Baseline Visit CHECKLIST

Total Meal Replacement (TMR) Diabetes Remission Programme

St Helena Health and Social Care Directorate (HSC)

Version 1 – Draft

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Visit Details

Participant study ID: _____
Date of visit: / / __
Staff initials: _____
Site: ☐ St Helena ☐ Ascension
Visit mode: ☐ In person ☐ Other ___

Before the Baseline Visit

- ☐ Screening eligibility confirmed
- ☐ Participant expressed interest in taking part
- ☐ Participant Information Sheet available
- ☐ Consent form available
- ☐ REDCap baseline event opened

Welcome and Orientation

- ☐ Voluntary nature of participation reconfirmed
- ☐ Visit procedures explained
- ☐ Opportunity for questions provided

Eligibility Reconfirmation

- ☐ Type 2 diabetes diagnosis reconfirmed
- ☐ Insulin status confirmed
- ☐ No material changes since screening
- ☐ Borderline eligibility identified and escalated (if applicable)

Informed Consent

- ☐ Participant Information Sheet reviewed with participant
- ☐ Data use and confidentiality explained
- ☐ Withdrawal rights explained
- ☐ Written informed consent obtained **before data collection**
- ☐ Consent date recorded in REDCap

Participant Administration

- ☐ Participant study ID assigned / confirmed
- ☐ Site recorded
- ☐ Group allocation recorded (intervention / control)
- ☐ Registry ID recorded

Baseline Measurements Collected

Anthropometry and Clinical Measures

- ☐ Height (baseline only)
- ☐ Weight
- ☐ Waist circumference
- ☐ Hip circumference
- ☐ Blood pressure
- ☐ Capillary blood glucose

Laboratory Measures

- ☐ HbA1c
- ☐ Liver function tests
- ☐ FibroScan completed or scheduled (if applicable)

Medication Status

- ☐ Diabetes medication status recorded
- ☐ Hypertension medication status recorded

Patient-Reported Outcome Measures

- ☐ EQ-5D-3L completed
- ☐ PAID questionnaire completed
- ☐ IPAQ short form completed

Data Quality Checks

- ☐ Required baseline fields completed
- ☐ Implausible or missing values addressed

Next Steps Confirmed

- ☐ Intervention participant: next visit and TMR start explained
- ☐ Control participant: follow-up schedule explained

After the Visit

- ☐ All baseline data entered into REDCap
- ☐ Consent form stored securely
- ☐ Any safety issues escalated

Retention of Checklist

☐ Routine baseline visit – checklist not retained
☐ Checklist retained due to exception (specify reason): _____

Linked Documents

Baseline Visit SOP
Screening Visit SOP
Participant Information Sheet
Consent Form
TMR Data Dictionary