<Insert Study Title>

Case Report Form (Visit X)

Date of Visit: □□/□□/□□□□

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| To Be Completed During Visit | Completed by  (Insert initials) |
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| INFORMED CONSENT | |
| Date and time participant given Participant Information Sheet | \_\_ \_\_ /\_\_ \_\_ /\_\_ \_\_ \_\_ \_\_ (dd/mm/yyyy)  \_\_ \_\_ : \_\_ \_\_ (hh:mm - use 24 hour clock) |
| Date and time participant signed consent form | \_\_ \_\_ /\_\_ \_\_ /\_\_ \_\_ \_\_ \_\_ (dd/mm/yyyy)  \_\_ \_\_ : \_\_ \_\_ (hh:mm - use 24 hour clock) |
| Version and date of Participant Information Sheet Provided | Version \_\_ .\_\_  Date \_\_ \_\_ /\_\_ \_\_ /\_\_ \_\_ \_\_ \_\_ (dd/mm/yyyy) |
| Name of person taking Informed Consent |  |
| Has a copy of the signed consent form been given to the subject? | Yes  No  If no, reason: |
| Has a copy of the signed consent form/participant information sheet been filed in the medical notes? | Yes  No  If no, reason: |
| Has a written entry detailing the consent process been made in the medical notes? | Yes  No  If no, reason: |

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| ELIGIBILITY CRITERIA  If any grey boxes are ‘selected’ the individual is not eligible to participate and must not continue into the study | | |
| INCLUSION CRITERIA | | |
|  | Yes | No |
|  | Yes | No |
|  | Yes | No |
|  | Yes | No |
| EXCLUSION CRITERIA | | |
|  | Yes | No |
|  | Yes | No |
|  | Yes | No |
|  | Yes | No |
| CONFIRMATION OF ELIGIBILITY | | |
| Is the participant eligible to enter the study? | Yes | No |
| Is the participant eligible to take part pending the results of eligibility bloods. | Yes | No |
| Following a review of the results of eligibility blood tests the participant eligible to take part. | Yes | No |

I confirm that the inclusion and exclusion criteria have been checked and this participant is eligible for enrolment in this study. (This must be performed by a PI/medic delegated responsibility/or appropriate individual named on the Delegation of Authority and Signature Log and **must be performed prior to randomisation and/or additional research activities/assessments**)

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| Name |  |
| Signature |  |
| Date (dd/mm/yyyy): | \_\_ \_\_ /\_\_ \_\_ /\_\_ \_\_ \_\_ \_\_ |

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| DEMOGRAPHICS | |
| Date of Birth (dd/mm/yyyy) | \_\_ \_\_ /\_\_ \_\_ /\_\_ \_\_ \_\_ \_\_ |
| Age (years) | \_\_ \_\_ |
| Gender | Male  Female |

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| ETHNICITY Please select the box that best describes the participant’s ethnic origin | | | | | |
| White | | Asian or Asian British | | Chinese | |
| White British | 1 | Indian | 8 | Chinese | 15 |
| White Irish | 2 | Pakistani | 9 |  | |
| Other White | 3 | Bangladeshi | 10 |
|  | | Other Asian | 11 |
| Mixed | | Black or Black British | | Other Ethnic Group | |
| White and Black Caribbean | 4 | Black Caribbean | 12 | Other Ethnic Group | 16 |
| White and Black African | 5 | Black African | 13 | If Other Ethnic Group  please specify: | |
| White and Asian | 6 | Other Black | 14 |
| Other Mixed | 7 |  | |

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| ANTHROPOMETRIC MEASURES | |
| Height | □□□.□ cm *Measure to the nearest 0.1cm* |
| Waist circumference | □□□.□ cm *Measure to the nearest 0.1cm* |
| Weight  Clothes weight of 0.5 to be entered into Tanita scales) | □□□.□ kg (measured to the nearest 0.1 kg) |
| Body Fat Percentage (measured with TANITA scales) | □□□.□ % |
| Muscle Mass (measured with TANITA scales) | □□□.□ kg (measured to the nearest 0.1 kg) |
| BMI | □□.□□ |
| TANITA print out receipt **stapled** to CRF: | Yes  No |

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| BLOOD PRESSURE (BP) AND HEART RATE (HR)  To be taken after the participant has been seated quietly for 5 minutes (seated position, back supported, arm resting on table). | |
| Measurement 1 | |
| Blood pressure | □□□/□□□ mmHg  Systolic  Diastolic |
| Heart Rate | □□□ bpm |
| Arm Used | Right  Left |
| Measurement 2 | |
| Blood pressure | □□□/□□□ mmHg  Systolic  Diastolic |
| Heart Rate | □□□ bpm |
| Arm Used | Right  Left |
| Measurement 3 | |
| Blood pressure | □□□/□□□ mmHg  Systolic  Diastolic |
| Heart Rate | □□□ bpm |
| Arm Used | Right  Left |
| Average Measurement  Calculate the average BP and HR from measurement 2 and 3.  Values .5 and above should be rounded up to the nearest whole number. Values of .49 and below should be rounded down to the nearest whole number. | |
| Blood pressure | □□□/□□□ mmHg  Systolic  Diastolic |
| Heart Rate | □□□ bpm |
| Was any advice given to the participant? | Yes  No |
| If yes, please detail advice given |  |

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| MEDICAL HISTORY  Does the participant have a history of: | | | | |
| Condition | Yes | No | Date first known  (year) | Select if date unknown |
| <insert name of condition> |  |  | \_\_ \_\_ \_\_ \_\_ |  |
| <insert name of condition> |  |  | \_\_ \_\_ \_\_ \_\_ |  |
| Other (please specify): |  |  | \_\_ \_\_ \_\_ \_\_ |  |

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| FAMILY HISTORY | |
| Does/did the participant’s mother have diabetes? | Yes, Type 1 Diabetes  Yes, Type 2 Diabetes  Yes, not sure which type  No  Unknown |
| Does/did the participant’s father have diabetes? | Yes, Type 1 Diabetes  Yes, Type 2 Diabetes  Yes, not sure which type  No  Unknown |
| How many full siblings does the participant have? | □□ |
| How many of the participants full siblings have diabetes? | □□ |
| Which type of diabetes do the participant’s siblings have? | No. of siblings with T1DM: □□  No. of siblings with T2DM: □□ |
| Do any of the participant’s 1st degree relatives have a history of: | |
| Cardiovascular Disease | Yes  No  Unknown |
| Stroke | Yes  No  Unknown |
| High Blood Pressure | Yes  No  Unknown |
| High Cholesterol | Yes  No  Unknown |
| Gestational Diabetes | Yes  No  Unknown |
| Chronic Kidney Disease | Yes  No  Unknown |

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| PHYSICAL EXAMINATION | | | |
| Body system | Assessment | \*If abnormal, clinically significant? | If CS, please detail |
| General Appearance | Normal  Abnormal  Not done | Yes  No |  |
| Skin | Normal  Abnormal  Not done | Yes  No |  |
| Eyes, Ears, Nose & Throat | Normal  Abnormal  Not done | Yes  No |  |
| Head, Neck & Thyroid | Normal  Abnormal  Not done | Yes  No |  |
| Cardiovascular | Normal  Abnormal  Not done | Yes  No |  |
| Respiratory | Normal  Abnormal  Not done | Yes  No |  |
| Abdomen | Normal  Abnormal  Not done | Yes  No |  |
| Extremities | Normal  Abnormal  Not done | Yes  No |  |
| Muscular-Skeletal | Normal  Abnormal  Not done | Yes  No |  |
| Neurological | Normal  Abnormal  Not done | Yes  No |  |
| Others (please specify) | Normal  Abnormal  Not done | Yes  No |  |

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| CONCOMITANT MEDICATIONS | |
| Does the participant currently take any medication? | Yes  No |
| Was a concomitant medication log completed? | Yes  No  N/A (not currently taking any other medication) |

Or

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| CONCOMITANT MEDICATIONS  Does the participant currently take any of the following medication? | | |
| Medication type | Assessment | Name of medication  (write UKN if not known) |
| <insert medication type> | Yes  No  Not known |  |
| <insert medication type> |  |  |
| <insert medication type> |  |  |
| <other, please specify> |  |  |

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| SMOKING HISTORY | |
| Smoking status | Current Smoker  Ex-smoker  Non-Smoker – move on to next section (alcoholic intake) |
| Number of cigarettes smoked per day | □□□ |
| Number of years smoked | □□ |
| Current Vaper? | Yes  No |

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| ALCOHOL INTAKE | |
| Do you drink alcohol? | Yes  Ex-drinker - move on to next section  Never drank -move on to next section |
| Number of units drank per week | □□□ |

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| BLOOD SAMPLE COLLECTION | | |
| Time of collection | \_\_ \_\_ : \_\_ \_\_ (hh:mm - use 24 hour clock) | |
| Name of sample | Sample obtained | Result |
| <insert sample name or type of collection vessel e.g.  1x **BROWN** 4.9ml Serum Gel  *(U&E, LFT, eGFR,* > | Yes  No, please specify\* | <insert appropriate number of boxes and units for the test> |
| <insert sample name e.g. FBC> | Yes  No, please specify\* |  |
| <insert sample name e.g. FBC> | Yes  No, please specify\* |  |
| <insert sample name e.g. FBC> | Yes  No, please specify\* |  |
| Blood results reviewed and signed for clinical significance? | Yes  No | |
| Where possible for consistency use the following reason codes: 1. Participant refusal 2. Technically difficult venepuncture 3. Lack of time 4. Delegated staff not available 5. Other, please specify | | |

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| QUESTIONNAIRES | | |
| Questionnaire Name | Completed | Score |
| <insert questionnaire name> | Yes  No | □□□ |
| <insert questionnaire name> | Yes  No | □□□ |

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| ACCELEROMETER  Participants should be given a log sheet to record on/off times & any activities undertaken when the GENEActiv has been taken off.  *The GENEActiv should be worn on the wrist for the duration of 7 days.*  ***Participants instructed to return the GENEActiv and completed activity log at the next visit or by post using provided pre-paid postal envelope.*** | |
| GENEActiv Dispensed | Yes  No |
| GENEActiv Serial Number | □□□□□□ |
| Pre-paid return envelope provided? | Yes  No |
| Log sheet and instructions provided? | Yes  No |
| Participant instructed to remove monitors on: | \_\_ \_\_ /\_\_ \_\_ /\_\_ \_\_ \_\_ \_\_ (dd/mm/yyyy) |

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| ADDITIONAL COMMENTS |
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| CRF COMPLETION CHECK | |
| CRF Checked by (full name) |  |
| Date CRF checked | \_\_ \_\_ /\_\_ \_\_ /\_\_ \_\_ \_\_ \_\_ (dd/mm/yyyy) |
| Signed |  |

<Insert Study Title>

Case Report Form (Visit X)

Date of Visit: □□/□□/□□□□

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| To Be Completed During Visit | Completed by  (Insert initials) |
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| WILLINGNESS TO CONTINUE | |
| Is the participant willing to continue with the study? | Yes  No |

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| ADVERSE EVENT REPORTING  Has the participant experienced any of the following? | |
| Adverse Events | Yes – ***please ensure they are added to the adverse event log***  AE number(s):  No |
| Serious Adverse Events | Yes - ***please complete Sponsor SAE form and inform trial manager***  SAE number(s)  No |
| If ‘yes’ to any of the above please complete the adverse event sections below: | |
| As a consequence of having an AE, has the participant seen their GP/consulted any health care professional/ experienced any changes in health since their last visit? |  |
| Have they been given new medication? | ☐ Yes - please update the concomitant medications log  Con meds numbers:  ☐ No |

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| EQUIPMENT COLLECTION | |
| Has the participant worn and returned the activity monitor? | Yes  No |
| Has the participant completed/returned the activity monitor log? | Yes  No |

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| DOSING | |
| IMP dose administered? | Yes  No |
| Time of dose administration | \_\_ \_\_ : \_\_ \_\_ (hh:mm - use 24 hour clock) |
| Dose prepared by? (insert name) |  |
| Dose checked by? (insert name) |  |
| Dose administered by? (insert name) |  |

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| CRF COMPLETION CHECK | |
| CRF Checked by (full name) |  |
| Date CRF checked | \_\_ \_\_ /\_\_ \_\_ /\_\_ \_\_ \_\_ \_\_ (dd/mm/yyyy) |
| Signed |  |

<Insert Study Title>

Case Report Form (Visit X)

Date of Visit: □□/□□/□□□□

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| To Be Completed During Visit | Completed by  (Insert initials) |
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| END OF TRIAL | |
| Date of trial completion/withdrawal | \_\_ \_\_ /\_\_ \_\_ /\_\_ \_\_ \_\_ \_\_ (dd/mm/yyyy) |
| Date last trial medication given | \_\_ \_\_ /\_\_ \_\_ /\_\_ \_\_ \_\_ \_\_ (dd/mm/yyyy) |
| Trial Outcome | |
| Did the participant… | Complete  Withdraw (complete the withdrawal section below |
| WITHDRAWAL  To be completed only where the participant did not complete the trial | |
| What was the reason for withdrawal | No longer wished to take part  Lost to follow up  Non-compliance  Medical contraindication  AE/SAE/SAR  Death  Other, please specify): |

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| CRF COMPLETION CHECK | |
| CRF Checked by (full name) |  |
| Date CRF checked | \_\_ \_\_ /\_\_ \_\_ /\_\_ \_\_ \_\_ \_\_ (dd/mm/yyyy) |
| Signed |  |