



Generation Scotland Management, Access and Publications Policy

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1.0 Introduction

1.1 Aim and Purpose of Generation Scotland

Generation Scotland (GS) is a collaborative effort of the following parties: the University of Aberdeen, the University of Dundee, the University of Edinburgh, the University of Glasgow, Greater Glasgow Health Board, Grampian Health Board, Lothian Health Board, Tayside Health Board and NHS National Services Scotland Information Services.

Generation Scotland was set up with the aim of creating a Scotland-wide multidisciplinary collaboration to provide a platform for research into the genetic basis of common complex diseases.

The purpose of Generation Scotland is to build and maximise the utility of its biomedical and genetic resources for the study of common complex disease, to increase scientific knowledge and support translational and stratified medicine.

This document summarises the management and policies of GS.

1.2 Glossary of Terms

A Glossary of Terms is appended at Appendix 12.

1.3 Summary of the Generation Scotland Resource

Generation Scotland has created a series of biomedical and genetic resources for the study of common complex disease, to increase scientific knowledge and support translational and stratified medicine. References describing the resources are included in Appendix 1 and are available with copies of the Participant Information Leaflets and Consent Forms on the Generation Scotland website (www.generationscotland.org). In brief, detailed information has been collected using self-administered questionnaires, data and biological samples obtained at research clinics. Consent has been given for samples and data to be used for medical research and allowing future re-contact and linkage to routine information systems. Ethical approval was obtained from Research Ethics Committees in Scotland along with the necessary NHS R&D approval for the three studies involved in creating the GS resources for future use. Research Tissue Bank Status has been awarded to all three studies providing generic approval for a range of uses but future projects may be subject to additional ethical approval. The GS Research Tissue Banks are administered by the GS Access Committee (GSAC).

2.0 Management of Generation Scotland

2.1 The Scientific Committee of Generation Scotland

During sample and data collection the GS **Scientific Committee** was responsible for the strategic direction and scientific aims of Generation Scotland. The GS Scientific Committee consisted of a group of senior investigators from the partner Institutions and was ultimately accountable to the public for the performance of Generation Scotland. Following the completion of sample collection, the responsibilities of the Scientific Committee have been inherited by the Executive Group, which includes representation from each academic partner institution.

2.2 Generation Scotland Executive Group

The Scientific Committee elected to appoint a **Generation Scotland Executive Group** which has been delegated responsibility for the management of the operational activities of Generation Scotland. The Executive oversees the work of the various Generation Scotland sub groups, including the Management Team, Expert Working Groups and Access Committee. The GS Executive comprises a senior academic from each of the Universities of Aberdeen, Dundee, Edinburgh and Glasgow. The terms of reference of the Executive are contained in Appendix 2. The Executive Group currently comprises Professor David Porteous, Professor Blair Smith, Professor Sandosh Padmanabhan and Professor Alison Murray.

2.3 Access Committee

A further group established by and reporting to the GS Executive is the **Access Committee**. This comprises members from all parties to the Generation Scotland Collaboration Agreement, including representatives of NHS R&D Offices and University Technology Transfer Offices, and is responsible for the smooth execution of this Management, Access and Publications Policy. Its terms of reference are given in Appendix 8. The Committee's work is at all times governed by the terms of the Collaboration Agreement, and is premised on fairness and transparency in the prioritisation of access to and use of the Derived Data, Project Data or Samples ("the Resource"). The Committee's decision making on the disbursement of the Resource is informed by any third party funder's terms and conditions; the NHS R&D Offices and the University Technology Transfer Offices have particular responsibilities within the Committee in this regard. The Committee meets every 8-10 weeks (or as required) by teleconference to consider approval of requests for use of the Resource. Straightforward requests may be considered by email. To have Generation Scotland consider a proposal for use of the Resource or approve a paper for submission please follow the guidance below and send the proposal or paper to the **Access Committee** e-mail address: access@generationscotland.org. The current chair of the Committee is Professor David Porteous, University of Edinburgh.

2.4 Generation Scotland Expert Working Groups

Expert Working Groups have been set up to advise on and assist with research in the key fields of mental health, cognition, chronic pain and quantitative genetic traits. The Expert Working Group Lead Investigators are all senior scientists with long-standing associations with GS. They act as adjunct members on the GS Access Committee on an ad hoc basis.

2.5 Generation Scotland Advisory Board

The work of the Scientific Committee and conduct of Generation Scotland was overseen by the independent **Generation Scotland Advisory Board** which reported to Scottish Ministers. Lord Sutherland chaired the group which met twice a year. On completion of the sample collection the Advisory Board was disbanded. The terms of reference of the Advisory Board are shown in Appendix 3.

3.0 Collaboration – General Issues

3.1 The Resource

Generation Scotland is run as a Resource for the research community. Requests to use the Resource are made from:

- Academic collaborators: employees who are party to the Generation Scotland Collaboration Agreement, or researchers or employees of an academic institution or the NHS.
- Commercial organisations: specific arrangements have been defined to allow commercial organisations to access Generation Scotland resources. The Commercial Access and Intellectual Property Policy is shown in Appendix 6.

The Resource is set up as a **supported access** Resource rather than as an entirely open access Resource. To access the Resource, consult the GS website which contains details of the particular Resources available (www.generationscotland.org) and details on how to access the resources. Please contact Generation Scotland (access@generationscotland.org) to discuss a proposal with the GS Management Team and to obtain password-controlled access to the Generation Scotland data portal at www.gsaccess.org providing more detailed information about the resources and access to the on-line Collaboration Proposal Form (CPF). All proposals for use of the GS Resource require completion of a Collaboration Proposal Form describing the proposed project/collaboration (see Appendix 7) and the GS Management Team will provide guidance on proposal submissions. Proposals are then reviewed by the **Generation Scotland Access Committee**. The remit of this committee is shown in Appendix 8. This Committee will reply, no later than 30 days after the next scheduled Committee meeting, to let you know if the collaboration is approved (e.g. does Generation Scotland have the relevant Derived Data, Project Data or Samples; is any proposed third party funding and/or involvement in a proposed project commensurate with the terms and conditions of the Generation Scotland Collaboration Agreement) and to provide advice on the next stages. If there is a possibility of overlap with other investigators or other groups who are working on related topics the Committee may put applicants in touch with these groups and invite them to discuss their ideas before proceeding with the request, avoiding duplication of research already approved. The Management Team, on behalf of the Committee, will also estimate the cost of using the Resource for a proposed collaboration (see below).

Once collaboration has been approved investigators will be required to complete, sign and return a data transfer agreement (DMTA). Each agreement is specific to an individual proposal and requires a signature from the collaborators' institution(s) and to be acknowledged by the Principal Investigator for the project. The approved Collaboration Proposal Form, as a description of the project, forms an appendix to this agreement and must be agreed by the collaborators before the form can be signed by either party. An example of a DMTA is included in Appendix 10.

A condition of Access approval is that collaborators return a copy of the final dataset used in their analyses along with derived variables and descriptions of these variables. After a period of 12 months other investigators will be free to apply for access to these derived Data, Project Data and Samples.

3.2 Access to NHS data

For those projects wishing to access NHS data in addition to Derived Data, Project Data and Samples sourced from Generation Scotland clinic questionnaires and samples, additional approval will be required from the Public Benefit and Privacy Panel for Health and Social Care

(PBPP) (<http://www.informationgovernance.scot.nhs.uk/>). Submission of this application to PBPP is the responsibility of the applicant, but must be discussed with Generation Scotland.

3.3 Analysis of existing data

Once a proposal for analysis has been approved the applicant will be allocated a “**Research Facilitator**”. This is a member of Generation Scotland who is qualified to guide the applicant on the Resource and associated meta-data. The Research Facilitator will provide a brief description of key variables used in most analyses and access to meta-data that will allow the applicant to identify the variables required. This will be provided by password-secured access to the Generation Scotland Resource Access Portal. Once the required dataset has been agreed and Generation Scotland has received a signed DMTA the Research Facilitator will work with the Data Source manager to provide the dataset and provide advice on analysis of the dataset. The DMTA and Collaboration Proposal Form define the approved uses of the data and responsibilities of the applicant (see Appendix 9).

3.4 Assays on Biological Samples including Genotyping

When planning a proposal that requires biological samples, informal contact with the Committee prior to submission of the Collaboration Proposal Form is strongly recommended (access@generationscotland.org). To obtain further information about samples or laboratory procedures please contact the GS Management Team to discuss. Decisions on the use of biological samples will take account of the amount of the stored samples required, the amount in storage and the perceived scientific value of the proposed study. The terms of any third party involvement will also be taken into consideration.

Collaborators are encouraged to use Generation Scotland Approved Laboratories for the analysis of GS samples, or an external provider approved by Generation Scotland (see Appendix 10 for current list). This ensures an efficient, cost-effective service that maximally protects the resource for long term and widespread use. Any order to genotype Generation Scotland DNA must be placed via the GS Management Team. In particular circumstances, it will be appropriate to provide samples for analysis in other laboratories, which should be discussed with the GS Management Team prior to submission of a Collaboration Proposal. In such circumstances, GS may ask for evidence of appropriate quality standards in the laboratory where samples are to be analysed.

After a project is approved, collaborators are required to sign and acknowledge a completed DMTA. Each agreement will include a project specific appendix (Collaboration Proposal form) detailing the data and/or samples Generation Scotland will make available and the analysis to be completed. Samples, including DNA, will not be released until an agreement has been completed and signed. An example DMTA is included in Appendix 9.

3.5 Collection of new data

The majority of Generation Scotland participants have consented for re-contact. However, any new Derived Data, Project Data or Sample collection would require separate funding and separate ethical approval (see section below) so where an applicant has suggestions for the collection of new Derived Data, Project Data or Samples a Generation Scotland Collaboration Proposal Form (CPF) (Appendix 7) must be completed on-line describing the proposed collaboration, including specific sections on the collection of new Derived Data, Project Data or Sample. Investigators are strongly encouraged to discuss their plans with GS well in advance of the proposed project start date. This will allow GS to provide supporting information

for funding bids and an estimate of costs. Quotes can be provided prior to completion of a CPF and GS access approval. The actual charges will depend on the final, approved CPF.

New Derived Data or Project Data would become the property of the recipient's Institution with the recipient's Institution granting a non-exclusive, royalty-free, perpetual licence to GS to incorporate the data into the GS database and make it available for other research proposals. Normally this will take place at the end of the agreed project, but earlier release will always be possible. Any proposal to extend the embargo period should be included within the CPF for consideration by the GS Access Committee.

3.6 Costs and grants

Generation Scotland currently receives funding via NHS Lothian R&D for the Project Manager. Funding does not extend to support for individual projects, and collaborators will be expected to meet additional costs. These will be determined on a project-by-project basis. Once it has been agreed that collaboration can proceed the Principal Applicant will be informed of how much it will cost, although preliminary estimates may have already been given. Distribution of indirect income will also be agreed at this stage. GS may provide a letter of support in principle prior to Access Committee approval, as proposals are usually only considered by GSAC once funding is in place. The applicant should notify GS when funding has been awarded as the application process can then continue to finalise the proposal in detail.

Applications to use the Resource from commercial organisations will be charged a commercial rate as defined by the Commercial Access and Intellectual Property Policy contained in Appendix 6.

3.7 Contact with study members

Contact details for participants are held separately and securely from all other study data within the NHS system at the Health Informatics Centre, University of Dundee. Contact details are not released to collaborators, and re-contact with participants for new studies requires an introduction from GS. Participants are always free to choose whether or not they wish to consider volunteering for a new research study. If they choose to do so, they remain free to withdraw at any time. The approved mechanism therefore is that that contact is facilitated by HIC and it is then up to the participants to contact the new study team if they are interested in taking part. No collaborator should ever attempt to contact study participants without the knowledge and formal approval of the Generation Scotland Access Committee.

3.8 Confidentiality

Protecting the confidentiality of the study participants is a primary concern of Generation Scotland. This is a particular issue as Generation Scotland is a national study with wide coverage. Collaborators will therefore have to be bound by an agreement (within the DMTA) to treat all information with utmost confidentiality.

3.9 Documentation

A description of the Generation Scotland Resource is available on the public website (www.generationscotland.org) and the private GS Access Portal (www.gsaccess.org), authorised access available by application to GS. More detailed information is available on study variables once collaboration has been agreed and once a completed data/material transfer agreement or letter of agreement has been received.

4.0 PR Policy

All press releases on research arising from the Project or Future Projects must be approved by the GS Management Team (access@generationscotland.org) and agreed with the Principal Investigator and any third parties, e.g. research funders, host institutions. The expectation is that the PI will lead any media enquiries and interviews, but GS expects to be informed and invited to support any such activity and, exceptionally, may lead such an activity. GS may also ask authors to prepare a précis of important papers to include on the GS website, in reports to funders or in applications for future core support.

5.0 Authorship and Publication

Authorship on papers arising from Generation Scotland studies should follow the GS Authorship Policy in Appendix 11a. The default position is that the GS Executive and/or their GS nominees will be co-authors.

Pre-submission versions of all papers using the Generation Scotland resource should be sent to access@generationscotland.org for review. We will wish to be assured that confidentiality has been protected; any patentable results have been identified and that the contribution of GS has been recognised; the paper will not bring the Project or Future Projects into disrepute; the study does not overlap with other papers published or in preparation; GS requirements (including Authorship Policy and Acknowledgements) have been followed.

Generation Scotland should be sent a copy of all publications, including published meetings and abstracts. This is essential to ensure proper documentation of outputs. We expect publications to include Generation Scotland or GS Executive members as co-authors and the resource to be referenced and acknowledged. We expect publications to be checked by senior authors for disclosure of potential IP and where this arises that this is discussed in advance with Generation Scotland. There is no requirement for conference abstracts to be approved prior to submission.

A checklist of requirements for papers arising from Generation Scotland along with some accompanying notes explaining these requirements and containing appropriate text to insert is contained in Appendix 11b. Named GS authors will fulfil standard requirements for authorship (including commenting on draft manuscripts and approving the final version prior to submission). Collaborators should send copies of the final submitted version to access@generationscotland.org. Collaborators should let GS know when a paper is accepted and provide an electronic copy of the final published version. It is the authors' responsibility to ensure papers are freely available for research as required by studies funded by the Chief Scientist's Office.

A list of publications arising from the studies can be found on the GS website (www.generationscotland.org).

6.0 Acknowledgements in Publications

GS has an agreed standard text for the **Acknowledgements** section that should be included in all papers:

“Generation Scotland received core support from the Chief Scientist Office of the Scottish Government Health Directorates [CZD/16/6] and the Scottish Funding Council [HR03006]. Genotyping of the GS:SFHS samples was carried out by the Genetics Core Laboratory at the

Wellcome Trust Clinical Research Facility, Edinburgh, Scotland and was funded by the Medical Research Council UK and the Wellcome Trust (Wellcome Trust Strategic Award “STratifying Resilience and Depression Longitudinally” (STRADL) Reference 104036/Z/14/Z).”

An optional addition, dependent upon the publisher’s requirements or constraints and in keeping with any other cohorts that may be acknowledged in the same study, is as follows:

“We are grateful to all the families who took part, the general practitioners and the Scottish School of Primary Care for their help in recruiting them, and the whole Generation Scotland team, which includes interviewers, computer and laboratory technicians, clerical workers, research scientists, volunteers, managers, receptionists, healthcare assistants and nurses.”

7.0 Intellectual Property

The intellectual property used in the project and arising from it is governed by the Collaboration Agreement. The Commercial Access and Intellectual Property Policy (Appendix 6) is informed by the Agreement.

8.0 Version and Feedback

This policy document is Version 6.7 and was last updated in June 2016. GS welcomes feedback, comments and suggestions for improvement.

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APPENDIX 1 DESCRIPTION OF GENERATION SCOTLAND RESOURCES

Resource GS:SFHS - Scottish Family Health Study

GS:SFHS is an intensively phenotyped, family-based cohort for the study of the genetic basis of common complex diseases and response to treatments. Recruitment ran from 2006 to 2011 and each participant gave blood samples (for DNA, serum and cryopreservation) and a urine sample. More than 24,000 participants in ~7000 families were recruited.

Study methodology:

Please see the following reference for a description of the methods used:

Smith BH, Campbell H, Blackwood D, Connell J, Connor M, Deary IJ, Dominiczak AF, Fitzpatrick B, Ford I, Jackson C, Haddow G, Kerr S, Lindsay R, McGilchrist M, Morton R, Murray G, Palmer CN, Pell JP, Ralston SH, St Clair D, Sullivan F, Watt G, Wolf R, Wright A, Porteous D, Morris AD. (2006). Generation Scotland: the Scottish Family Health Study; a new resource for researching genes and heritability. *BMC Med Genet.* 2006 Oct 2;7:74

Smith BH, Campbell A, Linksted P, McGilchrist M, Wisely L, Fitzpatrick B, Ford I, Hocking LJ, Jackson C, Kerr SM, Lindsay RS, Morton R, Palmer, CAN, Deary IJ, MacIntyre DJ, Campbell H, Dominiczak AF, Porteous DJ, Morris AD. (2013). Cohort Profile: Generation Scotland: Scottish Family Health Study (GS:SFHS). The study, its participants and their potential for genetic research on health and illness. *Int J Epidemiol.* 2013 Jun;42(3):689-700.

Data overview:

1. Pre-clinic questionnaire
 - a. Demographic details
 - b. Occupational history
 - c. Lifestyle – smoking, alcohol, diet and exercise
 - d. Personal and family medical history
 - e. Rose angina questionnaire
 - f. Musculoskeletal questions – including Chronic Pain Grade, history of fracture and fragility fracture, personal family history of joint replacement, HRT use, age at menarche and menopause
 - g. Current drug history, including prescribed and non-prescribed medications
2. Physical measurements
 - a. Height, weight, waist-hip ratio
 - b. Blood pressure x 2 (Omron BP Monitor), resting pulse x2
 - c. Ankle brachial pressure index (ABPI)
 - d. Spirometry
 - e. ECG
 - f. Bio-impedance
3. Cognitive function measurements
 - a. Eysenck Personality Questionnaire Revised Short Form
 - b. Logical Memory (Immediate & Delayed) from the Wechsler Memory Scale III
 - c. Digit Symbol from the Wechsler Adult Intelligence Scale III
 - d. Verbal Fluency
 - e. Mill Hill Vocabulary Scale
 - f. General Health Questionnaire – 28

4. Mental health measurements
 - a. SCID Brief screening interview for major depression
 - b. SPQ-B Personality Questionnaire
 - c. MDQ Mood Questionnaire

5. Biochemistry measures
 - a. Urea
 - b. Creatinine
 - c. Glucose
 - d. Potassium
 - e. Sodium
 - f. Total cholesterol
 - h. HDL cholesterol

Resource GS:21CGH - Genetic Health in the 21st Century

GS:21CGH aims to establish the genetic profile of a control population of people living in Scotland in relation to health and disease. 21CGH is a growing resource of control DNA and genetic and phenotypic information. Recruitment ran from 2006 to 2011 in Edinburgh, Aberdeen, Banff and Peterhead. Two blood samples (for DNA, PBLs and plasma) were collected from each participant as well as a urine sample (Aberdeen only) and associated phenotype information including basic physical observations, answers to a clinical/lifestyle questionnaire, and cognitive function measurements. Data obtained from participants in the clinics was entered into the 21CGH database using electronic collection methods. Consent was also obtained for access to and subsequent extraction of de-identified information from patient medical records. Around 2,000 unrelated individuals were recruited.

Study methodology:

DNA is extracted from all blood samples and archive and working stocks prepared. Purified blood cells will be stored and used to make lymphoblastoid cell lines. These will primarily be a resource for proteomics work but they may also be used for DNA extraction for future research.

The 21CGH resource should limit the need to obtain further fresh control blood/DNA samples and will provide a knowledge base to aid in the design of future genetic studies.

Resource GS:3D - Donor DNA Databank

The Generation Scotland Donor DNA Databank (GS:3D) has built a large collection of human control DNA samples and plasma from blood donors attending sessions at the Scottish National Blood Transfusion Service in more than 140 locations throughout Scotland. Recruitment took place during 2008 and the cohort contains almost exactly 5,000 samples and data.

Study methodology:

The purpose of GS:3D is to provide a long term, well characterised resource of human DNA control samples. This could lead to an improvement in the statistical power of many human genetics studies and avoid duplication of effort and expense. 'Case' samples are unique to each disease study, but the same control samples can be used across many studies if appropriately collected and characterised. GS:3D provides access to a collection of well-

maintained stocks of control DNA obtained with consent from the Scottish population. Donors answered a short questionnaire and allowed a sample of their blood and a filter that would otherwise be discarded to be used by the project. Questionnaire data was entered into the databank using optical mark read (OMR) technology. The collected data, DNA and plasma samples were unlinked and fully anonymised 28 days after collection.

Kerr et al. (2010). Generation Scotland: Donor DNA Databank; A control DNA resource. *BMC Medical Genetics* 2010, 11:166.

Data overview:

Questionnaire

Age group, Sex

Cultural Background

Participant and Parental Scottish Region or Country of Origin

Grandparental Origin (Scotland/Other)

SNBTS donor inclusion criteria

APPENDIX 2

TERMS OF REFERENCE FOR THE GENERATION SCOTLAND EXECUTIVE

During the planning (2001-2006) and pilot stages of the recruitment phase of Generation Scotland (2006-2011), governance was overseen by a scientific committee reporting to an independent Scientific Advisory Board (established under Nolan procedures by the CSO). Once fully up and running, on-going responsibility for the governance of Generation Scotland was then devolved to an Executive with representation from the Aberdeen, Dundee, Glasgow and Edinburgh Medical Schools, supported by a Management Group, responsible for the day-to-day running of GS, and an Access Committee that draws upon additional NHS R&D, Technology Transfer, Clinical and Scientific expertise.

The GS Executive is responsible for:

1. The governance arrangements of Generation Scotland
2. Generation Scotland's strategic direction and aims
3. Accountability to the public
4. The management of Generation Scotland with probity and integrity
5. The scientific rationale and scope within the broad consent given by Generation Scotland participants for medically relevant research into the genetic causes of disease
6. The consideration of any relevant ethical issues relating to Generation Scotland and how these might be addressed
7. The conditions under which researchers will be given access to Derived Data, Project Data and Samples collected by Generation Scotland
8. Oversee the operational and financial management of Generation Scotland
9. Oversee the portfolio of studies that are coordinated by Generation Scotland in order to create an internationally competitive resource
10. Oversee and, where appropriate, supervise the arrangements for handling and analysing the data and for statistical support
11. Establishing productive relationships between Generation Scotland and other biobanks
12. Encouraging the Scientific community to drive scientific outputs from the Generation Scotland portfolio, and act as a catalyst for interdisciplinary funding applications.

Founding membership of the GS Executive:

Aberdeen: Blair Smith

Dundee: Andrew Morris

Glasgow: Anna Dominiczak

Edinburgh: David Porteous

Current membership of the GS Executive (as at June, 2016):

Aberdeen: Alison Murray

Dundee: Blair Smith

Glasgow: Sandosh Padmanabhan

Edinburgh: David Porteous

APPENDIX 3

TERMS OF REFERENCE FOR THE GENERATION SCOTLAND ADVISORY BOARD

The GSAB was appointed by the Chief Scientists Office on behalf of the Scottish Executive and oversaw the activities of the Scientific Committee while recruitment was in progress. During its tenure (2005-2010) the GSAB adhered to the following principles:

1. The GSAB does not have executive powers. Its role is to comment on and provide advice for Scottish Ministers and the GS Scientific Committee on the GS project and its implications for the Scottish community.
2. Although GSAB will have an advisory role on ethics as in other matters of public interest, it will not assume a regulatory function as this is the responsibility of other bodies.
3. It will usually meet twice a year but not all dialogue will be conducted through formal meetings.
4. The GSAB may request information relevant to the discussions of the Board.
5. The GSAB will address the public through politicians and public statements.
6. Complaints will be referred to those with executive powers.
7. The GSAB is independent of the GS Scientific Committee.

Chair: Lord Sutherland of Houndwood

Members: Ms Val Atkinson, Dr Mair Crouch, Mr Jim Jackson, Professor Graeme Laurie

APPENDIX 4 TERMS OF REFERENCE FOR THE GS EXPERT WORKING GROUPS

Expert Working Groups (EWGs):

- Are likely to have been instrumental in establishing relevant components of the GS dataset.
- Will have clear indicators of specialist knowledge in the defined area.
- Will invest resources and assume responsibility for ensuring the integrity of the defined research area and related data, e.g. through checking, cleaning, validation and annotation.
- Will make this cleaned data and primary analyses available for further collaborative work.
- Will support and/or facilitate other collaborative proposals in the area.
- Will undertake and publish primary research in accordance with the GS publication policy.
- Will report to the GS Executive on progress and collaborations at least annually and on request in support of GS reports and bids for funding.
- Will have a nominated lead to co-ordinate the activity of the group and who will be the principal point of contact with GS.

GS:

- Will consider requests from prospective Expert Working Groups (EWGs) through the GS Access mechanism.
- Will formalise and publish the role of approved GS EWGs on the GS web site.
- Will refer research applicants to EWGs where relevant for help and advice.
- Will not oblige independent researchers to work directly with EWGs, but will ensure that their contribution is acknowledged in publications arising.
- Give appropriate recognition to EWGs for their contributions to enhancing the GS resource.

Conditions

GS EWGs are required to apply for recognition using the standard GS access process. The proposal must describe the proposed research area, detail the proposed work plan, describe the resources that will be available to support the EWGs actions and articulate the benefit to the GS core resource. The application should list the EWG members and their respective roles and expertise.

Each EWG must agree to a summary of their membership and area of interest appearing on the GS web site. Amendments to the scope of membership of the group must be submitted to the chair of the GS Access Committee for approval.

GS EWGs will be expected to feed back to the GS Project Manager and Chair of the GS Executive with regular progress reports (the nature and period of reporting will be defined by the GS Executive, but not less than annually).

Third party researchers who wish to access GS resources are expected to make best use of GS data and samples. As such, where data provided by EWGs are available and would add value to a research study, the applicant will be expected to liaise with the relevant EWG. EWG contributions to research publications should be acknowledged in line with the GS publications policy.

Formal collaboration with EWGs is not a condition of access to GS, and EWGs do not have preferential or exclusive access to GS data and samples.

Current Approved Expert Working Groups

Cognitive and related traits (Proposal GS12102 – Deary)

Mental health and related traits (Proposal GS12119 – McIntosh)

Pain and related traits (Proposal GS12117 – Smith)

Genome-wide genetic analysis (Proposal GS14202 – Hayward)

APPENDIX 5
TERMS OF REFERENCE FOR THE GENERATION SCOTLAND MANAGEMENT GROUP

1. Delegated responsibility for the operational activities of Generation Scotland
2. Responsible for all aspects of operational management of Generation Scotland studies including the on-going maintenance, promotion and building of the resource.
3. To process and coordinate on behalf of the Generation Scotland Executive all requests for new collaborations which are received via the Generation Scotland Collaboration Proposal Form.
4. Responsible for supporting the activity of the GS Access Committee in facilitating access to the resource for approved projects.
5. To report to the GS Executive Group

The Generation Scotland Management Group comprises the Chief Investigator, a Project Manager and an Administrator.

APPENDIX 6 COMMERCIAL ACCESS AND INTELLECTUAL PROPERTY POLICY

The Generation Scotland Collaboration Agreement governs (i) the intellectual property brought to the project by the collaborating institutions (Background Information and Background Rights) and (ii) the intellectual property arising from the Project and Future Projects.

1. Principles of Agreement on Intellectual Property:

- 1.1. Background Information, Background Rights and NHS Data is owned by the party bringing it to the Project; a non-exclusive royalty free licence to Background Information and Background Rights is granted between the parties of the Generation Scotland Collaboration Agreement for the purposes of carrying out the Project subject to third party rights (refer to Clause 7.1 and 7.2 of the Generation Scotland Collaboration Agreement);
- 1.2. Project Results and Project Rights arising from the Project and Future Projects shall be owned by the party generating them; identification, protection and management of Project Results and Project Rights, and associated costs, will be the responsibility of the party or parties owning the Project Results and Project Rights (refer to Clause 7.5 of the Generation Scotland Collaboration Agreement);
- 1.3. Each party grants the other parties a non-exclusive royalty free licence, to use its share in the Project Results and Project Rights (other than Project Results and Project Rights arising from Future Projects) for the purposes of (i) undertaking the project and (ii) internal, non-commercial research, teaching and/or clinical applications subject to review in light to any commercial/licensing opportunity in respect to a particular Project Results or Projects Rights (refer to Clause 7.12 of the Generation Scotland Collaboration Agreement);
- 1.4. Should a party wish to commercially exploit the Project Rights generated by another party during the project it may request a licence to do so on terms to be agreed (refer to Clause 7.11 of the Generation Scotland Collaboration Agreement);
- 1.5. Access to Project Results and Project Rights arising from Future Projects shall be negotiated between parties on a case by case basis (refer to Clause 7.12 of the Generation Scotland Collaboration Agreement);.

2. Responsibilities of the Parties in the Commercial Exploitation of Project Results and Project Rights

- 2.1. It is envisaged that the output of the Generation Scotland Project and Future Projects will generate new Project Results including but not limited to genetic analysis capability, informatics tools, educational tools, novel drug targets and novel diagnostic methods;
- 2.2. Any commercial exploitation of the outputs of the Project will be without payment to the participants or their heirs and without any acknowledgement of individual patient contribution;
- 2.3. Each party shall be responsible for the commercial exploitation of Project Results and Project Rights generated by that party; regular updates on such commercial

exploitation must be submitted to the Access Committee; in the case of jointly owned Project Results and Project Rights it shall be agreed between the parties who should take the lead (refer to Clause 8.3 of the Generation Scotland Collaboration Agreement).

- 2.4. Each party shall give due consideration to requests for access to its Background Information and/or Background Rights or NHS Data for the purposes of allowing another party to commercially exploit Project Rights generated by it; such access shall be on terms and conditions to be agreed and is subject to third party rights (refer to Clause 8.4 of the Generation Scotland Collaboration Agreement).
- 2.5. Each party shall give due consideration to requests from another party to commercially exploit its Project Results or Project Rights; such access shall be on terms and conditions to be agreed and subject to third party rights (refer to Clause 7.11 of the Generation Scotland Collaboration Agreement).
- 2.6. Should a party choose not to commercialise Project Rights the Future Directions Group may seek assignation of such Project Rights to another party, subject to agreement by both parties, to allow commercial exploitation to proceed; the party originally generating the Project Rights will share in any commercial income stream arising from this arrangement on terms and conditions to be agreed (refer to Clause 7.11 of the Generation Scotland Collaboration Agreement).

3. Income Sharing

- 3.1. Following deductions (e.g. for patent and legal costs) the net revenue derived from commercial exploitation shall be divided between the parties as follows: 25% to the University parties; 25% to the NHS parties; 25% to the party/parties which own the commercialised project rights; 25% to support the Generation Scotland initiative (refer to Clause 9.1 of the Generation Scotland Collaboration Agreement);
- 3.2. A policy shall be agreed by the Generation Scotland Scientific Committee within six months of signature of the Generation Scotland Collaboration Agreement to govern the allocation of funds accrued to the project (refer to Clause 9.3 of the Generation Scotland Collaboration Agreement).

4. Approval of third party (including commercial) collaborations:

- 4.1. Project Data, Derived Data and Samples arising from the Project can only be provided to third parties with the prior written approval of the Generation Scotland Scientific Committee; a function that has been delegated to the Access Committee (refer to Clause 6.3. of the Generation Scotland Collaboration Agreement).
- 4.2. The Executive Group shall be responsible for understanding the costs of maintaining and developing the Generation Scotland Resource across Scotland in order to inform a pricing structure for commercial access and which is commensurate with long term financial sustainability (refer to Clause 5.4. of the Generation Scotland Collaboration Agreement);
- 4.3. The “price” paid for commercial access to the Resource shall vary depending on the nature of the interaction. Service style agreements whereby Generation Scotland is unlikely to enjoy benefits additional to the payment for release of Project Data,

Derived Data or Samples will normally be priced at a higher rate than where longer term benefits for the Resource are perceived. The Executive Group shall be charged with ensuring that commercial price negotiations are undertaken by appropriately skilled and informed individuals, perhaps drawing on the skills extant within the project Parties NHS R&D Offices and the University Technology Transfer Offices (refer to Clause 5.4. of the Generation Scotland Collaboration Agreement).

**APPENDIX 7
GENERATION SCOTLAND
COLLABORATION PROPOSAL**

Current version available online at www.gsaccess.org

APPENDIX 8

TERMS OF REFERENCE FOR THE GENERATION SCOTLAND ACCESS COMMITTEE

1. To provide the management of the approaches to Generation Scotland for collaboration to use Project Data, Derived Data, NHS Data and/or Samples in Future Projects.
2. To review and approve or deny requests for new collaborations which are received via the Generation Scotland Collaboration Proposal Form. The policy which outlines the principles used in decision making is outlined on the Generation Scotland website.
3. To receive, scrutinize, assess and approve or deny: Collaboration Proposal Forms, Data and Material Transfer Agreements; and Authorship, Publications and Papers checklists.
4. To report regularly to the Executive on the collaboration requests received and their progress, the progress of publications, and compliance with Access agreements.
5. To ensure the Project, through its collaborations, conforms to the consent and ethical approval obtained and is not brought into disrepute and that participant confidentiality is respected.
6. To consult with the GS Executive concerning any need for revision of the Agreements mentioned in (3) above.

Membership:

- The membership includes representation from all parties of the Generation Scotland Collaboration Agreement, including representatives of NHS R&D Offices, University Technology Transfer Offices, clinical, ethics/governance, laboratory and IT expertise.
- The Access Committee is considered quorate if six or more members take part in a meeting.
- The current chair is Professor David Porteous (Edinburgh).

The GS Access Committee (GSAC) was formerly known as the GS Resource, Management and Development Committee (GS RMDC).

**APPENDIX 9
DATA / MATERIAL TRANSFER AGREEMENT**

PLEASE READ THIS DATA / MATERIAL TRANSFER AGREEMENT (“DMTA”) CAREFULLY.

| | |
|---------------------|--|
| GS Application Ref: | |
|---------------------|--|

| | |
|--------------------------------|--|
| Name of Recipient Institution: | [insert institution name] |
| Address: | |
| Name of Principal Applicant: | |
| Term: | From the last date of signature of this DMTA for a period of twelve (12) months. |
| Charges | <p>In consideration of the provision of the Data / Materials, Recipient Institution hereby agrees to make the following payments to the University of Edinburgh on behalf of the Generation Scotland Collaboration Parties together with any VAT eligible in respect thereof.</p> <p>[insert details of payment]</p> <p>Such payments shall be due within thirty (30) days of the receipt of invoice(s) from the University of Edinburgh Finance Office.</p> |

BACKGROUND

The University of Aberdeen, the University of Dundee, the University of Edinburgh, the University of Glasgow, Greater Glasgow Health Board, Grampian Health Board, Lothian Health Board, Tayside Health Board and the NHS National Services Scotland Information Services (collectively the “**Generation Scotland Collaboration Parties**” and individually a “**Generation Scotland Collaboration Party**”) through Generation Scotland have collected and are together custodians of certain data sets (“**Data**”) and biological research material and DNA (including derivatives of the same) (“**Materials**”). For the purposes of this DMTA, Materials shall include any extracts acquired in the course of the Research.

The Principal Applicant in terms of a proposal form submitted to the Generation Scotland Access Committee has requested the right to use certain of the Data / Materials to conduct research based on the Data / Materials (the “**Proposal Form**”).

The Access Committee has reviewed the Proposal Form and has agreed that the Recipient Institution may use the Data / Materials described in the Proposal Form as contained within Appendix B to conduct the research detailed in the Proposal Form (the “**Research**”).

The Generation Scotland Collaboration Parties are willing to supply the Recipient Institution with the Data / Materials for the purpose of conducting the Research for the Term on the terms and conditions set out in Appendix A.

BY PRINTING AND SIGNING THE RECIPIENT INSTITUTION ACKNOWLEDGES THAT IT HAS READ AND UNDERSTOOD THE TERMS OF THIS DMTA AND AGREES TO BE BOUND BY ITS TERMS AND CONDITIONS.

In order to complete this process, you must provide us with certain personal information. The personal information that we collect will only be used by us for administration purposes. It will not be passed on to others without your consent.

Please send any correspondence about this DMTA to access@generationscotland.org

This DMTA is made on signature of this DMTA by the Recipient Institution.

Signed by an authorised signatory for and on behalf of the **Recipient Institution**:

| | |
|--------------|------------|
| Print Name: | Signature: |
| Designation: | Date: |
| E-mail: | |
| Telephone: | |
| Fax: | |

Acknowledged by the Principal Applicant

| |
|------------|
| Signature: |
| Date: |

Appendix A

Terms and Conditions

1. GRANT AND SCOPE

- 1.1 Upon execution of this DMTA, Generation Scotland Collaborating Parties will supply the Data / Materials to Recipient Institution.

- 1.2 Data / Materials remain the property of some or all of the Generation Scotland Collaborating Parties. There is no transfer or licence or implied transfer or licence of rights in the Data / Materials from the respective Generation Scotland Collaboration Parties to Recipient Institution including (without limitation) any intellectual property rights. These Terms and Conditions do not restrict the rights of Generation Scotland Collaboration Parties to distribute the Data / Materials to other institutions or to publish any document relating to the Data / Materials.

- 1.3 Recipient Institution will use the Data / Materials in accordance with the principles of good laboratory practice and shall ensure compliance with all applicable laws, regulations and research governance pertaining to the Research.

- 1.4 Recipient Institution will retain the Data / Materials in a secure location on its premises and will not permit the Data / Materials or any part of it to come into the possession or control of any other organisation or any individual other than its employees who are involved in the Research under direct supervision of the Principal Applicant unless previously agreed in writing by the Access Committee. Recipient Institution will ensure that suitable systems are in place for the tracking of the Data / Materials while in its possession.

2 RESTRICTIONS ON USE

- 2.1 Recipient Institution will use the Data / Materials to carry out the Research only, and only for Research that has appropriate approvals in place (including without limitation research and development management approval and ethical approvals). Should Principal Applicant wish to share the Data / Materials with a collaborator outwith the Recipient Institution, the third party must make a separate application for access to the Data / Materials.

- 2.2 The Recipient Institution will not use the Data / Materials or any parts thereof for any commercial purpose or any purpose that is subject to consulting or licensing obligations to third parties, without the explicit consent and written agreement of the Access Committee.

- 2.3 Recipient Institution will not use the Materials in any experiments involving humans and will not use the Materials in contact with any cells or other materials to be infused into humans. Materials will not be released for use in animal research.

- 2.4 Recipient Institution will make no attempt to link the Data to other datasets (Generation Scotland or otherwise) held by different recipients or by the same Recipient Institution for different projects, without specific approval and agreement from the Access Committee.

3 RETURN OF DATA / MATERIALS

- 3.1 Data / Materials in the possession, or under the control, of Recipient Institution shall at Recipient Institution's expense be immediately returned to the relevant Generation Scotland Collaborating Party or destroyed (in each case as directed by the Access Committee) upon (i) the reasonable request of the Access Committee; (ii) notification by the Access Committee of the withdrawal of consent by individual cohort members for the continued use of their Materials (including any associated Data); (iii) termination of this DMTA, or (iv) breach of any of this DMTA by the Recipient Institution. If Recipient Institution is required to destroy the Data / Materials for any reason then it will ensure that this is done in compliance with all applicable laws, regulations, codes of practice and guidelines governing the use of the Data / Materials and will confirm in writing to the Access Committee that the Data / Materials have been destroyed.

4 INTELLECTUAL PROPERTY RIGHTS AND PUBLICATIONS

- 4.1 The Recipient Institution shall own any data, datasets, algorithms and/or derived variables used therein which may be derived from the use or analysis of the Data / Materials pursuant to the Research ("**Derived Data**"). The Recipient Institution hereby grants to each of the Generation Scotland Collaboration Parties a non-exclusive, royalty-free, perpetual, licence (with a right to sub-license) to Derived Data for the purposes of (without limitation) incorporation into the Generation Scotland database and/or research resource and its non-commercial research purposes.
- 4.2 Subject to Clause 4.3, the Recipient Institution shall be entitled to publish the Data / Materials and Derived Data subject to approval of the Access Committee as detailed in the Generation Scotland Management, Access and Publications Policy (a copy of which is available on the Generation Scotland website – www.generationscotland.org) as such policy may be updated and amended from time to time. Recipient Institution will where requested to do so by the Access Committee, provide Generation Scotland with a fully documented electronic copy of any Derived Data prior to publication in any form or within six (6) months of the completion of the Research, whichever is the sooner.
- 4.3 Recipient Institution will acknowledge Generation Scotland and include as authors members of Generation Scotland Collaboration Parties identified by the Access Committee to have played a key scientific role in the generation of the Data and the Materials in all publications relating to the Research.
- 4.4 In the event that Recipient Institution makes or observes any new discovery or improvement or invention relating to the Data / Materials or as a direct result of the Research ("**Invention**") then the Recipient Institution will bring this to the attention of the Access Committee. Each of the Generation Scotland Collaboration Parties will, at all times, retain the right to use any Invention for its non-commercial research purposes.

- 4.5 If any commercial revenues result from Recipient Institution's use of the Data / Materials, Derived Data and / or Inventions, the Generation Scotland Collaborating Parties shall be entitled to an equitable share of any such revenues that accrue to the Recipient Institution. The Recipient Institution must notify the Access Committee if such commercial revenues arise.

5 CONFIDENTIALITY AND CONSIDERATION

- 5.1 Other than as permitted pursuant to Clause 4.2 Recipient Institution will keep the Data / Materials confidential and will make no attempt to identify study participants.
- 5.2 The Recipient Institution shall take all reasonably practical measures to secure the safety and confidentiality of the Data / Materials and for that purpose, but without limitation, shall ensure that its Principal Applicant and its employees working on the Research are similarly bound by appropriate undertakings. Information shall not be considered to be confidential if it is required to be disclosed by a court of competent jurisdiction, by regulatory body or otherwise by operation of law. In the event of such a requirement, the Recipient Institution shall provide the Access Committee with written notification of the requirement to disclose and shall only disclose that portion of the Data / Materials and associated confidential information which it is legally obligated to disclose.

6 LIABILITY AND INDEMNITY

None of the Generation Scotland Collaboration Parties accepts any liability in connection with the Recipient Institution's use of the Data and/or Materials. None of the Generation Scotland Collaboration Parties represents that (i) the Data / Materials are of satisfactory quality or fit for any particular purpose; or (ii) use of the Data / Materials is free from infringement of third party rights, including intellectual property rights. To the extent permissible by law, the Recipient Institution will indemnify and keep indemnified on demand each of the Generation Scotland Collaboration Parties for any costs and/or damages whatsoever arising from Recipient Institution's use, handling and storage of the Data and/or Materials where such costs and/or damages arise as a result of the negligence or wilful misconduct of the Recipient Institution.

7 GENERAL

- 7.1 The Recipient Institution will neither assign, transfer, nor part with any of its interests, rights, duties or obligations under this DMTA.
- 7.2 Any notice or communication required to be given under this DMTA shall be in writing and shall be sufficiently served if sent by recorded delivery post to the Access Committee (in the case of the Recipient Institution) and to the Recipient Institution (in the case of the Generation Scotland Collaborating Parties). The notice will be deemed to have been duly delivered if delivered by post, forty eight (48) hours after being posted.

- 7.3 This DMTA is not intended to create benefit, claim, or right of any kind whatsoever enforceable by any person who is not a party to this DMTA. It is acknowledged and agreed by the Recipient Institution that each of the Generation Scotland Collaborating Parties are parties to this DMTA on a several basis, and may enforce its rights hereunder either individually or collectively (with one or more of the Generation Scotland Collaborating Parties).
- 7.4 This DMTA shall continue for the Term unless terminated earlier by written notice served in accordance with paragraph 7.2. The Term may be extended with the written permission of the Access Committee, on behalf of the Generation Scotland Collaborating Parties. Permission to extend the Term must be sought by the Recipient Institution three (3) months before the expiry of the Term. All confidentiality and other obligations of a continuing nature contained herein shall remain in force and shall survive this DMTA notwithstanding its termination as aforesaid.
- 7.5 The parties shall use good faith efforts to resolve any dispute, claim or proceeding arising out of or relating to this DMTA. In the event that any disputes cannot be resolved at this level then the senior executives of the relevant parties who have authority to settle the same shall use good faith efforts to resolve the same. If the matter is not resolved under negotiation within sixty (60) days of being notified to the senior executives of the relevant parties, it shall be finally settled under the Rules of Conciliation and Arbitration of the International Chamber of Commerce by one or more Arbiters appointed in accordance with said Rules.

8 GOVERNING LAW

This DMTA will be governed by the laws of Scotland and shall be subject to the jurisdiction of the Scottish Courts. This clause shall not prevent a party from seeking interim relief in any court of competent jurisdiction.

Appendix B

Collaboration Proposal Form / Research

[Here is appended a copy of the approved CPF]

APPENDIX 10
LIST OF ACCREDITED LABORATORIES

Prof Anna Dominiczak
BHF Glasgow Cardiovascular Research Centre
126 University Place
University of Glasgow
Glasgow
G12 8TA

Prof Colin Palmer
Biomedical Research Centre
University of Dundee
Ninewells Hospital & Medical School
Dundee
DD1 9SY

Dr Zofia Miedzybrodzka
Institute of Medical Sciences
University of Aberdeen
Foresterhill
Aberdeen
AB25 2ZD

Prof David Porteous
Wellcome Trust Clinical Research Facility
Western General Hospital
Crewe Road South
Edinburgh
EH4 2XU

APPENDIX 11

11a. GENERATION SCOTLAND PUBLICATION POLICY

Introduction

This policy has been agreed by the Generation Scotland Executive and the Generation Scotland Management Group. It is intended to inform authorship considerations and discussions relating to any scientific papers arising from work connected directly with Generation Scotland and/or using the Generation Scotland (GS) resource. All papers should be approved by Generation Scotland prior to submission for publication. Further information about this process is available at www.generationscotland.org. Any proposed deviation from the Authorship Policy should be discussed with GS in advance of submission for approval. Please submit all correspondence to: access@generationscotland.org

Policy

This policy applies both to “internal” publications, initiated by members of the Generation Scotland (GS) Executive Committee and the Expert Working Groups and “external” publications, initiated by collaborators which rely upon access to GS. Internal publications may include original research papers based on the GS resource (methods, participants, data, samples or other input or output), commentaries using GS as an example, papers describing GS and its work, or other original work. External publications are likely to be (a) original papers by researchers who have applied to use the GS resource; and (b) papers reporting research to which GS has contributed data or samples in a consortium. Other papers might report methodological developments, or comment on current relevant issues, in collaboration with academics from other studies or groups. The Policy on publication, whether ‘internal’ or ‘external’, is the same.

1. Authorship and style of authorship of reports and publications should be agreed upon at the start of any work intended to lead to publication. Consideration should be given at this stage to making authorship relatively inclusive, to allow credit to *all* those who warrant it by fulfilling the relevant criteria.
2. All authors should fulfil three criteria:
 - i. Each author should have made an ‘academic contribution’ to the study design, data collection and processing, analysis and/or reporting. The term ‘academic contribution’ implies both intellectual responsibility and substantive work.
 - ii. Each author should have critically reviewed the paper.
 - iii. Each author should be able to defend the paper as a whole (although not necessarily all the technical details).

Research papers should normally include the GS Executive members and/or their GS nominees as authors, providing the above criteria are fulfilled. Possible exceptions to this might include: (a) papers which are commenting on an aspect of genetic or related research, using GS as an example; (b) papers arising from an exemplar study that GS has facilitated but that is not based on the “core” GS resource, and (c) papers from research whose only use of the GS resource was of the DNA Donor Databank (3D). Nonetheless, consideration should be given in these cases to full acknowledgement of GS. The text specified in the Generation Scotland Management, Access and Publications Policy Section 6.0 and at Appendix 11b Notes 3 must also be included in this ‘Acknowledgements’ section. The Organisations funding the work must always be acknowledged, as well as any personal fellowships etc.

11b. REQUIREMENTS FOR PAPERS INVOLVING GENERATION SCOTLAND

All publications (e.g. submissions to journals) emanating from the Generation Scotland Project or Future Projects have to be sent to GS for review and approval. All papers are read to check confidentiality is protected; to assist in the identification of patentable results; to ensure that the paper will not bring the Project or Future Projects into disrepute; to try to identify overlap with other papers published or in preparation. GS also provides advice and feedback to authors where it feels this may be helpful. Listed below are the requirements for Generation Scotland Projects or Future Projects publications along with some accompanying notes either explaining these requirements and/or containing appropriate text to insert.

Please send correspondence regarding publications to access@generationscotland.org

List of Requirements for Generation Scotland PUBLICATIONS

Please ensure you send a copy of your draft publication to Generation Scotland as soon as possible.

Please ensure the following requirements are met:

- include GS Executive members and/or their nominees and/or “Generation Scotland” in the author list of external publications
- include “Generation Scotland” as a keyword
- check description of the study numbers is accurate ¹
- include an accurate description of the ethical approval ²
- include the specified text in the Acknowledgements section ³
- return/make available a copy of the final dataset used in the research as set out in the signed DMTA form ⁴
- send a copy of the final submitted manuscript and revised versions to GS
- let GS know when the paper is accepted for publication
- submit an electronic copy of the final paper to Generation Scotland
- liaise with Generation Scotland over media coverage ⁵
- provide a short scientific summary of this paper if requested by GS ⁶
- provide a lay summary if requested by GS ⁷

The appropriate affiliations and contact details of the GS Executive, Management and Expert Working Group leads as of June 2016 are as follows:

GS Executive

David J Porteous
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Pain

Blair Smith (see above)

QTL Genetics

Caroline Hayward
MRC Human Genetics Unit
Institute of Genetics & Molecular Medicine
University of Edinburgh
Western General Hospital
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Caroline.Hayward@igmm.ed.ac.uk

NOTES

1. Description of study numbers and other aspects of the GS Resource are available on the study website at: www.generationscotland.org

2. Ethical approval

Generation Scotland has received ethical permission for the creation of the GS resources. (GS:SFHS: 05/S1401/89 Tayside Committee on Medical Research Ethics A, GS:21CGH: 06/S1401/27 Tayside Committee on Medical Research Ethics A, GS:3D: 06/MRE00/105 Multi-centre Research Ethics Committee for Scotland A)

Generic Research Tissue Bank approval has also been granted for use of the resource. (GS:SFHS: 15/ES/0040 Tayside Committee on Medical Research Ethics B, GS:21CGH: 11/AL/0306 West of Scotland Research Ethics 4, GS:3D: 10/S1402/21 Tayside Committee on Medical Research Ethics B)

A statement describing this that should be included in all relevant papers is shown below:

“Ethical approval for the GS:SFHS study was obtained from the Tayside Committee on Medical Research Ethics (on behalf of the National Health Service).”

“Ethical approval for the GS:3D study was obtained from the Tayside Committee on Medical Research Ethics (on behalf of the National Health Service).”

“Ethical approval for the GS:21CGH study was obtained from the Scotland A Research Ethics Committee.”

3. Acknowledgements section

There is an agreed standard acknowledgements section that should be included as is or in a modified form to fit the journal requirements for all papers:

“Generation Scotland received core support from the Chief Scientist Office of the Scottish Government Health Directorates [CZD/16/6] and the Scottish Funding Council [HR03006]. Genotyping of the GS:SFHS samples was carried out by the Genetics Core Laboratory at the Wellcome Trust Clinical Research Facility, Edinburgh, Scotland and was funded by the Medical Research Council UK and the Wellcome Trust (Wellcome Trust Strategic Award “STratifying Resilience and Depression Longitudinally” (STRADL) Reference 104036/Z/14/Z).”

An optional addition, dependent upon the publisher’s requirements or constraints and in keeping with any other cohorts that may be acknowledged in the same study, is as follows:

“We are grateful to all the families who took part, the general practitioners and the Scottish School of Primary Care for their help in recruiting them, and the whole Generation Scotland team, which includes interviewers, computer and laboratory technicians, clerical workers, research scientists, volunteers, managers, receptionists, healthcare assistants and nurses.”

If the publication has been dependent on funding from a third party, this should also be acknowledged subject to any confidentiality provisions with the third party.

4. Final dataset

Not applicable if in-house analysis by GS is used.

5. Media coverage of Generation Scotland publications

Where appropriate, media coverage of Generation Scotland papers is encouraged to raise the study's profile and in particular to show study participants that the study is producing interesting and valuable findings. Please contact the Generation Scotland management team (access@generationscotland.org) if you know there is going to be a press release or if you have given any press interviews.

6. Short scientific summary of the paper

GS may ask the lead author to prepare a short summary of the paper that can be included with reports to funders, on the GS website or in publicity material.

7. Lay summary of the paper

Once a paper is accepted for publication, GS may ask the lead author to prepare a lay summary of the paper for circulation to Generation Scotland. This may also be used to publicise the paper, and will be placed on the Generation Scotland website.

APPENDIX 12 GLOSSARY OF TERMS

| | |
|---|---|
| Access Committee | means the Committee responsible for managing and approvals of approaches to Generation Scotland for collaboration to use Project Data, Derived Data, NHS Data and/or Samples in Future Projects |
| Background Information | means Information (other than the Project Data or NHS Data) which at the Commencement Date is in, or during the continuance of the Project, and other than as a result of the Project, comes into, the ownership or control of a Party, and which such Party is free to disclose; |
| Background Rights | means Intellectual Property Rights arising out of, or existing in, Background Information (other than Project Rights); |
| Data Material Transfer Agreement | means the agreement required to transfer Derived Data, Project Data or NHS Data collated as specified data sets and/or materials to an academic or commercial third party; |
| Derived Data | means the collective combination of Project Data and NHS Data; |
| Future Project | means any programme of work relating to the Project utilising Derived Data, Project Data, NHS Data and or Samples, or adding to Derived Data and or Project Data, identified by the Parties and approved by the Generation Scotland Scientific Committee and for which one Party or a collaboration of more than one Party may seek or be offered external funding; |
| Generation Scotland (GS) | means the collaboration between the Scottish University Medical Schools, Biomedical Research Institutes, the NHS in Scotland, the Chief Scientist Office and the Scottish Funding Council with the aim of creating more effective treatments based on gene knowledge; |
| Generation Scotland Advisory Board | means the Advisory Board as detailed in Appendix 3 appointed by the Chief Scientist Office on behalf of the Scottish Executive to oversee the activities of the Generation Scotland Scientific Committee as detailed in Schedule Part 3; |
| Generation Scotland Scientific Committee | means the Committee responsible for managing and administering the Project, and any delegated sub-groups, as detailed in Schedule Part 3; |
| Generation Scotland Executive Group | means the group responsible for managing the operational activities of Generation Scotland |
| Genetics and Healthcare Initiative Proposal | means the successful application to the Chief Scientist Office and Scottish Executive Health Department |
| Income | means all cash sums or other monetary considerations or non-financial proceeds in whatever form actually received in respect of the exploitation of any Project Results including without limitation licence fees, sale income, signing and option |

| | |
|------------------------------|---|
| | fees, milestone payments, equipment, discounts, stock and stock options; |
| Information | means (without limitation) drawings, specifications, photographs, models, processes, inventions, procedures, instructions, software, reports, papers, correspondence and any other technical or commercial information, data and documents of any kind, and including oral information if confirmed in writing within 30 days after the disclosure thereof; |
| Intellectual Property Rights | means processes and procedures, patents, design rights, (both registered and unregistered), including semiconductor topography rights, trade secrets, know-how, copyrights, trademarks, database rights and any other form of intellectual property protection either arising automatically at law, or arising further to any statutory procedure and including any application for registration of the same; |
| Joint Project Rights | means Project Rights owned by more than one Party; |
| Net Revenue | means all Income less deductions for any properly incurred costs incurred directly in connection with the development and commercial exploitation of the relevant Project Rights including, but not limited to revenue sharing obligations owed to third party funders, legal and other professional adviser costs, insurance, carriage and freight and Value Added Tax or other sales tax, import duties or similar applicable governmental levies or export insurance costs, patent costs including patent filing, prosecution, maintenance and renewal fees; |
| NHS Data | means data in relation to a Participant in respect of which an NHS Party is the Data Controller and in respect of which data the Participant in question has given his/her informed and valid consent to its use in connection with the Project and/or a Future Project, and which is provided by that NHS Party in response to a request therefore from a Party in connection with the Project or relevant Future Project; |
| Participant | means a healthy volunteer or NHS patient who has consented to provide, and has provided, Samples and/or data to be used for the Project and any subsequent Future Projects; |
| Project | means the work programme outlined in the Genetics and Healthcare Initiative Proposal subsequently funded by the Chief Scientist Office, Scottish Executive Health Department; |
| Project Data | means any data in relation to Participants that is collected pursuant to and in the course of the Project and Future Projects, but always excluding NHS Data; |
| Project Results | means results arising directly from the use of Derived Data, Information, Project Data and Samples, including but not limited to genetic analysis capability, informatics tools, educational tools, novel drug targets and novel diagnostic methods, arising as a direct result of the Project or Future Projects; |

| | |
|----------------|--|
| Project Rights | means Intellectual Property Rights (other than Background Rights) in any Project Results; |
| Resource | means Derived Data, Project Data, NHS Data, Samples databases and general expertise generated by the Generation Scotland Collaborating Parties as a result of the Project and Future Projects available for use by Parties and in collaboration with external third parties; |
| Samples | means human samples of body tissue or bodily secretions, or excretions of fluids, all taken from a Participant, and/or any material directly derived from or incorporating the Sample created and/or collected during the course of the Project or a Future Project. |