



Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

Privacy Notice

“Investigating the Epidemiology of *Mycobacterium bovis* infection in humans”

Introduction

We would like to draw your attention to a research study which is being carried out by St James's Hospital and Trinity College Dublin, between May 2022 and May 2024

Bovine Tuberculosis, a form of TB caused by *Mycobacterium bovis*, was a common disease in Ireland prior to pasteurization of milk and programmes to eliminate this infection in cattle herds. Despite efforts to eradicate the disease in Ireland, human infection with *Mycobacterium bovis* remains a public health concern, with 7 cases diagnosed in Ireland in 2019.

We hope the study will help us to gain a better understanding of *Mycobacterium bovis* infection and its transmission in Ireland to inform public health policy. This notice is being issued to explain how to find out more information about the research study.

This notice outlines the use of health information contained participants medical records for this study and the steps taken by St James's Hospital (SJH) and Trinity College Dublin (TCD), to protect your information and safeguard your rights under data protection legislation, (specifically the EU General Data Protection Regulation (GDPR) and Data Protection Acts 1988-2018).

SJH and TCD fully respect your right to privacy and actively seek to preserve your rights. Any personal information which is used for this study, will be treated with the highest standards of security and confidentiality, in accordance with data protection legislation.

In the following paragraphs we set out information in relation to the following:

- The Data Controllers.
- The Data Protection Officer (DPO).
- What Personal Data we collect.
- What we use your Personal Data for.
- How long will we hold onto your Personal Data.
- Who will have access to your Personal Data.
- International data transfers.
- Your rights.
- How we keep your Personal Data secure.
- Legal basis for processing Personal Data.
- Complaints.

The Data Controllers

SJH is the Data Controller of your medical records. SJH and TCD are joint controllers of the information taken from your medical records for this research project. A Data Controller is the legal entity which

determines how and why personal data is collected and used.

The Data Protection Officer (DPO)

The hospital DPO can be contacted directly at dataprotection@stjames.ie or Tel: 01 410 3021.

What personal data is collected?

Personal data means any information about you which allows you to be identified. The study intends to use information taken from 80 to 100 patients who were diagnosed with *Mycobacterium bovis* infection between 2000 and 2020 and who had their microbiological specimens processed by the Irish Mycobacteria Reference Laboratory (IMRL), located in SJH. The IMRL receives microbiological specimens from hospitals across Ireland.

The following information will be accessed and shared for this study:

- Age category, gender, country of birth, co-morbidities, rural or urban dwelling, time since entry to Ireland if foreign born, occupation.
- Site of TB disease, previous history of TB diagnosis and use of immunomodulatory medications.
- Potential past exposures to *Mycobacterium bovis*: e.g. Contact with a human TB patient, travel (for >2 weeks) to or residence in a country with high TB incidence, consumption of unpasteurized milk product, occupational contact with animals, physical contact with wild animals, pets and physical contact with any animal with TB.
- Your personal data will be **pseudonymised** during collection. This means any identifiers, e.g. name, DOB, address, will be removed and replaced with a code. The code will be kept securely by the research team until its deleted therefore fully anonymizing the data.

We will extract the bacteria itself, *Mycobacterium bovis*, from samples provided by patients at time of diagnosis, and undertake further testing with whole genome sequencing (WGS). WGS is a novel technology that allows a more detailed analysis of the bacterial genomic material and allows high resolution comparison with other strains of *M. bovis* to assess for any epidemiological links.

What we use your personal data for?

The data collected from you for this research study will only be used for this research study which we hope will allow us to better understand *Mycobacterium bovis* infection in Ireland, and why there has been a rise in human *M. bovis* infections in recent years.

How long will we hold onto your personal data?

Your personal data will be retained for 2 years during the collection and analysis phase of the study prior to being anonymized. All patient information will be fully and irrevocably anonymised following analysis of the data.

Who will have access to your personal data?

Your personal data will only be made available to the following individuals:

- M.D Candidate: Dr Mary Mansfield
- Project Investigators: Prof Tom Rogers and Dr Margaret Fitzgibbon
- IMRL Scientists: Dr Peter Flanagan and Dr Emma Roycroft

Will my personal data be transferred outside of the European Economic Area (EEA)?

No – We do not intend to transfer any personal data collected for the purpose of this study outside the EEA.

What are your Rights

If you have been diagnosed with **bovine TB** and fit criteria outlined above, your samples and information may be included in this study. Please contact us using the details provided should you have any questions or concerns about this, or should you wish that your samples/information be excluded from this study. If you do not contact the hospital to request not to be included, we will presume you are happy for your personal data and bio-samples to be used for this research study.

Under certain circumstances, by law you have the right to:

- **Right of access** – you have the right to request a copy of the information that we hold about you.
- **Right of rectification** – you have a right to correct data that we hold about you that is inaccurate or incomplete.
- **Right to be forgotten** – in certain circumstances, you can ask for the data we hold about you to be erased
- **Right to restriction of processing** – for example, if the information we have on file is inaccurate
- **Right to object** – you have the right to object to our use of your information for this research study.

If you wish to exercise any of these rights, then please submit a request to aio@stjames.ie. When submitting a request, the hospital will need information from you to confirm your identity.

How do we keep your personal data secure?

Personal data is stored confidentially and securely as required by the ICT Security Policy and Data Protection Policy. SJH is committed to ensuring that your data is safeguarded by appropriate technical and organisational security measures relevant to the processing in accordance with Article 32 GDPR requirements. When we store your personal data on our systems the data will be stored either on SJH premises or on secure IT platforms within the EEA.

What is the legal basis for processing?

We rely on this research being in the public interest (Article 6(1)(e) & 9(2)(j) of the GDPR).

Changes to this Privacy Notice

This Privacy Notice may change from time to time and any changes to the Notice will be communicated by way of a notice on the internet/intranet and public notice boards in the hospital.

Making a complaint

In the event that you wish to make a complaint about how your personal data is being processed by us for this research project or how your complaint has been handled, you have the right to lodge a complaint directly with the [Data Protection Commission](#).