PBC Ireland – Patient Registry

Data Use Policy

1. **Purpose**
   The purpose of this Data Use Policy is to outline how data from the PBC Ireland Patient Registry may be accessed, used, and shared for research, advocacy, and policy development. The policy ensures that all use of registry data protects participant confidentiality, aligns with their informed consent, and complies with ethical and legal standards.

2. **Guiding Principles**
   - **Patient-Centred**: The registry exists to amplify the voices and experiences of people living with PBC in Ireland.
   - **Privacy-First**: All shared data is de-identified or anonymised to prevent re-identification.
   - **Ethical Oversight**: The registry operates under IRB approval (U.S.-based) and follows GDPR and international best practices.
   - **Transparency & Accountability**: All data use must be documented and approved in advance.

3. **Eligibility to Access Data**
   Requests to access data may be considered from:
   - Academic researchers (in Ireland or internationally)
   - Health economists or policy analysts
   - Patient advocacy groups
   - Regulatory agencies
   - Pharmaceutical or biotech companies (with clear patient benefit)

   Researchers based outside of Ireland are welcome to apply, provided they comply with this policy and any relevant data protection laws in their jurisdiction.

   Applicants must demonstrate:
   - A legitimate research or public interest purpose
   - Alignment with the goals of the registry
   - The ability to comply with data protection standards

4. **Types of Data Available**
   Only de-identified or anonymised datasets will be shared. These may include:
   - Demographic data (e.g. age at enrolment, sex)
   - Self-reported survey responses (e.g. symptoms, quality of life)
   - Aggregated results from validated instruments (e.g. PBC-10, Fatigue Scales)

   No identifying information (e.g. name, date of birth, email, IP address) will ever be shared.

5. **Data Use Agreement (DUA)**
   All approved users must sign a Data Use Agreement outlining:
   - Scope and limits of data use
   - No re-identification of individuals

- Secure storage and access protocols
- Obligations to acknowledge PBC Ireland and share results or publications back with the registry

6. Review and Approval

Data access requests are reviewed by the registry coordinator (or advisory panel, if formed). Decisions will consider:

- Scientific merit or public value
- Ethical alignment with registry purpose
- Resource implications

7. Publication and Acknowledgement

Publications using registry data must:

- Acknowledge PBC Ireland Patient Registry as the source
- Share a pre-print or published copy with the registry team
- Include a disclaimer (if applicable) that the views are those of the authors, not PBC Ireland

8. Revisions and Updates

This policy may be updated periodically. The most recent version will be available at https://pbcireland.org .

Signed on behalf of PBC Ireland:

Name: Gerry Nesbitt, Founder PBC Ireland

Signature: ____________________ Date: 25th July 2025