



## Estimating the burden of zoonotic tuberculosis in Southwest England: The ZooTB Study Study Information and Invitation

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### About the study

We are investigating whether people who work with cattle infected with bovine TB develop an immune response to bovine TB themselves. We are asking around 160 people who have been in contact with TB-infected cattle to take a blood test, this will determine if you have a latent TB infection. We will also ask about your interaction with cattle and milk products, allowing us to investigate how bovine TB may be spread from cattle to humans. This research follows on from a pilot study we conducted in October 2021 at The Dairy Show.

### Why is this research important?

Each year in the UK, 30 to 40 people are diagnosed with TB due to *M. bovis* – the main cause of TB in cattle. *M. bovis* disease in people is known as zoonotic tuberculosis, which is why the study is called ZooTB. The symptoms of zoonotic TB are similar to other TB symptoms in people: a persistent cough, weight loss, fever, loss of appetite. We do not have an accurate estimate for the number of people who might have been exposed to *M. bovis* as a result of their occupational risk i.e., working with TB infected cattle - this study will help answer this.

### Who can take part?

Anyone aged over 18 years and who has worked with confirmed TB-infected cattle located in Southwest England can take part.

### What will happen if I take part?

Taking part involves:

- 1) Completing the consent form online** (accessed via the link at the end of this document)
- 2) Completing a short questionnaire about you and your contact with cattle:** The questionnaire can be completed in advance online or at the study site. This will take about 15 minutes to complete.
- 3) Providing a blood sample:** You will have a blood sample taken by an experienced phlebotomist at a study site.

As a thank you for taking part we will provide you with either a £5 food and drink voucher or equivalent light lunch/supper at the event.

### Where are the study sites?

We will host study test days at agricultural shows and events in Southwest England. Details of upcoming study test days will be listed on the study website: [www.bristol.ac.uk/zootb](http://www.bristol.ac.uk/zootb)

### What do I do next if I want to take part?

Additional study details are listed on the next page of this information sheet. *Please read these carefully.*

If you would like to take part in this study, click on the link (or copy and paste/type into your web browser)

<https://redcap.link/zootb>

Participation in the study is completely voluntary and there is no obligation to take part. If you have any questions, please get in touch with us directly at the study site or using the contact details at the top of this letter.

Thank you for finding out about the ZooTB study.

Drs Amy Thomas and Ellen Brooks-Pollock (study investigators)



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### Should I take part if I have no symptoms?

Yes, please! People with latent TB infection don't have any symptoms. Most people (90%) will never go on to develop symptoms. We are using the latent TB test to determine the risk of exposure to *M. bovis* in farmers and people who work with cattle. This will be important for the 10% who may go on to get symptoms.

### How will my blood sample be used?

After collection, your blood sample will be transported to North Bristol NHS Trust laboratory, where it will be tested for evidence of latent TB using the Interferon Gamma Release Assay (IGRA). This test assesses if you have been previously infected with *Mycobacterium sp.* by measuring an immune response to the bacterium. The test will be started as soon as the laboratory receive the sample. No information that could identify you would be given to anyone using the samples. Once the test has been completed, usually within 3 days after sample collection, your blood sample will be destroyed. However, you can consent for an optional extra blood sample to be collected and donated to the Bristol Biobank (<https://directory.biobankinguk.org/Profile/Biobank/GBR-1-112>), so that it can be used for further research relating to infection and immunity.

### What laboratory test will we conduct with your blood sample?

One method to assess if someone has been previously infected with *Mycobacterium sp.* is to measure a person's immune response to the bacterium using a blood-based test, called the Interferon Gamma Release Assay (IGRA).

### What will happen if I get a positive test?

We will inform you and your GP if your IGRA blood test is positive. A positive IGRA means that you likely have latent TB, caused by previous infection with either the bovine TB bacterium (*M. bovis*) or the human TB bacterium (*M. tuberculosis*). The majority of individuals with latent TB never develop any problems, but a small proportion may develop symptoms and benefit from treatment. Even if you do not develop symptoms, you might want to discuss this further. We would recommend contacting your GP, who can refer you to the local TB service if required.

### What will happen if I get an indeterminate or negative test?

We will inform you and your GP if your IGRA blood test is indeterminate. An indeterminate test means that we can't conclude that your blood sample is negative or positive. Even if you do not develop symptoms, you might want to discuss this further. We will inform only you if your test is negative. A negative test result indicates that *Mycobacterium* infection is unlikely.

### What are the possible benefits if I take part in the study?

By taking part you will be directly contributing to advancing our knowledge of zoonotic TB in the UK farming community. This will help improve policy and measures to support bovine TB and zoonotic TB control.

### How will we use information about you?

We will need to use information from you for this research project. This information will include your: initials, name, date of birth, contact details and GP contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.



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### What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study (data will be transferred to the University of Bristol Research Data Storage Facility [RDSF]. The RDSF provides secure, RCUK compliant long-term storage for research data).

### Where can you find out more about how your information is used?

You can find out more about how we use your information by contacting the research team (contact details are on page 1) or the University of Bristol Data Protection Officer ([data-protection@bristol.ac.uk](mailto:data-protection@bristol.ac.uk)).

### Can I withdraw from the study?

You can stop being part of the study at any time, without giving a reason.

### Who is responsible for this research?

Scientists are conducting this research under the responsibility of the University of Bristol. The study has been approved by the NHS Research Ethics Committee (Ref: 21/YH/0241) and it is funded by The Wellcome Trust.

### What if something goes wrong or I wish to complain?

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this study, please contact the study team (contact details on page 1). If you have any further complaints or concerns, you can contact the Research Governance Team, University of Bristol, Trinity Street, One Cathedral Square, Bristol, BS5 5DD ([research-governance@bristol.ac.uk](mailto:research-governance@bristol.ac.uk)). In the very unlikely event that you are injured there is no automatic insurance protection to compensate you, but you can still make a legal claim, the University has Public Liability Insurance that covers its legal liability in relation to study participation.

**Thank you for taking the time to read and consider this information.**