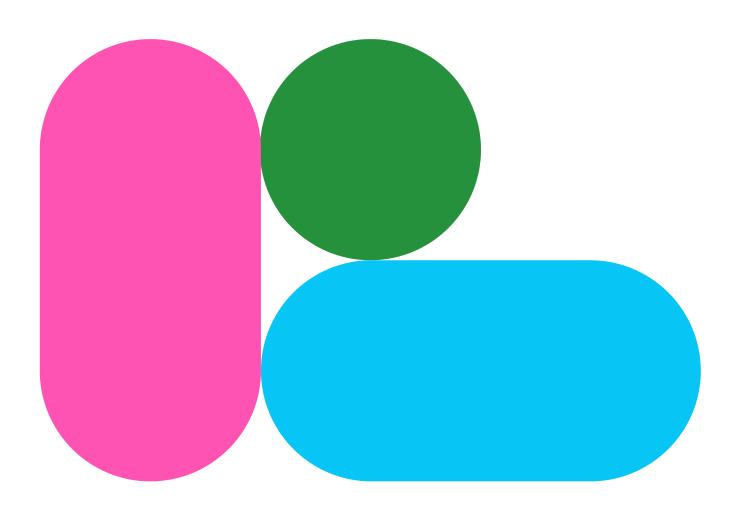


Publication Policy

Genomics England's Publication Policy POL-RM-002 v6.0

Date: 11/11/2025





1. Abbreviations / Definitions

100,000 Genomes Project	UK initiative to sequence 100,000 genomes from NHS patients in England with rare diseases and cancer, linking the genomic data to health records to advance genomic medicine and research.
Airlock	Process by which data is securely moved in or out of the Genomics England Research Environment.
Clinical Research Interface (CRI)	The pathway connecting users of the Genomics England Research Environment with NHS clinicians and vice versa, to enable collaboration and the return of potentially clinically relevant findings.
National Genomic Research Library (NGRL)	National database of genomic data, health data and samples from consented individuals that can be accessed for research purposes through the Research Environment; managed by Genomics England in partnership with NHS England.
NHS Genomic Medicine Service (NHS GMS)	The NHS GMS is the network of seven Genomic Laboratory Hubs (GLHs) working together with Genomics England to harness the power of genomics to improve health and collect data for research, which is held by Genomics England in the NGRL.
Publication	Any communication or disseminated work, including results, analysis, annotations, data, discoveries, findings, and/or interpretations, that are based on or derived from Genomics England-held data and/or analyses conducted within the Genomics England Research Environment. This includes, but is not limited to: scientific articles, abstracts, posters, presentation slides, reports, and theses submitted for degree accreditation.
Research Environment	The Genomics England Research Environment is a secure platform that approved researchers use to access de-identified genomic and clinical data in the NGRL and other research data held by Genomics England.
Research Network	The collective term for the community of individual researchers, clinical disease experts, healthcare professionals and approved life sciences industry partners who are given access to the data held by Genomics England for the purposes of carrying out research.
Research Registry	The catalogue of all research projects being undertaken on NGRL data, which can be <u>accessed here</u> .



2. Purpose Statement

Genomics England is committed to open science, knowledge sharing, timely publication of research findings and transparency of health data use for the benefit of participants and patients. This document outlines our policy for authorising Publications based on samples or data in the National Genomic Research Library (NGRL). The Publication Policy ensures recognition of the contributions of Genomics England, the NHS, our funders, and the acknowledgement and protection of NGRL participants who consented to share their health data for research.

3. Scope

- a) This Publication Policy applies to any Publication based on research conducted using samples and/or data in the NGRL or held by Genomics England with relevant consent for research. This includes data from the 100,000 Genomes Project, the Generation Study, the NHS Genomic Medicine Service, as well as data of any other type collected as part of a research study or cohort by Genomics England or as part of a collaboration or partnership agreement with Genomics England.
- b) It is the responsibility of anyone wishing to publish a Publication based on data held by Genomics England or on analyses conducted in the Research Environment to adhere to the obligations set out in this policy, as referenced in the Research Network Access Agreement and the Code of Conduct.

4. Publication Requirements

- a) All Publications must be associated with an approved research project registered in the <u>Research Registry</u> and one of the authors must be listed as a contributing researcher for that project.
 Publications include, but are not limited to, scientific articles, reviews, on-line reports, conference abstracts, research theses, and presentations.
- b) All Publications must be reviewed and approved by Genomics England as outlined in section 6 below.
- c) Genomics England does not allow publication of identifiable data, including unmasked non-zero phenotype counts of less than five. Any NGRL-sourced data in any Publication must have been reviewed and approved for release by Genomics England's Airlock process and transfer or publication of this data is subject to the <u>Airlock Policy</u>. Violation of the Airlock Policy, such as taking screenshots of the Research Environment or manually copying data, constitutes a serious breach of data access terms and will result in appropriate sanctions.
- d) Additional individual-level participant data or data outside the NGRL may be published where patient consent has been obtained through the <u>Genomics England Clinical Research Interface</u> or as part of a separate research study, provided the study has appropriate research ethics approval. Where this is the case, it should be noted in the Publication Review Request Form upon submission of the publication for Genomics England review. Proof of research ethics approval and consent may be requested by Genomics England.
- e) Submission of data to public repositories, knowledgebases or clinical reference databases is considered a public release of data and requires prior approval from Genomics England. Authors



intending to submit research findings to public repositories must inform Genomics England of their intention and seek approval by submitting a request through the Genomics England Airlock process. This requirement applies to submissions to, but is not limited to: GeneMatcher, ClinVar, LOVD, PharmVar, PharmGKB, gnomAD, COSMIC, DECIPHER, OMIM, ClinGen, dbSNP, EGA and Ensembl.

5. Acknowledgement and Data Access Statement Requirements

- a) Authors and co-authors should be listed in accordance with the guidelines issued by the International Committee of Medical Journal Editors (ICMJE). This also includes disclosure requirements for Artificial Intelligence (AI)-Assisted Technology use in accordance with ICMJE guidelines. Genomics England employees who contributed directly to the Publication sufficiently to warrant authorship should be individually listed and Genomics England may require this as a condition for submission.
- b) The NGRL and Genomics England can be cited in the following way:
 - The National Genomic Research Library, Genomics England (2024). https://doi.org/10.6084/m9.figshare.4530893
- c) All longer research Publications, including scientific papers, research articles, degree theses, and similar works, must include the following credit information in an appropriate section of the document (e.g. in the acknowledgement or methods section):
 - We gratefully acknowledge the participants of the National Genomic Research Library (NGRL), whose contributions made this research possible. Secure access to the NGRL under project ID [insert Research Registry Project ID] was provided by Genomics England, which delivers the NGRL in partnership with NHS England, and is wholly owned by the UK Department of Health and Social Care. The NGRL contains participants' health data collected by the NHS as part of their care, along with samples and data from their participation in research, for which fully informed consent has been obtained. This includes genomic and clinical data provided through the NHS Genomic Medicine Service, as well as data obtained through research studies, including the 100,000 Genomes Project and the Generation Study, both of which are delivered in partnership with the NHS, and from other research cohorts involving external collaborators.

For other shorter communications, such as conference presentations or posters, the following short text must be included:

- This research was made possible through access to the National Genomic Research Library (NGRL), a secure database and bioresource managed by Genomics England in partnership with the NHS.
- d) Genomics England may hold and make accessible data collected as part of research cohorts under separate agreements with external collaborators. Access to these datasets may be restricted, and Publications involving such data must comply with cohort-specific data exclusivity or publication embargo guidelines. Authors may be required to specifically reference or acknowledge these cohorts and their contributors in any Publication where data from these cohorts was used.
- e) To meet the reporting standards adopted by many major publishers and research funders, and the commitments set out in the <u>Concordat on Open Research Data</u>, it is a requirement for Publications to contain a data access statement, also known as data availability statement. It should describe where the data associated with the publication are available, and under what conditions the data can be accessed. Copy and complete this template for your manuscript's data availability section:



Data from the National Genomic Research Library (NGRL) used in this research are available within the secure Genomics England Research Environment. Access to NGRL data is restricted to adhere to consent requirements and protect participant privacy. Data used in this research include:

[Insert brief description of NGRL datasets accessed and any derived datasets generated, with file locations where appropriate to facilitate discoverability within the Research Environment. Descriptions must not contain participant identifiers or other information restricted under the Airlock Policy.]

Access to NGRL data is provided to approved researchers who are members of the Genomics England Research Network, subject to institutional access agreements and research project approval under participant-led governance. For more information on data access, visit: https://www.genomicsengland.co.uk/research

6. Publication Review by Genomics England

- a) Genomics England requires that the manuscript or final draft of any Publication is sent to Genomics England at least two (2) weeks before it is submitted for peer review. Genomics England will review Publications strictly in order of submission and within the agreed turnaround time of 10 working days. The Publication Review Request Form to submit a Publication for review can be found here.
- b) For theses prepared as part of a degree programme (e.g. PhD thesis), authors may submit simultaneously to Genomics England and academic examiners or peer reviewers. The thesis must be submitted for review via the Publication Review Request Form at least twenty (20) days before the viva voce examination or final assessment of the thesis.
- c) The review ensures that authors have adhered to the Publication Policy and any other relevant Genomics England policies, that the Publication is in line with the approved Research Registry project and the acceptable uses criteria as outlined in the NGRL Governance Framework, that the appropriate acknowledgement texts have been used as per section 5 above, and that no potentially identifiable data has been included in the Publication. The review is not a scientific assessment; Genomics England does not evaluate or take responsibility for the quality or validity of scientific content, nor does it restrict publications based on scientific merit.
- d) Authors should include the title and Project ID of the registered research project as recorded in the Research Registry in any communication with Genomics England about a Publication.
- e) Genomics England may use AI-based tools to support the timely and consistent review of submitted manuscripts. These tools operate exclusively within Genomics England's closed infrastructure and in accordance with the Genomics England AI Policy. No data from submitted manuscripts will be transferred outside Genomics England's servers or exposed to external AI platforms. Researchers will be given the option to opt out of AI-assisted review during the submission process via the Publication Review Request Form.

7. Post-publication Requirements

a) Authors must ensure that relevant data and files that contribute to the Publication are retained and properly organised in the Research Environment for potential future reference and reproducibility.



- b) Relevant supporting materials, such as code and supplementary data, should be made available either in the Research Environment or, where appropriate and in line with the Airlock Policy, through external repositories (e.g., GitHub) to ensure that the findings can be replicated and validated by other researchers.
- c) To maximise research impact for NGRL participants, any datasets derived from the NGRL are encouraged to be made available to the wider scientific community via the publication process and/or direct deposition in the NGRL.
- d) As per relevant clauses of the access agreements between Genomics England and researchers' organisations, authors must minimise the retention of duplicate or obsolete data within their Research Environment workspaces where these are associated with a Publication or completed project.
- e) Authors are required to promptly notify Genomics England of any post-publication updates, corrections, or retractions, particularly when incorrect data or methodological issues have been identified that could potentially affect the work of other researchers using related datasets.

8. Policy Breaches and Adjudication Process

- a) Adherence to the Publication Policy is the responsibility of each Publication author and failure to incorporate changes to a publication where reasonably requested by Genomics England will be considered failure to comply with this Publication Policy.
- b) If Genomics England determines that the content of a Publication breaches this Publication Policy, the Genomics England Airlock Policy, or any other relevant Genomics England policies or agreements, either during the Publication review or at any point thereafter, Genomics England will notify the lead and corresponding author(s) and reasonably request necessary changes. Failure to comply will result in the matter being reported to the author(s)' institution(s) and escalated to the independent Access Review Committee for adjudication.
- c) Serious breaches will result in appropriate sanctions against the author(s), including but not limited to revoking access to the Genomics England Research Environment, terminating their institution's access agreement, and/or seeking the retraction of the Publication.

To view publications from research on NGRL data, please see the <u>publications page</u> on our website.

For any questions or assistance regarding this policy, please contact us at <u>Research-Network@genomicsengland.co.uk</u>