PBC Patient Registry
Statement on Ethical Oversight

PBC Ireland Patient Registry

The PBC Ireland Patient Registry is a patient-led initiative established to collect patient-reported data from individuals living with Primary Biliary Cholangitis (PBC) in Ireland. Its purpose is to better understand the lived experience of PBC, support advocacy efforts and contribute to future research.

1. Ethical Approval

This registry has received ethical approval from an independent Institutional Review Board (IRB) based in the United States. The IRB is registered with the U.S. Department of Health and Human Services (HHS) and operates in accordance with international ethical guidelines including the Declaration of Helsinki.

2. Scope of Data Collection

The registry collects **self-reported, non-identifiable data** directly from participants via secure online forms. No clinical data is obtained from hospitals, healthcare providers or third-party sources. Participants are not recruited through hospitals or the HSE, and no intervention or treatment is involved.

3. Informed Consent

All participants are provided with a clear, accessible Participant Information Sheet and Consent Form before enrolling. Consent is explicitly obtained online, and participants may withdraw at any time without consequence.

4. Data Privacy and GDPR Compliance

All data are stored securely on a GDPR-compliant platform hosted in Ireland. Identifiable personal information (e.g. name, email) is stored separately from survey responses. No identifiable data are shared with third parties. Data extracts made available for approved research are fully anonymised and subject to a strict Data Use Agreement.

5. Why Irish REC Review Is Not Required

The registry does not involve clinical intervention, institutional collaboration, or access to health records in Ireland. It is a **patient-led observational project** collecting self-reported information under international ethical oversight. As such, formal approval by an Irish REC is not a regulatory requirement under current guidance.

6. Collaboration with Irish Academic Institutions

We are fully open to working with an Irish academic research institution that wishes to collaborate on publications and future studies using registry data. Should such a partnership arise, we would welcome the involvement of a recognised Irish Research Ethics Committee (REC) to ensure local oversight and compliance with institutional requirements. Our goal is to enable high-quality research while maintaining the highest standards of patient privacy, consent and ethical governance.

Gerry

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For more information or to view the IRB approval documentation, please contact:

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