<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 CRITERIAIf 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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| ETHNICITYPlease 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 Groupplease 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* |
| WeightClothes 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 | □□□/□□□ mmHgSystolicDiastolic |
| Heart Rate | □□□ bpm  |
| Arm Used | [ ]  Right[ ]  Left  |
| Measurement 2 |
| Blood pressure | □□□/□□□ mmHgSystolicDiastolic |
| Heart Rate | □□□ bpm  |
| Arm Used | [ ]  Right[ ]  Left  |
| Measurement 3 |
| Blood pressure | □□□/□□□ mmHgSystolicDiastolic |
| 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 | □□□/□□□ mmHgSystolicDiastolic |
| Heart Rate | □□□ bpm  |
| Was any advice given to the participant? | [ ]  Yes[ ]  No  |
| If yes, please detail advice given |  |

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| MEDICAL HISTORYDoes 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 MEDICATIONSDoes 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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| ACCELEROMETERParticipants 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)

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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 REPORTINGHas 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 logCon 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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| 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 |  |