

Personal Data Protection Notice

Background to National Renal Registry Malaysia (NRR)

- The NRR is an ethically approved clinical quality registry containing patient data collected for the express purpose of contributing to improved patient treatments and outcomes
- The NRR is an independent non profitable organization operated under Malaysian Society of Nephrology in collaboration with Ministry of Health Malaysia. The aim is to improve patient care.
- The collection, use, disclosure and access to data are all conducted in accordance with legal, ethical and national best practice guidelines

Malaysian Personal Data Protection Act 2010 (Act 709) – NRR compliance

1. General, Notice & Choice, Disclosure Principle

- Data submission to NRR is a requirement by Private Healthcare Facility Act 1998
- The Renal Registry has been approved by Medical Research and Ethics Committee (MREC), Ministry of Health with the NMRR Research Registration ID: NMRR-08-1587-2618.
- Through the approval, NRR has received approval for waived informed consent. Participation can be indicated by Public Notice.
- All the relevant NRR approved ethics documents, forms and policies are available on the NRR website and can be referred from <http://www.msn.org.my/nrr/documents.jsp>
- Open and transparent management of personal information
- Patient consent to participation is not required
- Submission to NRR falls under Non Application category of PDPA. NRR collects data for statistical purpose non-commercial purpose and is classified under Exemption Category of PDPA.
- All patients registered with NRR are eligible to be listed in Malaysian deceased donor recipient waiting list by default

2. Open and transparent management of personal information

- The NRR website provides the NRR Office contact details in the event of questions, concerns and complaints about the NRR.
- States that the NRR is not permitted to identify patients by law and that, to maintain absolute security and confidentiality, anyone wanting to use any of the data from the Registry will be required to obtain the approval in accordance to data request guidelines as stated in the website http://www.msn.org.my/nrr/data_request.jsp.

- The NRR Centre Participation in National Renal Registry Consent form addresses the policy and guideline for the participating to abide by. They have the ultimate responsibility for appropriately collecting and maintaining the NRR data, including ensuring privacy and confidentiality of their own patient's data.
- All personal information is kept strictly confidential: all data will be anonymised and aggregated in any presentations or publications and no patients or hospitals will be identified by name in reports.
- The Data Security Policy explains the security related to the collection, storage and accessibility of the information in the Registry.

3. Anonymity and pseudonymity

- Anonymity and pseudonymity is impracticable for the NRR as identification of individuals is required in order to:
 - i. Make the necessary changes to patients' records e.g. opting-out from the registry; editing erroneous data, deceased donor kidney recipient waiting list
 - ii. Due to the nature of the renal disease, cohort follow up of the patients is required
- However anonymity is preserved in the way that the data are used e.g. reports, presentations.
- Patients can opt-out their personal data at any time, with just an ID code remaining in the system.

4. Collection of solicited personal information

- The NRR collects personal information which is directly related to its functions and activities. Public Notice is available at participating centres.
- The NRR has all the appropriate ethics/governance approvals in place including approval of an opt-out process for participation, which is the gold standard for registries. This model presumes that patients will be willing to be included in the NRR. Patients are advised that they are / will be in the NRR but they are able to opt-out any of their personal information from the NRR at any time.
- Data collection does not occur without prior ethics approval from Medical Research and Ethics Committee (MREC), Ministry of Health with local research governance.

5. Dealing with unsolicited personal information

- Hospital staff can enter only required information on the NRR web tool.
- NRR staff only enter follow-up data provided by the patient or their proxy.

6. Use or disclosure of personal information

- The NRR data are summarised to provide information that can inform clinical practice and policy in renal related diseases care. All data reported are de-identified and aggregated.
- The NRR team is guided by the NRR Data Access Policy which outlines how data may be used and supplied.
- Any persons wishing to undertake research using NRR data need to submit a proposal for review by the NRR Advisory Committee, as well as having appropriate ethical clearances. Data are only supplied to researchers, in approved studies, in a non-identifiable format.
- Identifiable data are only used for data linkage or data quality checking processes by authorised staff/entities according to appropriate approvals for data linkage and the NRR Quality Assurance and Data Management Processes Policy e.g. ethics approved linkage with the Jabatan Pendaftaran Negara (JPN) (National birth and death registration authority).
- All NRR personnel sign a Confidentiality Agreement.
- All ENRR users sign a User Agreement which outlines the user policy.

7. Cross-border disclosure of personal information

- The NRR server and backups are maintained in Malaysia. No data are held offshore.

8. Quality of personal information

- The NRR Quality Assurance and Data Management Processes outlines the data verification processes employed by the NRR.
- NRR conducts regular reviews of data completeness and discrepancies for determining case ascertainment. Data quality checks are also built into the NRR Web application to ensure the quality of the data submitted.
- Training centre staff in data entry and use of the NRR Data Definition Dictionary takes place before any live data are entered. Site visits and data quality audits of randomly selected medical records are used to verify the accuracy of data collected by the NRR. Centre users have been informed to ensure to enter only true and correct information, provide timely and accurate data and provide timely response to data query.
- Information is provided in the NRR annual reports on the quality of the aggregated, de-identified data in the registry e.g. proportion of missing data per field.

9. Security of personal information

- The NRR Data Security Policy provides guidelines for all security-related aspects for the registry.

- NRR data are collected via a web tool that requires password access with varying levels of authority. The database itself is protected by Secure Sockets Layer – the highest available level of security.
- The servers are maintained in a secured data centre with state-of-the-art facilities in Cyberjaya. Data centre security: Biometrics authentication for access to server storage area, CCTV, Pyrogen Fire Suppression System, Uninterrupted Power Supply. Besides that, the servers are also secured by server hardware and softwares such as firewall, Intrusion Detection System, Antivirus.
- Personal information are encrypted and deidentified in the database.
- Any hard copy data are stored in locked cabinets contained within NRR Office in a building with swipe card access.
- All NRR staff, data analysts and Management Committee members sign a Non Disclosure Agreement whereby they undertake to maintain the confidentiality of any data that they access in the NRR.
- Centre Users can only access data for their own site. Each authorized user in the centre have their own user account and is accountable for their own logins. All activities in the web application are audited.
- It is important to update NRR Secretariat whenever there is a change in your personal information like mobile number and e-mail address and centre's information like centre address.
- If any staff who has access to NRR web application has left your centre or should no longer access to your patient record, please inactivate their access right accordingly or update NRR whose access should be terminated.
- Data are backed up on a daily, weekly and monthly basis. Business continuity plan is in place in the event the web application is down.

10. Access to personal information

- The Registry Forms provides details on the demographic and renal related diseases information entered into the NRR (which stipulates that the data are available from their hospital record).
- Personal details are reported by participating centres.
- Patients may contact the centre which they received treatment from (which act as data custodian) about their data.

11. Correction of personal information

- To ensure that any missing or discrepant data are corrected, the NRR conducts regular data cleaning activities in consultation with the hospital staff.
- A systematic data quality audit process is also in place.
- All inaccurate information is amended by the NRR office when it is notified or becomes aware that particular information is incorrect.
- An audit trail of web tool edits is maintained within the database.
- Registrants can amend their personal details in MyProfile.

12. Data Retention

- By NRR Advisory Committee's decision, paper based hardcopy data forms will only be kept for 3 years.
- Softcopy data since beginning will be retained permanently.