Data Protection Impact Assessment (DPIA)

Title of Research:	Assessment of the Impact of a Personalised Nutrition Intervention in Impaired Glucose Regulation		
Department:	Department of Electrical and Electronic Engineering		
DPIA conducted by and title:	[redacted] Research Nurse	**Date:**	10/08/2018 Version date 13/09/19

1. DPIA Summary

- The research aims to determine if DNA-based dietary guidelines can improve glucose regulation in pre-diabetic individuals significantly more than standard dietary guidelines following 6 weeks of the intervention. The study will recruit 180 individuals with pre-diabetes, who will be randomised on a 1:1:1 allocation to 3 study arms; Control, Intervention and Exploratory. Data collected from participants will include, personal identifiable data such as name, contact number, NHS number, email address and general practitioner (GP) details. The study will also collect medical history from participants during screening at the Imperial College Research Facility (ICRF) and lastly genetic samples of blood and saliva during scheduled clinical visits.

2. Identifying the need for DPIA

- The study requires participants to provide information about themselves, logged on Participant Details Form that will be stored at the [redacted] for the duration of the study. This also allows the trial to contact participants during the trial to schedule visits, follow ups and/or emergency situations. Participants email addresses will be stored until the data has been published to notify participants of publication of clinical trial results.

- At Screening, (Initial appointment) participants are allocated a Trial ID, a combination of alphabets and numbers to be used on all participants case report forms. On successful enrolment on the study, the participant is randomised via Sealed Envelope. To randomise, this online tool requires only Trial ID, sex and age range (either between ages of 18-40 or above 40 years old) to generate a randomisation number. No identifiable data is entered for the generation of a randomisation number. This is an online software application paid to be used for the purpose of randomising participants into clinical trials.

- Blood samples collected from participants at clinical visits are processed at Hammersmith Pathology. The samples are labelled with participant NHS number, hospital number and date of birth for processing. Results of blood profiles are posted on the Trust's database, Cerner. This is can only be accessed by members of staff who have completed training for Cerner and have the access card. Saliva samples and Blood samples for genetic testing collected will be randomised via the labelling with Participant ID, clinical visit number and date of sample collection. Samples will be transferred to the Centre for Bio-Inspired Technology (CBiT) at Imperial College London and signed over to a designated member of the Trial Team to be stored in a -80 degrees Celsius freezer before processing.

- Medical history collected from participants at screening will be queried in line with the study's inclusion and exclusion criteria. This information will be filed in the Participant's File and stored [redacted]. The study has an allocated shelf to store participants.

3. Describing the Data Processing

- The study aims to enrol 180 consented participants above the age of 18 with capacity to consent independently.

- Personal data processed will be participants names, date of birth, telephone/mobile numbers, home/postal address, general practitioners details, NHS number and assigned hospital number. Health information to be processed will be medical history- acquired from participants, clinical assessments of anthropometric measurements, blood pressure recordings, blood samples to test HbA1c at screening visit, glucose and insulin levels during Oral Glucose Tolerance Test (OGTT) along with total cholesterol, fasting triglycerides, LDL cholesterol, HDL cholesterol, vitamin D and B12 and saliva samples to analyse metabolism-based SNPs and Leptin levels.

- Participants' identifiable data will be handled by delegated members of the research team thus being, the Project Officer to schedule visits, the research nurse to record data in Participant's File and Cerner records and lastly the study dietician for follow up phone calls. The Chief Investigator and trial manager will have overall access of the master list but will only be accessed on a as needed basis such as during a serious adverse event. This will help to minimise exposure of participants details and maintain integrity of the study following anonymised randomisation.

- Personal data will be stored in both hardcopy and soft copy. Hardcopy will be Participant's File which will include identifiable details, medical history and a signed and dated informed consent form. eCase Report Forms (eCRFs) or Source Data will be data collated from study visits and will not include any personal data as participants will be randomised and only identifiable with their participant identification number. The key to identify data subjects will be stored separately from the research data and accessible by the CTM and members of the Trial Steering Committee.

- Randomisation numbers are derived online from sealedenvelope.com, which requires some information to be entered prior to randomising. It requires gender (male or female), age group (below 40 years or equal to and above 40 years) and lastly if participant has consented to be on the study. No personal identifiable details are entered online to randomise. The online tool randomises participant to one of the three groups on the study; Control, Intervention and Exploratory. When randomisation number is generated, it's emailed to the research for participant allocation and filing. The CTM has a master list of randomisation numbers and will confirm based on information entered of gender, age and consent that it correlates before signing off on it.

- Participants will be allocated a participant identification number which will be used for labelling of genetic information- saliva and blood samples, questionnaires and other study related documents relating to participants.

- Participants' Files and any source data will be kept in a [redacted] The

- Electronic storage of trial data will be stored in password-protected, encrypted hard-drives at Imperial College London, in a locked drawer with restricted access to designated individuals.

- ICT Security at Imperial College London has been involved with encrypting all study electronics for use. Study laptops, tablets and hard drives have been encrypted. All electronics are password protected and kept overnight in a locked safe in the filing room of the ICRF.

4. Legal basis for processing

- The study has undergone peer review both internal and external. It has been approved by the POB at the Imperial College Research Facility (where the study will be conducted) as well as National Institute of Health Research (NIHR) Clinical Research Network (CRN) for it's study portfolio.

Initial sign up

- Consent is captured at first visit (screening) of the study, where the Research Nurse will explain what data will be required, how long data will be stored for and how it will be used during and after study completion. The consent form outlines the specific genetic material to be collected, how genetic information will be used- for research purposes only and how it concerns third party organisations. When subjects have understood and agreed to the process, they initial the boxes at the end of each outlined statement, sign and date the informed consent form (ICF).

- It is a legal requirement for participants to be consented prior to enrolment and before any study related activities takes place. The consent form, as well as other participant materials, such as advertisement materials for participant recruitment, participant invitation letter, trial questionnaires, etc. have undergone Research Ethics Committee (REC) and Health Research Authority Research (HRA) approval. These bodies will regulate the conduct of the study to completion.

Following initial sign up

- Processing personal data once enrolled. Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller. See Article 6(1)(e)

- Personal and special data are necessary data to be collected for entry and continuation on the study and at study completion where study results have been published and participants are notified of results.

- Processing special categories of data is necessary for archiving purposes in the public interest, scientific or historical research purposes and statistical purposes. See Article 9(2)(j)

The above legal basis for processing have been explained to the data subjects via the PIS and Consent Sheet

5. Describe the information flow

Participant consent to Informed Consent Form where privacy notice is explained and given via hard copy. Copies will be made of the consent form for participant's safe keeping with other copies filed in participant's file, site file and TMF.

Personal data and medical history will be stored as hard- copies in the Participant's File and [redacted] This will be backed-up on site on encrypted hard-drives.

Participant file and source data will be kept locked in [redacted] for duration of study. eCRFs will be stored on encrypted, password-protected hard-drives. They will be temporarily stored on a shared encrypted folder on the BoxSync Cloud Service using nCrypted Cloud, with only members of the trial team having access. This will be done to facilitate data validation by another member of the trial team. Once validation has been performed, the eCRFs will be removed from the shared folder and stored on the encrypted hard-drives. Access to the shared folder will be controlled by the clinical trial team for a restricted period of time.

Participants are randomised following the screening visit. All paperwork relating to participant's study visit will only be identifiable with the participant ID. Randomisation via sealedenvelope.com only requires two main pieces of information to be entered; gender and age group. No identifiable data will be logged on the randomisation webpage.

Data collected during the study will be analysed at Imperial College London and on a Virtual Machine set up by Imperial ICT for the Medical Statistician (who will not receive any identifiable data) to access data remotely.

Data destruction/end,

- Telephone/mobile numbers will be deleted once the trial is complete.
- Email addresses will be deleted after the trial results have been published, as participants will be contacted to inform them about results publication.
- Anonymised genetic samples will be stored for up to 5 years after trial completion.
- Anonymised blood samples stored for up to 1 year after trial completion.
- Identifiable data will be stored for up to 10 years following trial completion.
- The destruction period is in line with Imperial College retention schedule.

Hard-drives and laptops used for the study will be transferred to the Centre for Bio-inspired Technology (CBiT) at Imperial College London. All data will be transferred to encrypted hard-drives which will be [redacted] and laptops will be wiped.

The above processes / systems / tools have been reviewed as adhering to College ICT requirments for collecting and storing special category data for the purposes of research.

6. Data Processor/ Contractor requirements
- DNA Nudge Ltd. are collaborating with Imperial College through funding the study, providing genetic testing and associated applications. The app software has not been reviewed by the college's ICT but by engineers within DNA Nudge Ltd. - Of note a trial monitor (third party) not contracted with the college but with DNA Nudge Ltd. will have access to the anonymised trial data in order to perform monitoring duties according to a monitoring plan.

- DNA Nudge Ltd. designed the APP and are responsible for it's development. DNA Nudge Ltd will not associate with study participants to upload the APP for participants in the Exploratory group. A member of the trial team (Research Dietitian) has been trained by DNA Nudge Ltd on how to upload the APP for study participant. Study participants who experience any technical problems will email the trial email address (aspire-dna@imperial.ac.uk), the project officer will redact any personal information (i.e. email address and any other identifiable personal information) from the email before forwarding the query to a member of the technical team at DNA Nudge Ltd.

7. **Identify the privacy and related risks**	8. **Privacy Solutions** [redacted]
a. Participant file and Source Data are stored at the ICRF file room which is accessible to other research staff conducting studies at the ICRF and is only accessible with an ID badge.	
b. Secondly, on the exploratory arm of the study where participants will be using an App on a smartphone which stores DNA data on nutritional requirements is vulnerable to cyber-attack as participants may use their smartphones for other purposes such as online shopping, social media etc.	-Records on the DnaNudge App are stored locally on the smartphone however they upload automatically on a secure cloud service (AWS) when connected to the internet. This is password-protected and maintained by DnaNudge Ltd.
c. Mishandling of data by trial team where access to participants file both hardcopy and soft copy shared to all.	-Trial team should be adequately trained and adhere to relevant SOPs for data handling of participants identifiable data. Identifiable data processed by the project officer and on a need-to-know basis only for members of the trial team.
d. Misuse of Data by DNA Nudge Ltd	Personal identifiable data and genetic samples (i.e. Blood and saliva) are not shared with DNA Nudge Ltd at any point during and after the study. Participant files and data stored at the ICRF and Imperial College London are not accessible by anyone employed by DNA Nudge Ltd unless they are with a member of the trial team.
e. Mishandling of data by the Trial Monitor. The trial monitor is contracted by DnaNudge to ensure the study is conducted and documented properly. As the trial monitor needs to be exposed to trial documents, i.e. participants file, this poses a risk to the study.	Per Good Clinical Practice (GCP), the trial monitor will indicate at start of visit to the PI, CTM and sponsor a schedule for monitoring visit. This will enable their visit to be facilitated by a member of the trial team. They will ensure a private monitoring room at the facility is booked and to set up the monitor with participant files and the Investigator Site File (ISF). The monitor will not have access to the filing room or participants clinical data on Cerner.

f. Ensuring data has a set retention period.	As stated within the PIS and Informed Consent Form, genetic samples of saliva given by participants will be stored for up to 5 years, blood samples stored for 1 year and all and any information, including personal identifiable data will be stored for 10 years at Imperial College London following study completion.

The following points were raised by regulatory bodies during review of the study which has since been adhered to;

1. Confirmation that only one invite and one reminder will be sent to participants.
2. To provide an abbreviated version of the Information Sheets (with a maximum of two pages) for participants.
3. Advised to reduce the number of bullet points of the Consent Form
4. To provide the Committee with an up-to-date copy of the insurance Schedule

9. Sign off/ Approvals		
Information Asset Owner	Data Protection Officer	Compliance and Information Governance Manager
.....	[redacted]	.....
Signature	Signature	Signature
[redacted]	[redacted]	
.....	.....	.....
Name	Name	Name
24/09/2018	13/11/19	
.....	.....	.....
Date	Date	Date