Generation Scotland

Access and Publications Policy

V7.0

August 2025

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Abbreviations:

Generation Scotland: GS

Generation Scotland Access Committee: GSAC

Generation Scotland Management Team: GSMT

Generation Scotland Scientific Steering Committee: GS:SSC

NextGenScot: NGS

1 Introduction

Generation Scotland (GS) is a collaboration between the following parties: the University of Aberdeen, the University of Dundee, the University of Edinburgh, the University of Glasgow, NHS Greater Glasgow & Clyde, NHS Grampian, NHS Lothian, NHS Tayside and NHS National Services Scotland.

Generation Scotland is longitudinal family focused cohort study aiming to support health research for public good. In its first phase Generation Scotland, in collaboration with Scottish GPs, recruited around 24,000 adults (aged 18 years and above) from Scottish families between 2006 and 2011.[i,ii] A pre-clinical questionnaire captured demographic, health and lifestyle data. During research clinic attendance, baseline physical, cognitive, and mental health measures were made and bio-samples were taken, all supplemented by linking to Electronic Health Records.

In follow-up recontact (2015–2019), ~9600 participants completed an online survey of mental health[iii] and ~1200 took part in a face-to-face assessments of psychiatric disorders and cognition, underwent brain imaging, and had biosamples collected.[iv]

In 2020, new rounds of questionnaire data were collected to measure the impact of the COVID-19 pandemic on teens and rural communities in Scotland (TeenCovidLife,[v] RuralCovidLife[vi]), and on the people of the UK as a whole (CovidLife[vii]). The CovidLife and TeenCovidLife surveys had three rounds of data collection and RuralCovidLife had one. The CovidLife questionnaires were sent out to GS participants and ~5,000 completed them. More details on these collections can be found here: https://genscot.ed.ac.uk/covid-19

A new wave of recruitment to Generation Scotland, called NextGenScot (NGS) began in May 2022, recruiting participants who live in Scotland from age 12 upwards. NextGenScot recruited additional family members related to the original GS participants, and also recruited new families to the study. NextGenScot recruitment is conducted remotely, with online consent and baseline questionnaires and postal saliva sample collection. Ethical approval for the Generation Scotland Research Tissue Bank covering Generation Scotland, CovidLife, TeenCovidLife, RuralCovidLIfe and NGS are from East of Scotland Research Ethics Service (EoSRES) Reference: 20/ES/0021.

The purpose of this document is to describe in detail the processes and procedures involved in accessing the Generation Scotland resource (defined as the data already collected, the samples, and recontact of the participants for the purposes of new data collection or recruitment into additional studies) for health research. All applicants must provide evidence (e.g. a CV) that they are a bona fide researcher at a qualifying institute, which includes those based in both public and private/commercial research organisations. We aim to enable researchers to conduct their studies in a transparent and streamlined manner.

Researchers should remember that the data provided can only be used for the aims of the approved proposal and for no other reason unless approved by Generation Scotland. Researchers must include a GS publication policy as detailed below in Sections 7 and 8.

We reserve the right to bar future access to researchers and/or their institution if the agreed processes are breached.

2 Management of Generation Scotland Access Process

2.1 Generation Scotland Management Team

The GS Management Team (GSMT) based at the University of Edinburgh oversees the application and approvals process on behalf of the Generation Scotland Collaboration.

2.2 Generation Scotland Access Committee

The GS Access Committee (GSAC) consists of members of the GSMT as well as experienced researchers based at the Collaborating Institutions with key expertise to review application from a scientific perspective. The GSAC responsibilities include:

- The management of the applications to Generation Scotland for the use of: Project Data, Derived Data, NHS Data, Samples or re-contact of participants to invite them to take part in Future Projects.
- To review and approve or deny applications to access the GS resource.
- To report regularly to the GS Scientific Steering Committee (GS:SSC) on the access requests received and their progress, the progress of publications, and compliance with Access agreements.
- 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.
- To consult with the GS:SSC concerning any need for revision of the Agreements.
- To review GS access applications with respect to the request for data, their information governance, scientific questions, sample use and whether the research is in the public good.

The GSAC reviews applications online as they are submitted, with an aim to review all applications within four weeks.

2.3 Generation Scotland Scientific Steering Committee

The GS Scientific Steering Committee (GS:SSC) advises Generation Scotland on strategic direction and scientific aims. It is chaired by Professor Dame Anna Dominiczak, Chief Scientist (Health) Scotland and has representatives from all of the GS Collaborating organisations. The GS:SSC reviews all applications for access to finite Generation Scotland resources. This includes applications to re-contact study participants, applications from commercial companies and applications to use biological samples. The GS:SSC reviews applications from countries that are not GDPR compliant. The GSAC may also ask the GS:SSC to review applications on occasion when they are unable to come to an internal decision.

3 Types of data and rules governing access

A wide range of data are available through the access process. Generation Scotland collects data directly through questionnaires and has data from in-person assessment clinics. Data is derived from biological samples. We also link to data made available by various third parties, and through linkage to medical records. These are available for use by bona fide researchers for research for the public good. Proposals for access may be refused. Reasons for refusal include, but are not limited to the following:

- Lack of availability of data/samples.
- Applicant not being a bona fide researcher.
- The scope of the research investigation: Requested data should be relevant to and justified by the research investigation.
- The proposed work, in the view of the GSMT/GS:SSC, risks bringing the study into disrepute.
- The proposed work risks disclosure of identifiable information relating to any individual participant (e.g. the sample size is too small).
- The proposed outputs of the project are outside the scope of GS participants consent, or Generation Scotland's ethical approval, or funders' terms and conditions, or the University of Edinburgh's policies and procedures.
- Third-party approvals: Access to data obtained via linkage to health and administrative records is subject to complying with the terms imposed on Generation Scotland by the original consent and ethical approvals.
- Biological samples are a finite resource and therefore need to meet the criteria outline in Section 5.3.

3.1 Questionnaire and data derived from biological samples

We ensure data collected by questionnaires are made available as soon as possible after data collection is complete. Data obtained from bio-samples are made available as soon as all assays have been completed and the data have been cleaned. Data is released once all potential identifiers have been removed, and disclosure risks considered such that data may be grouped where appropriate. Information derived from biological samples includes genome wide microarray genotype (GWAS), gene expression and methylation data.

3.2 Linkage data

Generation Scotland collects data using linkage to routine health and environmental databases. Linkage is generally conducted at an individual level (e.g. primary care records). These data are collected from external organisations. To do this, Generation Scotland enters into data usage agreements with the relevant data owners. These data usage agreements specify the conditions under which Generation Scotland can share these data with third parties (e.g. researchers). The data access conditions can differ for each dataset we link to, and may also change over time. Necessarily, we consider the following when we adjudicate requests to access linkage data:

- There is a high threshold for sharing these data, and data minimisation is required, for example the GS Data Team will filter for conditions of interest to the research question before provision of data.
- Changing access conditions: Data access conditions can (and do) change over time, sometimes with little warning. Generation Scotland, and third-party data users, are required to comply with any new data sharing conditions. This may impact research investigations in unforeseeable ways.
- Data quality: Generation Scotland provides linked data on the understanding that these are routine administrative records being used for a secondary (i.e.

research) purpose. We make no guarantees regarding the accuracy of the data and have no means of verifying the data.

3.3 Data Storage requirements

The applicant must provide a data management plan and Data Privacy Impact Assessment as part of their application. The data must be stored in a secure network system, at such standard which would be reasonably expected for the storage of valuable and proprietary sensitive/confidential data. Data should not be stored on a stand alone machine, but in a secure network.

The data must be stored so that there are and technical access controls that restrict access to the data to only the people who are listed on the application. Access logging and monitoring should be put in place. Access to server data processing facilities shall be restricted to duly authorised individuals only.

Participant-Level Data must but not be shared (directly or indirectly) with unauthorised individuals or unauthorised third parties;

Participant-Level Data must not be shared, stored or uploaded (directly or indirectly) to web-based or other repositories accessible by unauthorised individuals or unauthorised third parties.

Cloud and online storage of Materials is permitted provided:

- it is used in compliance with the provisions of DMTA;
- only authorised individuals can access the data;
- appropriate security measures are in place to protect the data from unauthorised and unlawful processing; and
- the Applicant Institution is fully responsible for the data.

4 Data access procedure

4.1 The Generation Scotland Resource

Generation Scotland was established and is run as a resource to be used by the health research community. We encourage and facilitate research uses of Generation Scotland by researchers from all disciplines across the world to maximise use of the resource. Requests to use the Resource are made from:

- Academic collaborators: researchers or employees of an academic institution or the NHS, or foreign health service institutions.
- Commercial organisations: specific arrangements have been defined to allow commercial organisations to access Generation Scotland resources.

The Resource is set up as a supported access Resource rather than as an entirely open access Resource. To access the Resource, researchers should consult the GS website which contains details of the application process (https://genscot.ed.ac.uk/). The vast majority of data are available for use on request and we do not consider the issue of potential overlap

between research projects. The website also describes the Resource allows you to interactively explore the data available, and is a useful place to start to give you a good idea as to whether Generation Scotland would be potentially valuable in addressing your research question.

4.2 Requesting access to data

Access to GS research data must be requested using the formal procedures described in this document. Researchers are required to complete an application form. The application should include a proposal with clearly stated aims and hypotheses and describe the relevant exposure, outcome and confounders that will be considered, justifying the data you require. Please note that you will need to complete a Data Privacy Impact Assessment (DPIA) and a data management plan. For multiple projects you must submit multiple forms; one per project.

For applications requiring data only, you will generally get a decision within four to six weeks of submission to inform you of the outcome.

4.3 Requesting access to samples

GS has collected many bio-samples. GS participants recruited in the first wave of recruitment consented to use of their samples for research, but only some of the samples can be sent outside of the UK. There are the following different sample types in the Resource:

- Serum
- Plasma
- Whole blood
- Urine
- DNA
- RNA

There may be a cost associated with identifying sample availability, particularly if the selection criteria require specific associated data. Researchers will be informed if this is applicable to their proposal. Ethical approval was obtained for all sample collections and included consent for future research including genetic studies. The GS biorepository is an NHS Research Ethics Committee (REC) approved Research Tissue Bank (RTB), REC reference: 25/ES/0013.

For UK applicants: biological material may be provided under the RTB's generic ethical approval provided the proposal falls within the remit of GS. If a proposal is outside of the remit, then separate ethical approval will need to be sought.

For non-UK applicants: biological material may be provided where the proposal falls within the remit of Generation Scotland. It is the responsibility of the applicant to ensure that prior to the export of samples the applicant is satisfied that the samples will be handled appropriately and that the required standards of the recipient institute and country have been met. Where applications fall outside of the remit of the GS RTB, proof of alternative ethical approval may need to be provided before samples are released (i.e. copies of ethics

application forms and/or approval letters). Not all samples have participant consent to leave the UK.

Researchers applying to access GS samples must fill out an additional application form.

The scientific strength of the proposal must justify the use of GS cohort samples, i.e. the data obtained from the samples will be analysed in conjunction with other data held by Generation Scotland. Requests for projects that could be carried out using samples available elsewhere will not be approved. Sample approval criteria:

- The analysis proposed does not already exist for the same time point, i.e. use of existing samples for data that is already derived. Requests to repeat or carry our very similar analysis will not be approved unless there are compelling reasons.
- The assay test platform should have proven quality assurance measures in place.
- The methodology should include measures to ensure the quality of any remaining sample is not jeopardised so that the sample can be utilised for assays which are able to use freeze thawed samples.
- The volume requested is reasonable and does not seriously deplete the resource.
- The work proposed is within the scope of the consents obtained for the specific samples.
- Data derived from the samples must be returned to Generation Scotland to be made available to other researchers, after an agreed embargo period (normally 9 months).

The samples in the GS biorepository are finite, i.e. there are limited stocks available. The GS:SSC and GS Management Team are responsible for ensuring that samples are used for projects that maximise the amount of data obtained from available samples and that these data are subsequently made available to other researchers.

4.4 Data and Materials Transfer Agreement

For academic applications, a Data and Materials Transfer Agreement (DMTA) must be signed by the recipient institution and acknowledged by the principal applicant before data or samples are released. The DMTA sets out the detailed terms of use of the resources provided. A template copy is available on the GS website (https://genscot.ed.ac.uk/for-researchers/access).

For researchers based at the University of Edinburgh researchers must sign a Researcher Responsibility Agreement which sets out the detailed terms of use of the resources provided.

For commercial applications, a contract will be negotiated between the applicant's company and the University of Edinburgh (or another Collaborating party) on behalf of GS. Reputational and financial due diligence will be done on all companies. The terms of the contract will be based on the standard academic DMTA.

4.5 International applications

We follow University of Edinburgh policy regarding international applications, and so are currently not accepting any applications from Russia or Iran.

All applications coming countries that are covered by UK GDPR adequacy regulations (https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/international-transfers-a-guide/) will sign a standard DMTA. All other countries must submit a Data Privacy Impact Assessment (DPIA), have their application and DPIA reviewed by the University of Edinburgh Data Protection Officer and sign an international DMTA.

4.6 Requesting a re-contact of study participants

The GS study team collects new data from the study participants primarily via online questionnaires. Data collection may be on the whole cohort or on a specific subset. Researchers are encouraged to apply for funding for data collection ideally at least 18 months in advance of the proposed start date for data collection. The costs of new data collection must be agreed with the GS Management Team. For projects seeking grant funding researchers are requested to submit a proposal to the GS Team, clearly indicating new data collection, as soon as possible to initiate the costing process. Researchers should notify Generation Scotland of the application outcome to enable forward planning of participant re-contact.

Ideally all grant proposals for data collection should be submitted for approval prior to grant submission. We are aware that given time constraints this may not be possible, but while Generation Scotland can provide a letter of support prior to approval, it should be clear that the researcher will have to apply to Generation Scotland for the re-contact study and there is no guarantee it will be approved. Ethical approval will be required. We appreciate that in most cases this will be sought after grant submission, but no data collection will be undertaken without appropriate ethics approval.

4.7 Amendments to existing data requests

An amendment to your original proposal must be requested if any of the following change during the course of your approved project:

- Significant extension of research scope (note we may request this is submitted as a new project if the GSMT deem appropriate);
- Change in start or end date;
- Additional researchers accessing the data;
- Change in institution, or addition of institution(s);
- Any additional data required;
- Change of funding source.

If a researcher wishes to re-use a dataset that has already been provided for a previous project (for example, to study a new aim or for a new student to use the data for their studies), a new proposal will be required. The proposal must include reference to the original project application number (GS reference number provided when an application is submitted). All principal applicants will be required to sign a new Data and Materials Transfer Agreement (DMTA)

If a project has been dormant (i.e. the researchers have not been in touch with GS) for more than 2 years, it will be considered 'closed' unless an amendment extending the project end date has been approved. This policy does and can change often and therefore older projects will need to be brought in line with current practices as much as possible. This may include (i) submitting a new proposal (ii) ensuring that co-applicants are known to GS, and (iii) generation of an updated dataset as mentioned above.

5 Charging model

GS does not receive funding to support core activities, therefore researchers will be expected to meet all costs for data access and provision, re-contact studies and sample provision. All researchers accessing GS data will be charged on a cost recovery basis. This cost will vary depending on the types of data requested and the amount of time required to facilitate your request.

Costs will be determined on a project-by-project basis. Once a proposal has been agreed in principle a costing will be provided. VAT will be charged in addition to the project costs where applicable. Data will not be provided until all necessary paperwork is completed and an invoice has been settled or a purchase order number is received by our finance department.

Additional data requests (i.e. data that were not included in the original proposal but subsequently required for any reason) will be subject to additional costs to cover data provision. Administrative amendments will not be charged unless a new DMTA is required as the result of adding a co-applicant in a different Institution.

Costs are reviewed on a regular basis. Costs that are quoted are therefore accurate at the time they are provided, and it is the researcher's responsibility to check that costs haven't changed if there is a significant lapse in time between obtaining the quote and starting the project.

5.1 Student projects

Generation Scotland is committed to enabling and supporting education through the use of study data to answer research questions via PhD and Masters' student dissertations. As described above the provision of data from Generation Scotland is through a cost recovery model, but we appreciate that not all studentships may provide sufficient funds to cover this we will review costs for these projects on a case-by-case basis. Applicants are advised to contact the GSMT with their project proposal.

6 Press Release Policy

All press releases on research arising from the Project must be approved by the GSMT (genscot@ed.ac.uk) and agreed with any third parties, e.g. research funders, host institutions. 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.

7 Authorship and Publication

Authorship on papers arising from Generation Scotland studies should follow the GS Authorship Policy that the researcher will acknowledge Generation Scotland in all publications relating to the Research, and will notify the Generation Scotland Access Committee prior to publication. Members of Generation Scotland Collaboration Parties who have played a key scientific role in the generation of the Data and the Materials may also be included as co-authors. Pre-submission versions of all papers using the Generation Scotland resource should be sent to genscot@ed.ac.uk for review at least one month pre-publication. We will wish to be assured that

- confidentiality has been protected;
- any patentable results have been identified;
- the contribution of GS has been acknowledged;
- the paper will not bring GS into disrepute;
- 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 and transparency to GS participants of data use.

We expect publications to include Generation Scotland or GS Team or GSMT members as co-authors and the resource to be referenced and acknowledged. There is no requirement for conference abstracts to be approved prior to submission. 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 genscot@ed.ac.uk. Collaborators should let Generation Scotland 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.genscot.ed.ac.uk).

8 Acknowledgements in Publications

Generation Scotland 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] and is currently supported by the Wellcome Trust [216767/Z/19/Z]. 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). Thank you to all the Generation Scotland participants."

The standard text for the Data Availability Statement - “According to the terms of consent for Generation Scotland participants, access to data must be reviewed by the Generation Scotland Access Committee. Applications should be made to genscot@ed.ac.uk.

9 Intellectual Property

The intellectual property used in the project and arising from it is governed by the GS Collaboration Agreement.

10 Version and Feedback

This policy document is Version 7.0 and was last updated in August 2025. GS welcomes feedback, comments and suggestions for improvement. Please contact genscot@ed.ac.uk

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[ii] Hannah Milbourn, Daniel McCartney, Anne Richmond, Archie Campbell, Robin Flaig, Sarah Robertson, Chloe Fawns-Ritchie, Caroline Hayward, Riccardo Marioni, Andrew McIntosh, David Porteous, Heather Whalley, Cathie Sudlow. (2024). Generation Scotland: an update on Scotland’s longitudinal family health study. BMJ Open. 14. 10.1136/bmjopen-2024-084719.

[iii] Navrady, L. B. et al. Cohort Profile: Stratifying Resilience and Depression Longitudinally (STRADL): a questionnaire follow-up of Generation Scotland: Scottish Family Health Study (GS:SFHS). Int J Epidemiol (2017) doi:10.1093/ije/dyx115.

[iv] Habota, T. et al. Cohort profile for the STratifying Resilience and Depression Longitudinally (STRADL) study: A depression-focused investigation of Generation Scotland, using detailed clinical, cognitive, and neuroimaging assessments. Wellcome Open Res 4, 185 (2019).

[v] Charlotte Huggins, Chloe Fawns-Ritchie, Drew Altschul, Archie Campbell, Clifford Nangle, Rebecca Dawson, Rachel Edwards, Robin Flaig, Louise Hartley, Christie Levein, Daniel McCartney, Stephanie Sinclair, Clare Dolan, Dawn Haughton, Judith Mabelis, Judith Brown, Joanna Inchley, Daniel Smith, Ian Deary, David Porteous. (2022). TeenCovidLife: a resource to understand the impact of the COVID-19 pandemic on adolescents in Scotland. Wellcome open research. 6. 277. 10.12688/wellcomeopenres.17252.2.

[vi] Anna Stevenson, Charlotte Huggins, Alison Forbes, Jim Hume, Grant Fulton, Claire Thirlwall, Janet Miles, Chloe Fawns-Ritchie, Archie Campbell, Clifford Nangle, Rebecca Dawson, Rachel Edwards, Robin Flaig, Louise Hartley, Christie Levein, Daniel McCartney, Ian Deary, Caroline Hayward, Riccardo Marioni, David Porteous,. (2021). RuralCovidLife: Study protocol and description of the data. Wellcome Open Research. 6. 317. 10.12688/wellcomeopenres.17325.1.

[vii] Chloe Fawns-Ritchie, Drew Altschul, Archie Campbell, Charlotte Huggins, Clifford Nangle, Rebecca Dawson, Rachel Edwards, Robin Flaig, Louise Hartley, Christie Levein, Daniel McCartney, David Bell, Elaine Douglas, Ian Deary, Caroline Hayward, Riccardo Marioni, Andrew Mcintosh, Cathie Sudlow, David Porteous. (2021). CovidLife: a resource to understand mental health, well-being and behaviour during the COVID-19 pandemic in the UK. Wellcome Open Research. 6. 176. 10.12688/wellcomeopenres.16987.1.