by the Tasmanian Health and Medical Human Research Ethics Committee. If you have concerns or complaints about the conduct of this study should contact the Executive Officer of the HREC (Tasmania) Network on (03) 6226 7479 or email human.ethics@utas.edu.au. The Executive Officer is the person nominated to receive complaints from research participants. You will need to quote the approval number for this project, H0013267.

8. Reimbursements for your costs

You will not be paid for your participation in this research project.

CONSENT FORM

I have read, or have had read to me and I understand the Participant Information.

I freely agree to participate in this project.

I will be given a copy of the Participant Information and Consent Form to keep

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

Participant's Name (printed) ……

Signature Date

Name of Witness to Participant's Signature (printed) ……

Signature Date

Declaration by medical practitioner: I have explained the research project, its purpose and data gathered, and believe that the patient who has signed above has the capacity to give consent.

Medical Pracitioner's Name (printed) ……

Signature Date