**<To be printed on Trust headed paper>**

**TB-DILI trial**

**Informed Consent Form**

Version v1.1 14 Jul 2022

**Name of Principal Investigator**:

**IRAS Project ID:**

**Participant Study ID:**

(To be completed after randomisation)

|  |  |
| --- | --- |
|  | **Please initial box** |
|  | I confirm that I have read and understand the Participant Information Sheet, Version <insert current PIS version number and date > for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. |  |
|  | I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw, then the information collected so far cannot be deleted and that this information may still be used in the study analysis. |  |
|  | I understand that relevant sections of my medical notes and data collected in the study may be looked at by authorised individuals from the Nottingham Clinical Trials Unit (University of Nottingham), the Sponsor (Nottingham University Hospitals Trust), NHS bodies, the study research group, and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and for a copy of this signed consent form to be sent to the Nottingham Clinical Trials Unit.  |  |
|  | I understand thatthe Nottingham Clinical Trials Unit, the Sponsor and the trial research group will collect, store, analyse and publish information obtained from my participation in this trial. I understand that my personal details will be kept confidential. |  |
|  | I understand that the Nottingham Clinical Trials Unit and the study research group will be provided with my personal details to send me study questionnaires and important study communications. I understand that I may also be contacted for the purpose of obtaining follow-up information if I do not return completed study documents as requested. I give my permission for this information to be kept until the end of the study, at which point it will be deleted and for the Nottingham Clinical Trials Unit to contact me. I understand that if I withdraw my personal details will be deleted. |  |
|  | I understand that the information held and maintained by my GP, NHS Digital and other central UK NHS bodies may be used to help contact me or provide information about my health status.  |  |
|  | I agree to my GP being informed of my participation in this study. |  |
|  | I understand that the anonymised information collected about me may be used to support other research in the future and may be shared with other researchers. |  |
|  | I agree to take part in the above study. |  |

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| --- | --- |
|  | **Please initial either box** |
|  | **Optional** *The following are optional, and you can still take part in the study if you answer “No”* | **Yes** | **No** |
|  | I agree to be contacted and informed about future studies. I understand that there is no obligation, and I will just be informed of what the future study will involve.  |  |  |
|  | I understand that my name and telephone number will be held by Esendex (text messaging provider) and their subprocessors and will be used to contact me by text message. I give permission for this information to be retained by Esendex for two years or until the end of the study (whichever occurs first). I understand that if I withdraw my personal details will be deleted. |  |  |

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| **Optional routine data collection** | **Please initial box** |
| 13. | I understand that I am not consenting to take part in the main trial and will not undergo the visits, procedures or assessments described in the patient information sheet. I agree that my standard of care data will be accessed for the research and understand how it will be processed. |  |

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Name of Participant Date Signature

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Name of person taking consent Date Signature

(You must be on the delegation log)

*Original signed ICF to be kept in the Investigator Site File. 3 copies: 1 for participant, 1 for the medical notes and 1 to be sent to the Nottingham Clinical Trials Unit.*