



## **Protocol on the processing of personal data**

### **From the non-statutory Inquiry into the licensing and use of the sodium valproate in women of child-bearing potential in the State.**

#### **Aim of this protocol**

The Inquiry aims to establish the facts surrounding the licensing, regulation, prescribing and historical use of sodium valproate in the State. As part of this Inquiry, personal data and special category data will be collected and processed to as part of the review. The processing of personal data and special category data will be necessary to allow individuals to tell their specific story and circumstances. In furtherance of the Terms of Reference, the Chair will oversee the proper management of records generated during the Inquiry.

The aim of this protocol is to inform participants as to how the Inquiry will collect, process, store and retain their personal data throughout the Inquiry process and upon the cessation of its work.

#### **Who is a Participant in the Inquiry process?**

A 'Participant' means a person who is participating in the Inquiry, whether due to their status as a person with a diagnosis of foetal valproate spectrum disorder (FVSD), (or on the diagnostic pathway), the mothers and other family members of such persons, or otherwise, and includes children.

#### **From whom else will personal data be received by the Inquiry?**

##### *Unsuccessful Participants*

The Inquiry may receive personal data from individuals who wish to participate in the Inquiry process, but who are deemed by the Chair as ineligible to qualify as Participants. Individuals who do not qualify as Participants will be written to by the Inquiry to communicate this decision. If any medical or health records have been furnished to the Inquiry by the individual, this will be returned to the individual where possible. If it is not possible to return this documentation containing sensitive information to the sender, the Inquiry may destroy same.



The Inquiry may retain the name, address, contact details and date of birth of the unsuccessful participant until the cessation of the Inquiry. By the cessation of the Inquiry, this information will be destroyed.

### *Stakeholders*

A ‘stakeholder’ includes, but is not limited to, those bodies and organisations set out at Appendix 1 to the Terms of Reference of this Inquiry. Submissions and documentation may be received by the Inquiry which contains the personal data of data subjects.

### **What legal basis does the Inquiry have for collecting personal data?**

The lawful basis for processing the data required by the inquiry, including individual personal data, is the in performance of an Official or Public Task. The legal basis for processing personal data is enabled by regulations made under S.38(4)(b), S.51(3) and S.60(6) of the Data Protection Act 2018. The regulations were made by way of [statutory instruments S.I. 350 of 2025, S.I. 351 of 2025 and S.I. 352 of 2025](#) signed on the 21<sup>st</sup> of July 2025.

Personal data will be shared by a data subject on a voluntary basis. A Participant’s rights under the General Data Protection Regulation may be restricted pursuant to S.I. 352 of 2025. Where a Participant provides personal data to the Inquiry, their rights may be restricted where the Inquiry deems it necessary, and only for so long as is so necessary, to safeguard a relevant objective, such as the execution of the Terms of Reference, or where it is proportionate to the need to safeguard that objective.

The Minister for Health and the Inquiry Chair are Joint Controllers for the processing of personal and special category data. A Joint Controller Agreement was signed between the Minister for Health and the Chair of the Inquiry on the 21<sup>st</sup> of July 2025.

### **What personal data will the Inquiry collect?**

Those seeking to participate in the inquiry will initially contact inquiry staff either by phone, by email (to [info@svinquiry.ie](mailto:info@svinquiry.ie)), by post or via the [online query form](#) on the Inquiry’s website. To enable the Chair to evaluate whether an individual or family member may participate in the



inquiry (in accordance with the Terms of Reference), inquiry staff will collect the following information in initial and follow up correspondence.

- *A person diagnosed with FVSD, or on diagnostic pathway for FVSD:*
  - Name;
  - Date of birth;
  - Address;
  - Phone number;
  - Email address.
  - Status of FVSD diagnosis or referral, including clinical documentation.
- *A mother of person with a diagnosis of FVSD, or on diagnostic pathway for FVSD:*
  - Mothers name;
  - Mothers Address;
  - Confirmation mother took sodium valproate during that pregnancy, including clinical documentation where necessary;
  - Name of affected child;
  - Date of birth of child;
  - Address of child;
  - Status of child's FVSD diagnosis or referral, including clinical documentation.
- *Parent, guardian, or family member to act as point of contact for communications with the inquiry (i.e. the person making initial contact):*
  - Family member Name;
  - Family member Date of birth;
  - Family member Address;
  - Family member Phone number;



- Family member Email address.
- *Financial Supports*
  - A bona fide Participant who engages with the Inquiry or appears before the Inquiry, at its invitation, is entitled to claim for the payment of some expenses reasonably incurred by reason of that engagement/attendance. The Inquiry aims to ensure there is no financial impediment to a Participant engaging with the Inquiry and assisting it in its functions. In the exercise of this function, the Inquiry may pay some necessary and reasonably incurred expenses in accordance with its internal guidelines for the payment of expenses. In some instances, it may be necessary for the Inquiry to seek the bank account details necessary to make payment of expenses. These details will be destroyed at the cessation of the Inquiry.
  - In a case of undue hardship where a Participant may not be able to discharge expenses upfront, the Inquiry may seek a summary of the Participant's financial circumstances. These details will be destroyed at the cessation of the Inquiry.
- *Counselling supports*
  - Any personal data collected by a psychotherapist working at the direction of the Chair, or any other suitably qualified person engaged on behalf of a Participant, will be in given in strictest confidence. The Chair, nor the Inquiry staff will process any information or data received by the relevant psychotherapist. Any confidential materials, such as questionnaires, that are received by a psychotherapist in the course of their work on the Inquiry, shall be returned to the Inquiry once its evidential function has been completed. Such material will be returned to the Inquiry office in a sealed box and stored until the cessation of the Inquiry. On the cessation of the Inquiry, any such personal data will be destroyed upon the direction of the Chair.



- *Oral Statements and submissions*
- The Inquiry will receive personal histories and experiences of those affected by FVSD, primarily from participants and families. This information will be given to the Inquiry at oral interviews to be conducted in private. The Inquiry may also receive written statements or where practicable, video or audio statements from Participants.
- Written submissions compiled by stakeholders, to reflect the views of any participants for whom oral or written history may not be appropriate, with the consent of those participants.

### **What is special category data?**

Certain types of sensitive personal data are subject to additional protection under the General Data Protection Regulation. These are listed under Article 9 of the GDPR as “special categories” of personal data. The special categories are:

- Personal data revealing racial or ethnic origin.
- Political opinions.
- Religious or philosophical beliefs.
- Trade union membership.
- Genetic data and biometric data processed for the purpose of uniquely identifying a natural person.
- Data concerning health.
- Data concerning a natural person’s sex life or sexual orientation.

The Inquiry is authorised to process special category data pursuant to S.51(3) of the Data Protection Act of 2018 and statutory instrument [S.I. 351 of 2025](#) in so far as it is necessary for, and proportionate to, the substantial public interest.

### **How will personal data be stored by the Inquiry?**

- Any data in hard-copy format will be stored in secured offices within the inquiry’s premises.



- Any electronic data will be stored on dedicated Microsoft OneDrive folders with the appropriate levels of security and encryption restricting access to key staff only.
- In accordance with its obligations under the Terms of Reference the Inquiry has completed a Data Protection Impact Assessment.

### **Who has access to the personal data?**

Neither the Minister for Health nor the Department of Health, will have access to any personal data while the non-statutory inquiry is being conducted, nor while the final report is being prepared.

The inquiry Chair and team will process the data independently of the Minister for Health and her officials and will have autonomy in determining processing actions in furtherance of delivering a final report.

The Inquiry will not share any personal data with any party outside of the inquiry Chair, inquiry staff, and authorised third parties working on the instruction of the Chair, such as a stenographer, an interpreter or a clinical psychologist.

Personal data submitted through the inquiry website's 'Contact Us' form will be stored on the server of Fusio Holdings Limited ("Fusio"), the Inquiry's website designer and host, for 14 calendar days from the date the form is submitted. Access to this personal data is restricted to those employees of Fusio who support the Inquiry's website.

### **Where is the personal data stored?**

- *Hard copy data*
  - Any data in hard-copy format is stored in secured offices within the inquiry's premises. The premises are protected by a fob key entry system and personal data will be stored securely.



- Digital data
  - Digital data is stored on dedicated Microsoft OneDrive folders with the appropriate levels of security and encryption restricting access to key Inquiry staff only. The Inquiry's server is located within the EU.

OneDrive is a cloud storage service that protects data in the cloud using multiple security features including:

- security monitoring systems and automation
- suspicious activity monitoring
- ransomware detection and recovery
- version history for all file types
- virus scanning
- content protection using file encryption
- password protected and expiring sharing links
- mass file detection notification and recovery
- two-factor authentication

- *Inquiry website*
  - The server of Fusio Holdings Limited is located within the EU.
  - The website is firewalled using WordFence security system. Fusio also utilise Two Factor Authentication for user logins to minimise the risk of a data breach.

### **Can personal data be used for any other purpose?**

Personal data collected, processed and stored by the Inquiry may only be used in so far as it is reasonably necessary to execute the terms of reference.



### **Will my personal data be included in an interim or final report to the Minister for Health?**

The Chair may, at her discretion, refer in her interim and/or final report to the Minister for Health, to the oral testimony of Participants. The Chair may utilise the following methods to protect the personal data of participants.

- Redaction
- Anonymization
- Pseudonymisation

It is not intended, that the Chair will provide the personal details of any Participant in the interim and/or final report.

The terms of reference of the Inquiry provide that the Minister for Health may, subject to legal advice, provide stakeholders (including individuals and families who gave oral testimony) with a confidential copy of the final report in advance of the publication.

### **What will happen to personal data on the cessation of the Inquiry?**

At the cessation of the Inquiry, decisions will be made regarding the disposal or retention of records, balancing data subjects rights with the Minister for Health's obligations under the National Archives Act 1986 and the National Archives (Fees) Regulations 1988. The Chair will also evaluate what documentation, and personal data may be destroyed and what data is worthy of permanent preservation by the National Archives.

On or before the delivery of a final report to the Minister, the Chair may engage with the National Archives to categorise documentation which is worthy of consideration for permanent preservation in the National Archives. In this regard, the Chair will act as a 'certifying officer' for the purpose of compliance with the National Archives Act and Regulations.

Documents and data relating to a Participant's engagement and/or stakeholder submissions may be deemed by the Chair to be worthy of permanent preservation in the National Archives.

Upon dissolution of the Inquiry, the inquiry's records will be transferred to the Department of Health and will remain closed for thirty years. After thirty years, the records of the Inquiry will be transferred to the National Archives and may be made available for inspection by the public under section 8 of the National Archives Act, 1986.





**Helpful contact information:**

- Data Protection Officer  
Sodium Valproate Inquiry  
7/8 Mount Street Upper  
Dublin 2  
dataprotection@svinquiry.ie
  
- Data Protection Commission  
6 Pembroke Row  
Dublin 2

Signed:

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Bríd O’Flaherty BL

Chair

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