

# Genomics England Publication Policy

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# 1 Document History

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## 1.1 Version History

Version	Date	Description
3.1	17/03/16	Updated to include Publication Committee Chair's comments and annexes
3.2	21/03/16	Updated with Team Science publication reference
3.3	22/03/16	Formatted into GeL template and minor edits
3.4	05/04/16	Initial policy to inform discussions with Chair of Publication Committee
3.5	27/04/16	Amended section 9
3.6	18/05/16	Amended following review by Genomics England Board
3.7	14/07/16	Funders comments taken in
3.8	18/09/17	Amended section 7; acknowledging the use of patient data

## 1.2 Reviewers

This document must be reviewed by the following:

Name	Title	Version
Mark Caulfield	Chief Scientist	3.6
Tom Fowler	Deputy Chief Scientist & Director of Public Health	3.4
Mark Bale	Head of Science Partnerships	3.4
Nick Maltby	General Counsel and Company Secretary	3.5
Tim Hubbard	Head of Genome Analysis	3.4
Clare Turnbull	Chief Scientific Officer for Cancer	3.4
Sir John Bell	Chair, Genomics England Publications Committee	3.6

## 1.3 Approvers

This document must be approved by the following:

Name	Responsibility	Date	Version
Mark Caulfield	Chief Scientist		3.6
Sir John Bell	Chair, Genomics England Publications Committee		3.6

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## 2 Definitions

100,000 Genomes Project	a programme of whole genome sequencing announced by the Prime Minister in December 2012, the principal objective of which is to sequence 100,000 genomes from patients with cancer, rare inherited disorders and infectious diseases drawn from the NHS in England, and to link the sequence data to a standardised, extensible account of diagnosis, treatment and outcomes;
100,000 Genomes Project Protocol	The protocol approved by the East of England and South Cambridge Research Ethics Committee on 20 February 2015 as amended from time to time;
Genomics England	Genomics England Limited of Dawson Hall, Charterhouse Square, London, EC1M 6BQ;
Genomics England Team	the individuals engaged by Genomics England to manage and implement the 100,000 Genomes Project;
GeCIP	the Genomics England Clinical Interpretation Partnership which is the collective term for the community of individual researchers, NHS clinical disease experts and NHS healthcare professional and trainees who are given free access to the dataset of the 100,000 Genomes Project for the purposes of carrying out research and improving the understanding and practice of clinical genomics;
GeCIP Rules	The document titled as such as amended from time to time;
GeCIP Domain	a disease-specific, function-specific or other domain identified by the GeCIP Board as a domain for work within the GeCIP or a group of GeCIP Members approved in accordance with the GeCIP Rules as a group undertaking work in a particular area;
GeCIP Member	an Approved Person (as defined in the GeCIP Rules) that is a member of GeCIP and has entered or will enter into a membership agreement by signing the GeCIP Rules Agreement (as defined in the GeCIP Rules);
Institution	An employer of a GeCIP Member being a higher education institution or the provider of education courses to a student;
Office of the Genomics England Chief Scientist	The Office of the Genomics England Chief Scientist;
Proposed Publications	any Publication or draft Publication that is intended to be sent for publication or review;
Publications	any publication containing results, analysis, annotations, data, discoveries, findings and/or interpretations that are based upon and/or derived from data and results generated by the 100,000 Genomes Project;
SOP	standard operating procedure.

### 3 Introduction

1. The 100,000 Genomes Project is a programme of whole genome sequencing announced by the Prime Minister in December 2012, the principal objective of which is to sequence 100,000 genomes from patients with cancer, rare inherited disorders and infectious diseases drawn from the NHS in England, and to link the sequence data to a standardised, extensible account of diagnosis, treatment and outcomes.
2. It is an essential aspect of the 100,000 Genomes Project that the results and discoveries resulting from 100,000 Genomes Project are published promptly.
3. This document sets out the policy of Genomics England as regards the publication of Publications.
4. This document is not a SOP because it does not define ways of working. Subsequent SOPs may be created that adhere to this policy and ensure organisational consistency, coherence and compliance. This document is key to decision-making on publications, and should be used in conjunction with other applicable Genomics England policies.
5. Genomics England has set up the Genomics England Clinical Interpretation Partnership (GeCIP) for the purposes of carrying out research and improving the understanding and practice of clinical genomics. The overall aim of the GeCIP is to create a thriving, sustainable research environment for individual medical researchers, NHS clinical disease experts, NHS healthcare professionals and trainees. This will stimulate and encourage new research endeavour and information exchange. GeCIP domains will add value by incorporating pertinent information for each disease to the totality of the Genomics England knowledge base. This community will analyse and regularly refine the clinical interpretation of the 100,000 Genomes Project dataset. All members of the GeCIP must comply with the policies set out in this document.
6. Genomics England has established a Publications Committee to oversee and decide on matters relating to publication of the findings of the 100,000 Genomes Project.
7. All principles expressed in this document are based on the current version of the 100,000 Genomes Project Protocol and may be amended as the 100,000 Genomes Project evolves.

### 4 All Publications are to be issued on behalf of Genomics England

8. All Publications will be made on behalf of **The 100,000 Genomes Project** and Genomics England as a banner heading.

## 5 Authorship

9. All of the authors and co-authors of each manuscript will be identified in any publication or output in accordance with the guidelines issued by the International Committee of Medical Journal Editors (ICMJE) which provide that authorship should be based on the following 4 criteria:
  - substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; and
  - drafting the work or revising it critically for important intellectual content; and
  - final approval of the version to be published; and
  - agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
10. GeCIP members are expected to work collaboratively rather than competitively, and to treat each other with respect and courtesy. To meet this goal in any publication all GeCIP members and the Genomics England team should work towards balancing the needs of data producers, data analysts, students, postdocs and faculty members to secure outputs from this programme.
11. The order in which authors are named in each publication shall be based on work done in relation to that specific publication with the application of starred authorship to recognise that there may be multiple co-authors making equal leadership contributions. We envisage almost all publications from this programme will use a system of starred lead or co-lead authors. This must fairly reflect the work the authors have done to enable the publication. It is not possible to envisage every type of publication that may arise from such a forefront programme and so we have adopted a series of principles which aim to produce a fair outcome for the outputs from this programme.
12. Genomics England strongly endorses the concept of “Team Science” and will follow recommendations of the Academy of Medical Sciences Report<sup>1</sup> to which Genomics England have contributed. We require all publications to record clearly authorship contributions so that team members can be credited appropriately for their contribution. Even where the journal does not require this we expect every publication to delineate every author’s contribution under an appropriate series of headings. These statements are increasingly relied upon for career progression and national and international assessment of research quality. Finally, there are systems such as the ORCID system which allows authors to record their contributions so that organisations who wish will have a public record of an authors’ contribution to a specific output.

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<sup>1</sup> Improving recognition of team science contributions in biomedical research careers, March 2016 (<http://www.acmedsci.ac.uk/policy/policy-projects/team-science/>) GENOMICS ENGLAND PUBLICATION POLICY

13. Some individuals in the Genomics England Science and Bioinformatics Team will usually be named as co-authors on papers focused on early primary discoveries, large-scale analyses describing disease associations or papers reporting genomic structure, and some papers relating to ethics that are made after release of data into the GeCIP domains. For the Genomics England team the approach to authorship must be proportionate, fair and transparent.
14. We recognise that after a primary paper has been published that the added value of the GeCIP domain in terms of functional characterisation, deeper phenotyping or additional analyses means the Genomics England team should usually be recognised as co-authors and will not normally be joint starred lead authors. The exception may be where the Genomics England Team have made a major contribution to downstream analyses. Again, the approach to authorship must be proportionate, fair and transparent.
15. The clinicians from Genomic Medicine Centres responsible for recruiting the patients whose data were included in the publication must be co-authors, even if they are not members of the GeCIP domain. For rare diseases, this should include the nominated/lead clinician from the collaborating centre. It is important outputs recognise the effort that may have been expended by a clinical team in characterising and establishing a group of families with rare disease. In some cases this reflects a substantial effort and we expect the starred authorship to reflect this where this is so and we request that the relevant clinician identify themselves to the appropriate GeCIP Lead. For cancer, this should include at least one clinician from each Genomic Medicine Centre at which patients with that cancer type were recruited.
16. Presentations, ideas, and results from GeCIP activities presented at internal meetings and conference calls are privileged communications. GeCIP domains must share all research plans with the Office of the Chief Scientist so we can avoid duplication of effort. It is inappropriate to initiate new work that is substantially similar and could be perceived as competing, unless this has been sanctioned by the GeCIP Steering Committee.
17. The decision as to who will be named as an author of a Publication and the order in which they will be named will be made by members of the GeCIP domain along with the Office of the Chief Scientist. These will be the members who write the Publication. The recommendations on authorship will be discussed with the domain and shared with the Chief Scientists Team.
18. No person shall be identified as an author of a Publication if they do not wish to be identified as an author.
19. In the event of any disagreement in relation to the authorship of a Publication, the Publication Committee will advise the Genomics England Board whose decision on

authorship of the Publication will be final. The Board may ask the Genomics England Publication Committee to offer final recommendations on authorship where there is not agreement. These will be final and binding.

## 6 Review of Publications for Patentability

20. The Genomics England Publication Committee has been formed and will be chaired by Professor Sir John Bell. Its terms of reference and membership are at appendix 1.
21. No proposed publication shall be sent for review until permitted under Section 22 or 23 below save where it relates to GeCIP Results that have already been published.
22. When the Proposed Publication is in a form suitable to be sent out for peer review or publication, the GeCIP Member responsible for the Proposed Publication shall submit a complete and accurate copy of the final version of the proposed publication to the Office of the Genomics England Chief Scientist.
23. The proposed publication may be sent for review or publication fifteen working days after the manuscript has been received by the Office of the Genomics England Chief Scientist unless within that fifteen working day period, the Office of the Genomics England Chief Scientist has informed the GeCIP Member responsible that it wishes to delay the publication or disclosure to protect intellectual property.
24. If the Office of the Genomics England Chief Scientist informs the GeCIP Member responsible for the proposed publication or presentation that it wishes to delay the submission of the manuscript so that patent application(s) can be filed, then it shall not be submitted for publication. In addition it must not be presented in any way that could constitute formal disclosure for a further period of thirty working days or until the Office of the Genomics England Chief Scientist informs the GeCIP lead and authors it is cleared for submission, whichever is the sooner.

## 7 Acknowledgements

25. All Publications must acknowledge the contributions of:
  - Genomics England and the GeCIP to enabling the research covered by the Publication;
  - those funding the 100,000 Genomes Project including the National Institute for Health Research and any other GeCIP funders;
  - all clinicians and appropriate members of healthcare teams that contributed to the data and results covered by the Publication.



All Publications shall include the following form of words or such other acknowledgement as may be approved by the Office of the Genomics England Chief Scientist:

“This research was made possible through access to the data and findings generated by the 100,000 Genomes Project. The 100,000 Genomes Project is managed by Genomics England Limited (a wholly owned company of the Department of Health). The 100,000 Genomes Project is funded by the National Institute for Health Research and NHS England. The Wellcome Trust, Cancer Research UK and the Medical Research Council have also funded research infrastructure. The 100,000 Genomes Project uses data provided by patients and collected by the National Health Service as part of their care and support.”

We expect Public Health England and Health Education England to be acknowledged where relevant. We also expect that publications will reference earlier key publications that describe the 100,000 Genomes Project.

## 8 Implementation

26. There will be an over-arching Genomics England Publication Committee that will oversee implementation but in reality we view this as policy that will largely be implemented and managed at the level of the GeCIP Domain and the GeCIP Domain Members.

## 9 Students

27. Nothing in this document shall prevent or delay any registered student of an Institution from submitting for a degree of the Institution a thesis based on the results obtained during the course of work undertaken using the GeCIP data, the examination of such a thesis by examiners appointed by the Institution, or the deposit of such a thesis in a library of the Institution in accordance with the relevant procedures of the Institution, provided that the Institution shall send a copy of the thesis to Genomics England at least before the degree is awarded. At the request of Genomics England the Institution shall ensure that the thesis is placed on restricted access in the Institution's library in accordance with the Institution's relevant procedures.

## GENOMICS ENGLAND LIMITED

### TERMS OF REFERENCE FOR THE PUBLICATION COMMITTEE

In these Terms of Reference the following terms shall have the following meanings:

**“Author(s)”** shall mean the main or associate contributors to the Publication that has been included in the Request.

**“PC”** shall mean the Publication Committee, being an advisory committee to the Office of the Chief Scientist on matters of publication, including those by users utilising Genomics England data.

**“PC Secretariat”** has the meaning given by paragraph 1.

**“Board”** means the Board of Directors of Genomics England.

**“GED”** means Genomics England Data, any information included within the research infrastructure of Genomics England.

**“IP Management”** means the research management company or team that is designated by the Genomics England Legal Counsel as responsible for the control of Intellectual Property owned by Genomics England.

**“Proposed Publication”** means a complete and accurate copy of the final version any written, illustrative, or graphical information that is intended for release into the public domain that is based on GED.

**“Project”** means the 100,000 Genomes Project.

**“Protocol”** means most recently NRES REC-approved version of the protocol for the Project.

**“Request”** means a request for approval of a Proposed Publication.

#### Introduction

These Terms of Reference have been produced to identify and formalise the roles, tasks and responsibilities of the PC.

#### Membership and Attendance

The PC Chair shall be appointed on the recommendation of Genomics England’s Office of the Chief Scientist. The first Chair of the PC shall be Professor Sir John Bell.

The members of the PC shall be, subject to acceptance, the following:

- (a) Professor Patrick Maxwell,
- (b) Professor John Tooke,
- (c) Dr Tom Hudson,
- (d) Dr David Bick,
- (e) Professor Stephen Holgate, Professor Parveen Kumar,

(f) Dame Kay Davies, and

(g) Professor Chris Day.

Only members of the PC shall have the right to attend meetings. However, other individuals such as the Executive Chair, the Chief Scientist and other staff of Genomics England, external advisers to Genomics England, and members of Genomics England Advisory Committees shall be invited to attend all or part of any meeting as the PC Secretariat considers appropriate. Named Observers to PC meetings may be admitted, after agreement with the PC Secretariat.

The PC Chair may seek input from relevant Authors, GeCIP Members or leads/subleads, by invitation only, to attend part of PC meetings that involve their Publication in order to provide information during the meeting before making a decision around the Request(s) of the Author(s).

The Chair, supported by the PC Secretariat as appropriate, shall ensure that:

- (a) meetings are co-ordinated effectively and cover Potential Publications adequately according to the Publication Policy and the Intellectual Property Policy;
- (b) the Protocol, policies and standard operating procedures relating to publication are complied with;
- (c) members are familiar with the sections of the Protocol relating to uses of the data and the complementary Genomics England Publication policy;
- (d) there is sufficient representation of members of the PC for quorate decisions and recommendations;
- (e) any conflicts of interest are dealt with;
- (f) decisions are made with clear, recorded feedback and justifications;
- (g) there is consistency of application of use cases;
- (h) amendments to use cases are made where necessary via the appropriate mechanism; and
- (i) the Chairs of the Data Advisory Committee, Ethics Advisory Committee and Science Advisory Committee are consulted where appropriate.

Members of the PC must:

- (a) Familiarise themselves with the pre-meeting materials from the PC Secretariat in advance;
- (b) endeavour to attend each meeting;
- (c) submit adequate notice of any absence from meetings, and
- (d) be familiar with the Genomics England Protocol and Publication Policy.

Membership of the PC may be revoked in accordance with each member's letter of appointment, in agreement with the Chair.

## 1 PC Secretariat

Genomics England's Chief Scientist or his nominee shall act as the secretariat of the PC (**PC Secretariat**).

The PC Secretariat shall ensure that:

- a) Papers are of an appropriate standard, accurate, and available in good time to ensure adequate review by members;
- b) minutes and agendas are drawn up with the help of the Chair;
- c) action points made by the PC are recorded including those actionable within Genomics England or requests for further information from the Author;
- d) in relation to each Request submitted to the PC, the meeting which discusses it must result in a statement indicating whether the PC considers the Request is appropriate for publication and setting out a justification, or requesting further information to enable such a decision to be reached;
- e) members are updated by the PC Secretariat of important developments within Genomics England via regular communications;
- f) provide support and briefings from the other Company committees;
- g) the Chair is assisted in creating reports for Genomics England on decisions and recommendations of the PC;
- h) an up-to-date list of members and expert contributors including their expenses and duration of membership (if applicable) is maintained;
- i) attendees/members are supported as needed in becoming familiar with any relevant internal documents, and
- j) finances relating to the actions of the PC are managed, such as those surrounding travel costs or outsourcing expert opinion guests.

### **Frequency of Meetings**

The PC shall meet at least quarterly or more frequently and at such other times as the PC Secretariat shall require.

### **Notice of Meetings and Proceedings at Meetings**

Meetings of the PC may be called for by the PC Secretariat at the request of the Chair.

In the absence of the PC Chair, an appointed deputy who has been selected by the Chair shall fill the position within a specific meeting.

Unless otherwise agreed by the Chair, five days before the relevant meeting notice of each meeting shall confirm the venue, time and date together with an agenda of items to be discussed, shall be forwarded to each member of the PC and any other person required to attend. Supporting papers shall be sent to PC members and to other attendees as appropriate, at the same time.

Meetings of the PC may be conducted when the Chair and members are physically present together or in the form of either video or audio conferences.

- a) At the discretion of the Chair, Authors may be asked physically or otherwise to attend the PC meetings regarding their Publication.

Each meeting shall consider Requests in such order as the Chair shall determine.

Requests that are deemed to be (by the Chair or as indicated in any minutes) immaterially different to previous Requests where an outcome was agreed by the Committee, such Publications may be assigned the same outcome by executive decision of the Secretariat and the Office of the Chief Scientist and subsequently the Committee will be informed by the Secretariat of this decision in a manner agreed upon by the Chair.

Where the Committee is not unanimous in its decision, a majority vote will decide the outcome as to which category the Publication falls within under section 0. If the votes are tied the PC Chair shall have a casting vote.

The quorum for a PC meeting shall be three members including the Chair. No meeting of the PC shall take place without the PC Secretariat.

At a meeting of the PC, unless a quorum is participating, no recommendation is to be voted on, except a proposal to call another meeting.

### **Minutes of Meetings and summary of Recommendations**

The PC Secretariat shall minute the proceedings and recommendations of all PC meetings (including the names of those present and in attendance) and shall ensure the PC is properly constituted and advised.

The Chair and members (and any advisors as relevant) shall communicate any declared or perceived conflicts of interests. These shall be minuted accordingly, at the beginning of each meeting. Conflicts of interest should be restated at the time where a Request pertinent to the interest is going to be discussed within the meeting.

Minutes of PC meetings shall be circulated to all members of the PC and, once agreed, to all members of the Board, unless a declared conflict of interest exists.

Recommendations of PC to release a Publication shall be reported to the Genomics England Communications Team.

### **Duties**

The PC will review and respond to Requests to inform IP Management's strategic decisions and the prompt publication of scientific literature as one of the aims of Genomics England.

Discuss May report to the Data Advisory Committee with suggestions for security risks particular to certain Requests where the Publication includes, for example, variant sequences; and

The PC shall, in conducting all of its duties in accordance with these Terms of Reference, act in a way that it considers in good faith, would be most likely to promote the protection of innovation in accordance with:

- the Genomics England Intellectual Property Policy that sets out the conditions under which subject matter is likely to be protected;

- the Genomics England Publication Policy that sets out the fair and reasonable terms under which GED based publications may be released and contain appropriate citations;
- the relative contribution of authors whether they be employed by Genomics England or otherwise;
- the materials provided before meetings, detailing the nature of the Request, the requesters' background, and other information the PC Secretariat and /or the Chair sees as relevant to the review of the Request;
- acting in the public interest and protecting public confidence (including that of participants and potential participants) in publication of variants or potentially re-identifiable data; and
- any potential Intellectual Property Right flagged by IP Management that may be disclosed or compromised by the release of the Publication.

The PC shall:

- (a) act as a responsive consultant, providing timely advice, guidance and recommendations on Requests including responding to all Requests within 15 working days; and
- (b) hold further meetings to arrange amendments that may include the construction of a patent for which the Publication can be delayed for up to 40 working days.

## **Reporting**

**The PC Chair shall:**

- a) report formally to the Office of the Chief Scientist on its proceedings and any recommendations made after each meeting;
- b) Be entitled to report advice to the Board, Data Advisory Committee, Ethics Advisory Committee and Science Advisory Committee regarding any revisions to the Publication policy that the PC considers desirable. Such advice will be based on observations of Requests that include issues that said committees have expertise in.

The PC will broadly output one of four possible outcomes in response to requests:

1. Accept a Request which is ready for publication.
2. Accept a Request with preconditions or alterations that must be met in order for the Publication to be released.
3. Refuse a request and produce a report as to the reasons for this and, where appropriate, advise which relevant changes are to be made before re-submission.
4. Postpone publication for up to 40 working days in order to secure any relevant IP.

## **Other Matters**

The PC shall, once a year or as deemed necessary by the Office of the Chief Scientist or the Chair of PC, review its own performance, constitution and these Terms of Reference to ensure it is operating at maximum effectiveness and recommend any changes it considers necessary to the Board for approval.

The PC shall consider any relevant guidelines when recommending any changes to these Terms of Reference.

## **Authority**

The PC is authorised by the Board to seek through the PC Secretariat any information it requires from any employee or contractor of Genomics England in order to perform its duties.

In connection with its duties the PC Chair is authorised by the Board to:

- commission any reports, surveys or information which it deems necessary to help fulfil its obligations;
- secure the attendance of external advisers at its meetings;
- within any budgetary restraints imposed by the Board all at Genomics England's expense.

Although the PC can seek the advice and assistance of any of Genomics England's executives, it needs to ensure that this role is clearly separated from their role within the business.

## **Appeals**

Where the PC has decided against granting publication in response to a Request, the Publication submitter may initiate an appeals process led by the Genomics England Caldicott Guardian and the Office of the Chief Scientist.

- a) In the first instance, where the Caldicott Guardian and the Office of the Chief Scientist disagree with the decision of the PC, the application will be resubmitted to the PC.
- b) Resubmissions will include rationales/evidence as to why reconsideration is appropriate, sourced from the applicant themselves or relevant members of the PC or Genomics England.

In the absence of a resolution after resubmission, a subcommittee of the Board, comprising external members (who do not form part of the PC or Office of the Chief Scientist) shall hold a special meeting to provide a resolution of the matter. Their decision shall be final and binding on the applicant.

All decisions regarding appeals will be made with reference to the Publication Policy and these Terms of Reference.

The sub-committee of the Board referred to in paragraph 0 will make decisions regarding publication in exceptional cases only, for example where the PC has been found not to have followed proper procedure.

**Procedure**

Subject to the constitutional documents of Genomics England and these Terms of Reference, the PC shall determine its own procedures.

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Dated..... 2016

Signed by: