# BRIGHT Study

**Benefits of Retained Insulin for Good HealTh**

**Study 2 - Participant Consent v1.0 02July2025**

| Participant ID | | | | | |
|---|---|---|---|---|---|
| | | | | | |

| | CONSENT STATEMENTS | Please add your initials against each statement to confirm your consent. | |
|---|---|---|---|
| **1.** | I confirm that I have read the participant information leaflet for BRIGHT study 2 (version 2.0, dated 31/07/2025). I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. | | |
| **2.** | I agree to take part in the study (as set out in the information provided) | | |
| **3.** | I agree that the research team may contact my clinical care team (including my GP) to confirm details about my health and treatment for this study and to share clinical results relevant to my care. | | |
| **4.** | I agree that the research team may obtain information about my health, that is relevant to this research, from my medical records via manual record checks or by linking to NHS electronic healthcare records. | | |
| **5.** | I understand that taking part in this study is voluntary and that I may withdraw at any time without giving any reason and without my clinical care being affected. I understand that if I withdraw from the study the research team will keep the information they have already collected to use in this research. | | |
| **6.** | I understand that relevant sections of my medical records & data collected for this research may be looked at by people from healthcare research regulators or from the NHS Trust for monitoring and audit purposes. | | |
| **7.** | I understand that anonymised information collected in this study will be stored indefinitely after the end of the study, and may be shared with other researchers, to support further research & healthcare improvement. | | |
| | **Your Agreement To Statements 8 and 9 Is Optional And Declining Will Not Prevent You From Taking Part In This Study:** | **Please circle YES or NO and add your initials beside your answer** | |
| **8.** | I agree to gift samples and data, collected during this study, to the Peninsula Research Bank (PRB), managed by the NIHR Exeter Clinical Research Facility and understand that they may be used in future research. I understand that these studies will be approved by a steering committee and my samples will not be used for any of the following: Sold for profit, used in animal research, used in research into the termination of pregnancy or reproductive cloning, screened for markers predictive of disease, with the exception of genetic causes of diabetes. Samples may be provided anonymously to researchers from the UK and abroad including academic organisations and commercial companies. | **YES** | |
| | | **NO** | |

| Participant ID | | | | | |
|---|---|---|---|---|---|
| | | | | | |

| | **Your Agreement To Statements 8 and 9 Is Optional And Declining Will Not Prevent You From Taking Part In This Study:** | **Please circle YES or NO and add your initials beside your answer** | |
|---|---|---|---|
| **9.** | I would like to be contacted about other research studies and agree that my contact details will be held on a secure database for that purpose. I understand that my details will be retained until I request that they be deleted. The database will be managed by the Peninsula Research Bank (PRB) and I will only be contacted about studies that are approved by a steering committee. | **YES** | |
| | | **NO** | |

| **PARTICIPANT NAME (PRINT)** | **SIGNED** | **DATE** |
|---|---|---|
| | | |
| **RESEARCHER NAME (PRINT)** | **SIGNED** | **DATE** |
| | | |

***Note to Consenting Researcher:***

*Please ensure that this signed consent form (with sample barcode labels attached) is placed in the study site file. Please ensure that a copy of the consent is provided to the participant for their records.*

***Attach Barcode Set Labels or Record Barcode Set Numbers For Each Visit Below:***

| | |
|---|---|
| Visit 1 – Clinic MMT Sample Barcode Set | Visit 2 – Home MMT Sample Barcode Set |
| Visit 3 – Home MMT Sample Barcode Set<br>(a subset of participants only) | |