[Date]

[Name]
[Address details]
[Suburb, State, Postcode]

Dear [Name],

I am writing to you on behalf of the Australasian Shunt Registry. The Registry has received notification from your neurosurgeon, that you, your child or a person for whom you act as guardian, has recently undergone a shunt related neurosurgical procedure. To ensure the success of the Registry, it is important that as many patients undergoing shunt-related procedures are included in the Registry. This letter is to provide you with information and to ask you to participate in the Australasian Shunt Registry.

What is the Australasian Shunt Registry?
Shunts are commonly used to treat hydrocephalus which is a swelling of the brain due to a build-up of cerebrospinal fluid. Hydrocephalus can be caused by a number of factors including infection, genetic abnormality, birth defect, injury, head trauma, or certain central nervous system tumours.
Shunt systems drain excess fluid from the brain to another part of the body where the fluid is absorbed. Shunt systems come in a variety of forms. They can be made of different types of materials and some may have a valve. The operation is very successful but complications, caused by infection, over or underdrainage, or misplacement can be common. Repeat surgery is often required.

The purpose of the Shunt Registry is to monitor how well shunts perform by recording information on every person having a shunt operation. Information collected will include the reason a shunt is required, frequency of operations, outcomes, and the reason why a shunt may fail. The information from the Registry is then used as tool for neurosurgeons to improve future patient outcomes by providing a resource for quality assurance and monitoring shunt performance and safety and it is hoped that the probability of adverse outcomes associated with CSF shunts can be reduced.
Overall, the registry aims to improve patient safety and quality of care for patients with hydrocephalus and related conditions by monitoring and analysing the procedures performed throughout Australia. To be successful, the Registry needs to collect information on as many shunt surgeries as possible and so we are asking for your participation by allowing us to record the required information.

What information is recorded?
The information recorded in the Registry includes the name, address, date of birth, gender and hospital record number of the patient. It also includes the name of the neurosurgeon as well as information pertaining to the type of shunt or shunt components implanted or removed. The Registry records the clinical reasons for why the operation was necessary such as the type of hydrocephalus or other diagnosis and if a pre-existing shunt was blocked or infected.

How is the information recorded?
Although we are asking to record operation details in the Registry, <u>you are not required to do anything</u>.
Immediately after the shunt-related procedure, the neurosurgeon completes a Shunt registry data collection form which contains the same information that is kept in your/your child's medical record. The completed form is then securely forwarded to the Neurosurgical Society which houses the Registry and the information entered into the secure electronic database.

We will keep your information confidential
Privacy is of upmost importance to us. All information is held in a secure, encrypted and password protected database and can only be accessed by authorised Shunt Registry staff. All data will be handled in accordance with the Australian Privacy Principles. The combined information from the registry will be published and reported periodically.
<u>There is no information published in the reports that will allow identification of any individual.</u>

Risks and benefits
We hope that the results from this study will provide information that will improve the quality of outcomes for patients that undergo shunt related surgeries in the future. The reports generated from the Registry will be used to examine and compare the performance of various types of shunts and their components, as well as other outcomes such as infection rates and shunt revision rates.
There are no risks to you/your child having their details in the Registry.

Participation
Participation in this project is voluntary. The care provided to you/your child will not be affected in any way whether or not you choose to participate in the Registry. Should you wish not to participate in the Registry, please complete the enclosed Opt Out form and return to us in the Reply paid envelope provided (or send to Shunt Registry, Reply Paid 90824 Melbourne 3000), email the Shunt registry (shunt.registry@nsa.org.au) or fill in the opt-out form on our website [www.shuntregistry.com.au]. You may choose to remove some or all of your information.

Sincerely

Dr Mark Dexter
Neurosurgeon
Chair, NSA Registry Committee

This project has been approved by [insert name of ethics committee]. If you have any concerns about the conduct of this study, please do not hesitate to contact the Executive Officer of the Ethics Committee [insert ethics committee number] and quote number [insert ethics approval number]