TMR Data Management Plan (DMP)

Guidance for Data Handling Staff

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This Data Management Plan outlines how data will be collected, stored, secured, analysed, and eventually archived for the Total Meal Replacement (TMR) diabetes study in Saint Helena. The plan is designed to meet the expectations of UK research funders and complies with GDPR and local data governance.

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1. Types of Data Collected

The study will collect a combination of clinical, behavioural, and self-reported data. Clinical data include demographic details, medical history, anthropometric measurements, blood pressure, and laboratory results such as HbA1c, lipid profiles and renal function tests. Details of medication use, including dose changes and cessation, will be recorded throughout the study.

Participants will also complete standardised questionnaires, including the EQ-5D-3L for quality of life and the PAID instrument for diabetes-related emotional distress. A subset of participants will take part in Ecological Momentary Assessment, providing repeated brief updates about their mood, cravings and adherence through mobile prompts.

Qualitative interviews will produce audio recordings and transcripts. These will be anonymised before analysis. Analysis datasets derived from the raw data, as well as the statistical code used to produce results, are also considered part of the study data.

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2. Data Collection and Entry

Data will be collected and managed using **REDCap**, hosted on secure UK servers that fully comply with GDPR. REDCap forms will include built-in checks to prevent entry errors, such as range checks and logical constraints. Clinical assessments will be performed by trained staff, and data will be entered directly into REDCap whenever possible. EMA data will be collected via mobile devices and linked to participants using their study IDs. Qualitative recordings will be uploaded to encrypted institutional storage.

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3. Data Storage and Security

All identifiable data will be stored securely within REDCap in clearly separated identifier fields. Access is restricted to clinical staff and designated members of the research team. REDCap uses encrypted web connections, role-based permissions and automatic server-side backups. Pseudonymised datasets will be created for analysis by removing direct identifiers and replacing them with unique study codes. Indirect identifiers will be minimised or coarsened to reduce the risk of re-identification.

Audio files and transcripts will be stored in secure institutional repositories with restricted access. Statistical code will be stored in version-controlled systems — likely GitHub — to ensure reproducibility.

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4. Legal and Ethical Compliance

The study will comply with the **UK General Data Protection Regulation (UK GDPR)** and the **UK Data Protection Act 2018**, as well as relevant Saint Helena legislation. The Saint Helena Health Directorate will serve as the Data Controller for participant data. The UK partner institution will act either as Data Processor or Joint Controller, depending on the specifics outlined in the Data Sharing Agreement.

Participants will provide informed consent after receiving clear information about how their data will be used, how long it will be stored, who will have access to it, and their rights under GDPR. They will be informed that pseudonymised data may be used for future ethically approved research.

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5. Data Quality Assurance

All staff involved in data entry will receive training. Data completeness, timeliness and accuracy will be checked regularly using REDCap reports. Periodic audits will compare REDCap entries with source documents to ensure accuracy. Analytical datasets will be checked for consistency and will be documented thoroughly using data dictionaries.

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6. Data Sharing and Reuse

After publication of the main results, pseudonymised datasets may be shared with external researchers through controlled-access mechanisms. Small cell sizes and any data that could risk re-identification will be removed or aggregated. Data requests will be reviewed by a Data Access Committee. If possible, datasets may be archived within a secure research repository that complies with GDPR.

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7. Data Retention and Archiving

Identifiable data will be retained for at least **ten years** after study completion, in accordance with institutional policy and funder expectations. After this period, identifiable data will either be securely destroyed or irreversibly anonymised. Pseudonymised datasets and statistical code will be retained indefinitely to support reproducibility and potential secondary analyses.

This Data Management Plan ensures that all data from the TMR study are handled responsibly, securely and transparently, while enabling high-quality research.