PIMMS-WL Trial Baseline Case Report Form

FOR TRIAL OFFICE USE ONLY

PIMMS-WL Trial Number: | | | - | | | | | Initials: | | | |

Date of Visit: D D M M M Y Y Y Y

Randomisation Group: UC ☐ INT ☐

Notes:

Section 1: Consent for Screening

1. Has the participant completed the PIMMS-WL Screening Consent Form? Yes ☐ No ☐
2. Date of Screening Consent: D D M M M Y Y Y Y
3. Version of Participant Information Sheet: V | | . | | Date: D D M M M Y Y Y Y
4. Version of Screening Consent Form: V | | . | | Date: D D M M M Y Y Y Y

Section 2: Ethnicity

1. What is your ethnicity?

White	☐	Pakistani	☐	Black Caribbean	☐	Chinese	☐
Mixed	☐	Bangladeshi	☐	Black African	☐	Other	☐
Indian	☐	Other Asian	☐	Black Other	☐	If other, specify: _____	

Do not wish to disclose ☐

Section 3: Screening Measurements and Eligibility Check

1. Does the participant have a pacemaker fitted? Yes ☐ No ☐

If yes, do <u>NOT</u> use the TANITA scale and no body fat measurement can be recorded.

2. Height: ☐☐☐.☐ cm
3. Weight: ☐☐☐.☐ kg
4. BMI ☐☐.☐ kg/m² = $\frac{\text{Weight (kg)}}{\text{Height x Height (m}^2\text{)}}$
5. % Body Fat ☐☐.☐ % % Body Fat not recorded ☐

'We would like to re-affirm some of our study entry criteria with you'.

6. Are you planning to have child immunised within the National immunisation programme? Yes ☐ No ■
7. Have you attended your child's first immunisation appointment? Yes ■ No ☐
8. Are you currently attending a weight loss programme or participating in a weight management research study? Yes ■ No ☐
9. Are you willing to give consent to notify your GP? Yes ☐ No ■
10. Have you been diagnosed with a serious mental health difficulty requiring hospitalisation in the last two years? Yes ■ No ☐
11. Have you been diagnosed with anorexia and/or bulimia in the past two years? Yes ■ No ☐

12. Is the participant eligible for PIMMS-WL? Yes ☐ No ☐

<u>Note</u>: In order to be eligible, only **<u>unshaded</u>** boxes should be ticked

If **yes**, obtain full written informed consent and continue to section 4 below

If **no**, thank the participant for their interest and do not complete the rest of this CRF. Go to section 12 to complete signature section.

Section 4: Consent for Trial

1. Has the participant completed the full PIMMS-WL Consent Form? Yes ☐ No ☐
2. Date of Consent: D D M M M Y Y Y Y
3. Version of Participant Consent Form: V ☐.☐ Date: D D M M M Y Y Y Y

Section 5: Pregnancy Details

'I would like to ask you some questions about your pregnancy'

1. What was your weight before you were pregnant? ☐☐☐.☐ kg Unknown ☐
2. Name of Baby 1: First Name: _____ Surname: _____
3. Baby Date of Birth: D D M M M Y Y Y Y
4. Name of Baby 2: (if twins) First Name: _____ Surname: _____
5. Baby Date of Birth: D D M M M Y Y Y Y
6. In total, how many children have you given birth to? ☐
7. How many children are living in your household? ☐
8. During this last pregnancy, did you have any pregnancy related health complications? Yes ☐ No ☐
9. If yes, please can you tell me what those were?
   a. Gestational diabetes mellitus? Yes ☐ No ☐
   b. Pre-eclampsia? Yes ☐ No ☐
   c. Gestational hypertension? Yes ☐ No ☐
   d. Pre-term delivery? Yes ☐ No ☐
   e. Postpartum haemorrhage? Yes ☐ No ☐
   f. Neonatal intensive care / special care baby unit admission? Yes ☐ No ☐
   g. Other? Yes ☐ No ☐
   h. If other, please specify: _____
10. What type of delivery did you have?
    - Normal vaginal delivery ☐
    - Instrumental vaginal delivery (Forceps/ vacuum) ☐
    - Elective (planned) caesarean section ☐
    - Emergency caesarean section ☐
    - Other ☐

    If other, please specify: _____

Section 6: Breastfeeding

1. Did you try to breastfeed your baby? Yes ☐ No ☐
2. How are you currently feeding your baby?
   - Exclusively breastfeeding ☐
   - Exclusively formula feeding ☐
   - Both breastmilk & formula ☐
   - Other ☐
   - If other, please specify: _____
3. If currently breastfeeding, how long (from the birth of your baby) do you intend to keep breastfeeding?
   - Up to 3 months ☐
   - Up to 6 months ☐
   - Up to 9 months ☐
   - Up to 12 months ☐
   - More than 1 year ☐
   - As long as possible ☐
   - Unsure ☐
   - Not applicable ☐

Section 7: Sleep

1. On average how many hours of **uninterrupted** sleep do you get per night? _____ hours

Section 8: Health Questionnaire Checklist – ALL PARTICIPANTS

1. Has the baseline questionnaire booklet been collected? Yes ☐ No ☐
2. If no, please specify reason not completed _____
3. If no, has a freepost envelope been provided? Yes ☐ No ☐

Section 9: Scales and POWeR Checklist – INT GROUP ONLY

1. Have a set of weighing scales been given to the participant? Yes ☐ No ☐
   a. If yes, what type? BodyTrace scales? Yes ☐ No ☐
   USB scales? Yes ☐ No ☐
2. If BodyTrace, scales serial number: | | | - | | | | | | | - | | | | | | | - | |
3. Have you attached a weight record card to the red book? Yes ☐ No ☐
4. Date of first immunisation appointment: | D | D | M | M | M | Y | Y | Y | Y |
5. Registration code for POWeR | P | I | M | M | S | 1 | 0 | | | 0 |

Section 10: Checklist – ALL PARTICIPANTS

1. Obtained screening consent?
2. Assessed eligibility for the PIMMS-WL trial?
3. Obtained full consent?
4. Given information leaflet on diet and exercise?

Section 11: Checklist - INT GROUP ONLY

1. Provided patient with weighing scales and instructions?
2. Have you attached a PIMMS-WL trial sticker to the red book?
3. Have you attached a weight record card to the red book?
4. Have you asked participant to self-weigh and record weight once a week?
5. Have you informed the participant about the POWeR website, given the POWeR invitation card and start up instructions and recorded the POWeR registration code from the card?

Section 12: Form Completed By:

Name of researcher: _____

Signature: _____ **Date** D D M M M Y Y Y Y

FOR TRIALS OFFICE USE ONLY:					
Received:		Checked:		Entered:	
Date:	Initials:	Date:	Initials:	Date:	Initials: