Airwave Health Monitoring Study
Tissue Bank Protocol

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Executive Summary

The Airwave Health Monitoring Study Tissue Bank (AHMS) is an epidemiological study of police service employees (officers and staff) in Britain. It was established to investigate possible long-term health effects associated with use of the TETRA radio system among the police service.

It is recognised that the cohort also provides a valuable opportunity for broader research into common diseases affecting a well-defined occupational group. It includes substantial numbers of men and women who are being followed up for many years. Participants who took part in a health screen gave broad consent for collection and storage of blood and urine samples for future research, and linkage to health and other records. Up to 95% of the volunteers who have been screened have given consent for sample storage. Those who have opted out of this clause have had their samples destroyed after testing in laboratory.

Since the launch of the study in 2003, 28 (of 54 that existed at the time) police forces agreed to participate. We currently have c. 53,000 participants, of whom c. 46,000 have undergone a health screening. This includes extensive lifestyle and questionnaire data, cognitive tests, clinical measurements and collection of biological samples. Follow-up of the cohort is progressing through access to past and future medical, occupational and other health-related records, and re-screening.

In 2013, AHMS were given Tissue Bank status by NRES. This has facilitated programmes of research without need for individual project-based ethical approval. AHMS has been set up to collect and store samples and data to establish a sampling framework from which people, who are presumed healthy at donation, can be selected based on their genotype and / or phenotype to be invited for observational studies or clinical trials.

The value of the Study is greatly enhanced by a follow-up health screening of participants. Researchers will be able to detect developments or changes in the characteristics of the target population at both the group and the individual level. As longitudinal studies extend beyond a single moment in time, they can establish sequences of events.

AHMS has Research Tissue Bank status with generic approval for projects receiving material or data. All external researchers that propose to recall participants need to have their own project-specific ethics approval.

Objectives of the Tissue Bank

A primary aim of AHMS is to promote collaboration with other research groups both within and outside the college to avoid wasteful competition in the use of limited and precious resources.

AHMS is a rich and growing resource with comprehensive phenotyping (the observable physical or biochemical characteristics of an organism, as determined by both genetic makeup and environmental influences) of its participants. State-of-the art methods can be used on the participants' data and samples to investigate genetic and environmental causes of disease, as well as the pathways to those diseases.

AHMS is providing a national cohort of volunteers who wish to participate in clinical research and are willing to provide clinical information and samples that enable identification of suitable volunteers for future studies by genotype and phenotype.

We will continue to invest in the cohort by:

- Re-screening members of the cohort and obtaining further biological samples from them
- Offering questionnaires and other evaluations such as cognitive testing.
- Following up the cohort members via national registers and obtaining other health-related data from the NHS and other agencies.

By collecting and storing tissue and data AHMS is providing the foundation for:

- Research related to a specific disease or group of diseases.
- Research across biomedicine for yet unspecified research questions.
- Research into the molecular mechanisms involved in disease development and its response to possible resistance to treatment.
- The discovery and validation of new targets and biomarkers for detection, diagnosis, treatment stratification, and development.

Follow Up of the Cohort

The cohort is followed in two ways: actively, by rescreening participants; and passively, by obtaining health and other data about the participants from the NHS and other agencies.

Re-screening Programme

The average age of the cohort at baseline was c. 40 years; and with the mean number of cohort-years per participant exceeding nine years, it is appropriate to follow up participants with a new health screen. This will help identify the evolution and aetiology of chronic diseases (e.g. diabetes and incidence of metabolic syndrome) and diseases that may be related to Airwave exposure (mainly cancer).

Participants are offered a comprehensive health screen (clinical measurements, collection of biological samples, and a questionnaire). The clinical measurements performed include height,

weight, waist-hip, blood pressure, bio-impedance, electrocardiogram (ECG), pulse-wave velocity (PWV), grip strength, spirometry, step test and heel ultrasound. The ECG is interpreted by a cardiologist from the Glasgow CARE cardiology service; from this information we tell participants whether, on the evidence of the ECG itself, a GP consultation is or is not advised.

Cognitive function tests are performed in order to help researchers understand cognitive decline in the population (including neuropsychiatric and neurodegenerative effects which may be linked to sickness absence and early retirements).

Some blood of the blood collected is used for haematology and clinical chemistry tests. The remaining biological samples are stored for future use in research, and to recall participants for further research.

Informed consent is obtained by trained staff at the clinics. The consent is broad and requests permission to carry out future research using the samples and data collected, to follow participant's health via medical records, and to contact them in the future.

A feedback of baseline clinical measurements including ECG and blood test results (haematology and clinical chemistry) is given to the participants. If any of the results are of clinical significance, participants are advised to consult their GP for follow up or further investigation. We do not directly inform participants' GPs of their results.

Sample Size and Selection

We aim to re-screen at least 50% of participants screened at baseline (n=21,500). All participants who previously had a health screening are eligible to participate and are invited by letter to take part in the follow-up re-screening programme.

Invitation letters are sent out to participants offering an appointment at a local screening clinic, which are intended to be located within reasonable commuting distance of their home. Interested participants can book an appointment either by phone or online.

Support of the Police Federation has also been sought to increase uptake and improve participation across England, Wales & Scotland.

Design of the Re-screening Protocol

The format of the re-screen is based on the protocol operated during the enrolment phase, with some additions and deletions based on our evaluation of the usefulness of each component.

The physical measurements included in the Airwave Study protocol were chosen based on their relevance, reliability, and resources (time and money) available. With respect to relevance, the inclusion of a measure at baseline was dependent on other epidemiological studies having indicated that it was significantly associated with health outcomes. For reliability, methods were chosen within a quality assurance framework that involved calibration, maintenance, ease of use, training, monitoring and data transfer to IT systems.

Blood Pressure

Blood pressure and pulse rate are measured using the Omron 705-IT blood pressure monitor. After correctly applying the blood pressure cuff, staff need only press a button on the monitor before waiting for the cuff to automatically inflate then deflate. Following this, the health care professional will need to enter the values; systolic and diastolic blood pressure (and pulse rate) readings to an electronic form specifically designed for their computer. Three consecutive blood-pressure readings are recorded at an interval of 30 seconds. The blood pressure measurement process takes two to three minutes in total.

Weight and Bio-impedance

Marsden digital weighing scales are used to measure a participants' weight. This is repeated twice.

Bio-impedance is measured using the Tanita BC-418 MA body composition analyser. Staff ask participants to remove their shoes, socks and heavy outer clothing and then to step onto the electrically conductive footpad of the body composition analyser. The staff member then presses a button to start the analysis, during which weight and other variables are measured. The health care professional again enters the values on the electronic form. This whole process takes around three minutes. People contraindicated from using Tanita include people with metal implants, pacemakers, joint replacements, and pregnant females.

Standing and Sitting Height

This is measured using a SECA Leicester Stadiometer. Both measurements are shoeless. A stool of fixed height is used for measuring the sitting height. The values are entered by the health care professional into an electronic form. The process takes about three minutes.

Waist and Hip Circumference

Waist circumference at the level of the umbilicus is measured using a Wessex non-stretchable sprung tape measure. Hip circumference is the point yielding maximum circumference below the waist. Staff manually enter the readings into the computer, which automatically warns staff of impossible or implausible values.

Electrocardiogram (ECG)

An Atria 6100 ECG machine is used to take ECG recordings. A 12-lead ECG may support the detection of asymptomatic ECG abnormalities such as silent myocardial infarction, left ventricular hypertrophy, left axis deviation and ventricular ectopic beats.

The ECG Core Lab cardiology service at the University of Glasgow is responsible for management, review and Minnesota coding of 12 lead/25 mm/s ECGs for all participants. Staff members are responsible for sending good quality ECG recordings with correct patient demographic data to the ECG Core Lab by telephone. Each ECG received at the ECG core lab is reviewed and assessed by Professor Peter Macfarlane (ECG Core Lab Director), or in his absence, when an immediate report is required, a Consultant cardiologist. 'Confirmed' copies are sent monthly to the core AHMS team at Imperial

College. Professor Macfarlane also reviews the Minnesota Codes assigned to each ECG by the Glasgow computer system and edits them if required.

Pulse Wave Analysis (PWA)

PWA is measured using a Vicorder device. The Vicorder provides non-invasive measurement of peripheral and central blood pressures in combination with haemodynamic parameters and arterial stiffness. The cuffs are applied over the brachial and femoral artery. Arterial pulse waveforms are recorded using PVR (pulse volume recording) measurements from a standard vascular cuff. The waveforms can be acquired in up to two sites simultaneously to provide pulse transit time (TT) and pulse wave velocity (PWV) measurements for the assessment of arterial stiffness.

Spirometry

The Vitalograph alpha touch 6000 spirometer is used to measure lung function.

Staff are trained to demonstrate the correct measurement procedure to participants in order to increase the quality of measurements obtained. Three measurements of lung functions are taken within a maximum of six minutes. Electronic data capture of the flow curves provides feedback to staff about the quality of measurement.

Grip Strength

Grip strength is measured using Jamar J 00105 hydraulic hand dynamometer. Total muscle strength declines with age and it has been hypothesized to be a predictor of morbidity, loss of function and mortality in later life. Grip strength is the simplest method of assessment of muscle function in clinical practice.

Feedback Reporting of Results to Participants

A feedback report is provided to participants listing their results, stating whether or not results lie within the reference ranges for each assay / measurement. The letter is sent to the participant only, not their GP. The report is reviewed by a clinical doctor before being issued.

The feedback includes the measurements carried out in the initial visit and blood test report. By reporting reference ranges, the participant is provided with enough information to give meaning to the measurements taken, so that they may act on the results if necessary and arrange to see their general practitioner or other relevant health professional.

If the participant has any cause for concern with regards to their health following the screen, they are advised to address these concerns with their GP.

The legal duty of care for staff conducting enrolment is determined by the research context and applies mainly to safe and competent collection of questionnaire data, baseline measurements, and blood or other samples. Staff do not have the same duty of care that they would have in a clinical setting. However, even in this research context, there may be occasions when staff consider there to be a professional or ethical obligation to draw attention to abnormal measurements (such as elevated

blood pressure) or incidental findings (such as possible melanoma). In such circumstances, participants will be encouraged to contact a relevant health care professional.

The target for issuing the feedback report to participants is eight to twelve weeks, subject to workload.

Participants are not notified of any further findings that may result from future assays, analyses or other procedures that are not provided for in their feedback letter.

Sample Collection and Processing

The aim is to collect blood and urine samples in such a format as to facilitate the widest possible range of future assays.

Blood Samples Collected

About 40 ml of blood is collected during the follow-up assessment visit. The "vacutainer" system is used to collect these blood and urine samples. During venepuncture, the hypodermic needle is connected to these vacutainer tubes. These tubes contain the required additives. They are held under a slight vacuum, which draws enough blood to fill them. Each tube has a unique barcode, which is the participant's identifier for this clinic visit. Blood must be collected in a defined order to avoid cross contamination of anticoagulants. The blood samples are collected from non-fasting participants.

Collected blood and urine samples and derived aliquots for storage per individual

BLOOD SAMPLE	QUANTITY	PURPOSE	ALIQUOTS
SST	3 × 5ml	Biochemistry	5 × serums
EDTA	1 × 9ml	Haematology and HbA1C	2 × plasma + 2 × RBC + 1 × buffy coat
PST (Li Hep)	1 × 4ml	Plasma	1 × Plasma
ACD	1 × 6ml	DMSO blood	2 vials of whole blood
Tempus tube	4ml	RNA	2 vials
Urine	1 × 12ml	Storage for future	5 vials

Blood samples are collected in the order as shown above.

Treatment of Blood in the Clinic

- **SST:** The 3 tubes stand for 40 minutes before spinning at 4,300 RPM for 10 minutes on a centrifuge at the clinic.
- **PST:** is spun for 12 minutes at 3,000 RPM at the clinic.

- **RNA Tempus:** the health care professional shakes the tube vigorously for 15 seconds so that the whole blood mixes well with RNA stabilising agent and stabilizes the RNA and transcript profile for future use.

The biological samples are sent overnight by courier, held at 4 - 8 ^{0}C, to Charing Cross Hospital pathology laboratory. Upon receipt, the samples are logged, aliquoted, analysed and stored temporarily in -80^{0}C freezers before onward transport to the NIHR long-term storage facility in Milton Keynes.

Urine Sample

A mid-stream urine sample is collected in a sterile urine pot, aliquoted and cryogenically stored for future use.

Analysis of Samples

The following assays/procedures are carried out at Charing Cross Laboratory on participant blood samples.

- **SST:** sample is used for measuring serum blood chemistry. Biochemistry profile includes cholesterol, HS C-reactive protein, HDL, GGT, HbA1c, Apo-lipoprotein A1, Apo-lipoprotein b, Creatinine, triglycerides.
- **EDTA:** is used for haematology analysis and HbA1c. Haematology profile includes RBC, WBC, Haemoglobin, Haematocrit (HCT), Mean cell volume (MCV), Mean cell haemoglobin (MCH), Mean cell haemoglobin concentration (MCHC), platelets and DLC.
- **ACD:** These aliquots can be used subsequently for immortalization of peripheral lymphocytes with Epstein Barr virus in order to produce supplies of high molecular weight genomic DNA representative of all genomic regions, as well as mRNA transcripts.
- **Tempus RNA:** These aliquots can be used to measure gene expression profile of important gene targets. Gene expression measurement is becoming an increasingly important tool in research.

The stored urine sample could be used subsequently for assay of the urine proteome, metabolome and potentially, for characterization of the gut microbiome. Currently, no upfront analysis of urine is performed.

Follow-up Questionnaire

Collection of lifestyle and other potentially health-related information through self-completed questionnaires and interview complements the physical measurements and biological samples collected at the baseline assessment visit for AHMS. Baseline medical history can also be used to select populations of interest within the cohort to follow with respect to molecular and genetic predictors of disease progression and prognosis.

Following completion of the consent procedures, the touch-screen self-administered questionnaire is used to collect most of the information. This questionnaire typically takes participants 30-40 minutes to complete. Because it is self-administered, it ensures confidentiality and privacy to participants' response to potentially sensitive questions.

The questionnaire can be categorised into the following broad areas of interest: socio-demographics and occupation; lifestyle exposures (including smoking, alcohol, physical activity and diet); psychological state; cognitive function; family history of illness; mental health; medical history and general health. All the questions selected are from validated questionnaires and have been previously used in large population studies.

We are currently developing extensions to the questionnaire jointly with collaborators from the Universities of Edinburgh, Manchester, Glasgow and Swansea that will allow evaluation of:

- Exposure assessment and creation of job exposure matrices (JEMs) relevant to the police forces, with a focus on chemical, physical, infectious and psychosocial risk factors that may be associated with chronic disease or reduced health and wellbeing;
- Examining relationships between operational and organisational risk factors and mental health, with a view to identification of factors that promote resilience within the workplace and future development of workplace-based interventions, co-designed with key stakeholders. This will act as an exemplar case study.

Passive Follow-up

Permission is obtained as part of the consent procedure to access past and future medical and other health-related records. Participants must consent to long-term follow up from medical records to be accepted for a re-screen.

Health records are used to supplement information recorded at enrolment about previous medical history, family history, investigations (e.g. radiology reports and blood tests) and exposures (e.g. medication, occupational health). Most importantly, access to such records is needed to provide follow-up information related to cancers, cause-specific mortality and other health events.

Mobile telephone numbers and e-mail addresses are collected to allow re-contact for future research. These identifiers help to ensure that participants are not lost during follow-up. Any re-contact with participants for future research activity will be conducted by AHMS staff only. No identifiable information will be released to the future researchers.

The sections below explain health datasets obtained on the cohort. We are actively pursuing other data covered by our consent that may become available.

Death and Cancer Registries

We have "flagged" participants through national registries in order to be notified of cancers, certified causes of death, as well as loss of follow-up (due to emigration, for example). We have an ongoing agreement with NHS Digital and NHSCR (its Scottish equivalent) to provide these data regularly.

Hospital Records

The Airwave Study data repository needs to include information about health events and activities that are experienced by participants when they attend hospitals. HES are the national statistical data warehouse for England of the care provided by NHS hospitals and for NHS hospital patients treated elsewhere.

For each episode of care, HES includes information about:

- Patient identifiers (including NHS number);
- In-patient, day case and out-patient episodes, maternity records and psychiatric census;
- Administrative details (e.g. admission and discharge date) and the organisation providing the treatment;
- Clinical information relating to diagnoses (ICD10 codes) and procedures;
- OPCS4 codes: Classification of Interventions and Procedures (OPCS-4) is a procedural classification for the coding of operations, procedures and interventions performed during in-patient stays, day case surgery and some out-patient attendances in the National Health Service (NHS).

In all cases, the provision of these data to AHMS should be acceptable since all participants have given signed consent at enrolment for extraction of their individual hospital records and other health-related information.

Other data including GP records (Wales and Scotland)

We are actively pursuing the addition of GP record data in Wales and Scotland through SAIL and Albersoft Ltd respectively. Other data such as prescription data in Wales and Scotland are also being sought.

Support for Other Research

A key objective of AHMS is to use the data, samples and our register of active participants to support research and researchers.

Discovery of the Cohort

AHMS is promoting itself via its own website and by registering on web-based registers of biobanks, such as those listed below:

- The Airwave Health Monitoring website (https://www.police-health.org.uk)

- MRC cohort directory (https://www.mrc.ac.uk/research/facilities-and-resources-for-researchers/cohort-directory/
- Joint Programme – Neurodegenerative Diseases (JPND) initiative (http://www.neurodegenerationresearch.eu/jpnd-global-cohort-portal/
- Dementia Platform UK (https://portal.dementiasplatform.uk/)

Application Process

Applications to access data and samples for research projects must be submitted to the Study's Access Committee for consideration. A research proposal will be requested, in which the researcher may be asked to provide proof of peer review and confirmation that the research is scientifically and ethically sound.

The Access Committee comprises the Principal Investigator (PI), a member of the AHMS team, an epidemiologist and a lay representative of the Police Federation. The Committee reviews each application and decides whether the project complies with the terms of donor consent, whether the project is scientifically worthwhile and has reasonable chance of success. It may then authorise the release of samples and / or data, as appropriate.

Applications can be for any combination of data, biological samples, and permission to contact the cohort via the AHMS team, to invite them to join a separate research study with its own ethical approval.

AHMS policy applies equally to academics and private or public-sector researchers, whether they work in, or with, a for-profit or not-for-profit organisation, subject to them having relevant ethical approval.

Use of Biological Samples

Blood and urine samples are banked to provide a resource for collaborative research projects that encompass a wide variety of techniques including biochemistry, molecular biology, and biomarker studies. The strategy is to collaborate with research groups involved in a range of medical conditions with the aim of devising new treatments and therapies and promote preventative interventions.

AHMS endeavours to make bio-samples available to researchers provided that the:

- Stated research objectives have been approved by the Access Committee;
- Proposed research is covered by the scope of the donor consent;
- Research is sufficiently funded and resourced;
- Necessary bio-samples can be sourced and supplied;
- Proposed research is supported by the institution or organisation in which it will take place;
- Researcher's organisation enters into a contract that governs the transfer and use of any biological samples and data.
- The researcher accepts the AHMS Publications Policy.

Where relevant, we can make available to the researcher basic demographic information (typically, age at collection, gender and ethnicity) about the sample donor for quality assurance purposes.

Return of Samples and Data

Each researcher's institution must sign a material and / or data transfer agreement. This stipulates that, following completion of their project, any material that has not been used should be returned to AHMS. Researchers are asked to provide their results back to the tissue bank for linking to results from other projects using samples from the same donor.

Invitations to Join Research Studies

Invitations to participants to join external studies approved by the Access Committee will be sent by AHMS staff and will always come from AHMS, not the external researcher. Participants may be selected for such studies based on their genotype and / or phenotype, and AHMS will support this selection process as required.

Information regarding the new study would be provided to all invited participants, and any risks and benefits explained. Participants who express an interest in taking part will be sent an invitation for joining or providing more samples according to that study's protocol.

There is no obligation for participants to take part in these additional studies. Participants are free at any time to fully withdraw from AHMS, which allows for destruction of any remaining biological samples; or they can request simply to be excluded for further invitations and correspondence.

Management of AHMS

The AHMS team is based at the Department of Epidemiology & Biostatistics, part of the Imperial College School of Public Health and one of the outstanding NHS and University partnerships in the country. It is based at the Imperial's St Mary's campus at Paddington, London.

Day-to-day operation of AHMS is carried out by a small team that comprises data managers, statisticians, a research fellow, part-time clinician, and an administrator. They report to a Senior Scientific Manager, Mr Paul Downey, and the Principal Investigator (PI), Professor Paul Elliott. He in turn reports to the Directorate of Public Health and Primary Care in ICHNT .

The operation of AHMS has historically been governed by a Steering Group set up by the Home Office. It comprises officials responsible for commissioning the research into the Airwave radio system, representatives of working Police officers and staff at all levels, and independent scientific experts.

An Access Committee governs use of data and samples, as outlined on page 11.

Storage of Samples

We are consolidating the long-term archive of the AHMS bio-sample collection at two centres (Oxford & Milton Keynes) operated by the National Biosample Centre - https://ukbiocentre.com/. The

samples are stored according to an agreement between UK Biocentre Ltd. and Imperial College, which governs the terms under which they are managed. The National Biosample Centre is licenced by the Human Tissue Authority (HTA) - https://www.hta.gov.uk/establishments/nihr-national-biosample-centre-12624. The Designated Individual for the HTA Licence is Philip Eeles.

At present, a proportion of the collection is maintained at UK Biostores Ltd, who are licenced by the Human Tissue Authority - https://www.hta.gov.uk/establishments/uk-biostores-services-limited-12623.

Delivery of Screening Services

All clinical measurements and venepuncture is carried out by trained health care professionals with appropriate duty of confidentiality. To assist Imperial College deliver the Study nationally we contracted the screening services organisation, ToHealth Ltd, a commercial health screening company. However, the company will cease trading in December 2018. From January 2019, the rescreening programme will be managed directly by the AHMS team, supported by experience contract staff who have been delivering the programme, as employees and contractors of ToHealth Ltd.

Analysis and storage of biological samples is carried out by the pathology laboratory at Charing Cross Hospital, London. The results are securely delivered to AHMS each week. Samples are stored locally in -80^{0}C freezers (owned by AHMS) and shipped monthly to the NIHR National Biosample Centre in Milton Keynes.

The ECG taken during the screen is interpreted by the Electrocardiology Group within the Institute of Health and Well Being of the College of Medical, Veterinary and Life Sciences at the University of Glasgow ("Glasgow CARE").

The questionnaire is designed and operated using software and infrastructure from Snap Surveys - https://www.snapsurveys.com/. Coded results are downloaded periodically by the AHMS team.

When corresponding with participants by letter, we use the secure Docmail service- http://www.docmail.co.uk/.

Archiving of Paperwork

Paper consent forms are kept with participants' records by the screening delivery team. They are scanned and a copy is forwarded to AHMS for long term storage. Hard copies are kept in the Imperial College Archive. Other paper-based information such as registration forms, ECG printouts, questionnaires, food diaries and similar are securely stored for a short period prior to being shredded.

Ethical Issues & Consent

Consent has been obtained from all participants to take part in AHMS. The study was originally founded to investigate the possible health impact of Airwave radio use. The wider utility of the study

to facilitate a broad range of biomedical research has been widely recognised. By continuing to contribute to the resource, participants are increasing its scientific value.

Participants may personally benefit from the health screen freely offered by AHMS through identifying previously undiagnosed, treatable conditions, e.g. hypertension.

Because it is not possible to anticipate all future research uses from the samples and data collected, wide-ranging consent was sought for future research in general, subject to approval by the relevant ethics committee.

Participants who attend a follow-up screen renew their consent to be a part of AHMS as well as the procedures being carried out at the clinic. They are provided with an information leaflet prior to their visit, which explains the purpose of the follow-up study and what to expect in the clinic. They are encouraged to ask any questions and get satisfactory answers before signing the consent form.

Consent to participate in Airwave Study will apply throughout the lifetime of the tissue-bank unless the participant withdraws. Further consent will be sought for any proposed activities that do not fall within the existing consent.

Right to Withdraw

Participants have been advised at enrolment that they have the right to withdraw from AHMS at any time without giving reasons. This is essential to preserve and demonstrate the voluntary nature of participation.

Via the study website - https://www.police-health.org.uk/withdrawal-from-study – two withdrawal options are offered, we ask that participants make their intent clear when they contact us with a final decision.

The following is statements are taken from the Airwave website:

No Further Contact: We will not contact you again. We may continue to use samples and information provided previously, and to obtain and use further information from your health records.

No Further Access: We will not contact you again or obtain further information about you. We will anonymise your data by erasing all personally identifying information linked to your data. Personal identifiers stored in secure archives may remain for the lifetime of the archive but will not be used again.

You can also instruct us to destroy or retain any biological samples you donated to us. During enrolment, we provide information to participants about

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If, having discussed their concerns and options, a participant decides to withdraw, then AHMS would seek written confirmation of the level of withdrawal from the participant. Some minimal personal data

are necessarily retained, to ensure that participants who have withdrawn are not inadvertently contacted again.

Permission to Contact Participants

It was clearly explained to participants during enrolment that they may be contacted by AHMS for various reasons, including:

- To collect new information (such as questionnaire data, measurements or samples) for the benefit of the tissue bank.
- To seek consent to propose new uses for the samples and data that have passed scientific and ethics review but does not fall within the existing consent.
- To ask participants whether they would be willing for researchers to contact them to discuss possible involvement in a study that requires new information or samples.

It was emphasised that agreeing to re-contact is voluntary and they may still be part of the tissue-bank even if they decline to be re-contacted.

No personal contact details will be shared with any third-party researchers and so any re-contact will always be conducted by AHMS staff.

Information for Participants and the Public

Donation of samples to AHMS is a gift and we are grateful to everyone who consents to donate. Consenting to donate or refusing to donate samples does not affect routine care in any way, and donors' personal details remain confidential. Samples and their associated data will only be used for ethically and scientifically approved research. Everybody who has given consent for long term storage of samples since the start of the Study is a part of the tissue bank.

When researchers are issued with samples for projects, the samples are identified via a pseudonymised identifier so that no participant can be identified by their samples. Only relevant clinical information is released to researchers. All participant identifiers are removed.

There are updates on the Study website - https://www.police-health.org.uk/ - that links to scientific publications that involve the use of Airwave Study samples and data. Periodically a newsletter is also sent by email (where available) or by post to all participants.

Expectation of Financial Gain

Participants are not offered financial or other inducement to contribute to AHMS irrespective of whether the use of data or samples might ultimately lead to profit. Imperial College may work in partnership with the private sector (e.g. the pharmaceutical or biotech industry) to develop any invention for the benefit of patients. Part of the profits earned from inventions may come back to Imperial College.

Data Handling and Security

AHMS is committed to protecting the confidentiality of data and samples. Systems have been established for the secure data flow and storage of data in order to protect confidentiality.

Secure Operating Environments

All data will be migrated from its current air-gapped network based at the Paddington campus to the College's ISO27001 certified secure environment – the "Enclave". This is a fully managed infrastructure and secure environment providing high availability, resilience and business continuity through multiple servers, back-ups and disaster recovery measures.

Two Enclaves have been developed. Data relating to participants from all sources will be transferred securely to one of these environments, where they will be linked:

- For identifiable data, we use the Identifiable Zone. Access is locked down to the core AHMS team who need to use data of these sensitivity.
- For research data, there will be the Pseudonymised Zone, designed for internal and external researchers whose work does not require access to the identifiable data. Access to this area is also restricted and controlled appropriate to the need of the data held and the uses to be made of it.

We have also shared our pseudonymised research data with Dementias Platform UK. It is made available to their Dementia research projects subject to approval by the Access Committee.

Other appropriately encrypted cloud-based services will be used to share data with researchers who have been granted access to the Airwave dataset.

Extracts of data that have been fully anonymised may be made available to researchers for whom this is sufficient. They are still required to sign a confidentiality agreement with Imperial College and are then permitted to make local copies of research data in order to carry out the work approved by our Access Committee.

A robust data security model has been designed to protect sensitive personal and medical data from the potential risk of unauthorised access. The information held is sensitive in nature and therefore requires protection from unauthorised access or distribution. All information input, viewed or extracted is be protected so that only users with the correct authority and access can create, view, amend or delete information. Access to the system is be governed by authentication and authorisation privileges that check:

- Access is by an authorised person and the user is who they say they are. This is controlled by a username and complex password;
- The user accessing the system is authorised to do what they are attempting to do. That includes searching, updating, deleting and uploading information at the appropriate authorised level for the database(s) or table(s).

In summary, the security architecture provides the maximum protection available through implementing best practice network, hardware, software and data security measures.

Coding of Samples and Data

Samples supplied to researchers are pseudo-anonymised with a 5-digit identifier that links the components, i.e., questionnaires and samples of a single clinic visit together. Participants also have a separate participant identifier that links together the various clinic visits individuals make.

Pseudonymisation

During the follow-up health-screen, the clinic and ToHealth Ltd hold identifying information (such as name, address, birth date, sex) together with information collected from the participant during the visit. All identifiable information is separated from participants' other data and samples where possible. It is linked using a code that has no external meaning (not the NHS number, for example).

All identifiable information is held centrally by Imperial College in a restricted access database. Only a few named people within Imperial College have access to the "key" to the code for relinking the participants' identifiable information with their health data and samples (i.e. "reversible pseudonymisation"). It is necessary to retain this link with identifiable information to:

- Allow follow-up of participants' health;
- Verify correctness and completeness of data against original records;
- Establish correct linkages among databases;
- Recall participants for additional research; and,
- Find specific data or samples if participants withdraw.

Maintaining Confidentiality

AHMS is committed to maintaining confidentiality of personal data and samples collected from the population. This research project is registered for data protection and the requirements of the Data Protection Act 2018 apply in full. All personal information collected is used solely for biomedical research purposes.

Researchers and AHMS staff must sign a confidentiality agreement. Researchers must not attempt and should be not be able to identify individual participants from the anonymised data or samples that are provided to them.

Re-identification

The security policy is designed to minimise the risk of identification of individual participants from the data received by researchers. Even if it was possible to identify an individual through analysis, all researchers are bound by written undertaking that they will maintain the privacy of that participant.