

GeCIP Publication Policy

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1. Document Version History

Version	Author	Date approved	Summary of main changes and reasons
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 Genomics England 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
4.1		16/11/18	Full redraft

2. Purpose Statement

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. This document sets out the policy of Genomics England as regards the authorisation of publications.

3. Scope and applicability

1. This document does not define ways of working. For details on how to use the GeCIP Publication Policy in practice please see the GeCIP Publication Guidance to ensure organisational consistency, coherence and compliance.
2. The GeCIP Publication Policy and GeCIP Publication Guidance are key documents to decision-making on publications, and should be used in conjunction with other applicable Genomics England policies (e.g. Genomics England IP Policy).
3. This document applies to publications which include, but are not limited to; peer reviewed manuscripts, pre-publications (e.g. BioRxiv), conference abstracts, conference posters, conference presentations.
4. Genomics England has established a Publications Committee to mediate on matters relating to publication of the findings utilising the Genomics England dataset.

4. Out of Scope (Students)

Nothing in this document, or the GeCIP Publication Guidance, 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.

5. Review of Publications by Genomics England

All publications need to be provided to Genomics England for review at least **15 working days before** being submitted for review. Responsibility for enacting both the GeCIP Publication Policy and GeCIP Publication Guidance lies with the GeCIP team, GeCIP team Lead, Chief Scientist, Deputy Chief Scientist, Director of Bioinformatics and Genomics England Publication Committee.

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6. Authorship

1. All of the authors and co-authors of each publication will be identified in any output in accordance with the guidelines issued by the International Committee of Medical Journal Editors (ICMJE). See the GeCIP Publication Guidance document for further information.
2. Presentations, ideas, and results from GeCIP activities presented at internal meetings and conference calls are privileged communications. GeCIP domains must register all research plans in the Research Registry.
3. 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 the Publication authors, members of the GeCIP domain along with the GeCIP team Lead, Deputy Chief Scientist and Director of Bioinformatics.
4. In the event of any disagreement in relation to the authorship of a publication, the GeCIP team may ask the Genomics England Publication Committee to offer recommendations on authorship. An appeals process is available for Publication submitters should there be disagreement with the recommendation of the Publication Committee. This is outlined in the GeCIP Publication Guidance.
5. All publications resulting from the 100,000 Genomes Project dataset will be made on behalf of The 100,000 Genomes Project and Genomics England Limited. Please see the GeCIP Publication Guidance for details regarding acknowledgement.

7. Implementation

Both the GeCIP Publication Policy and the GeCIP Publication Guidance will be implemented by the GeCIP members, GeCIP team, GeCIP team Lead, Chief Scientist, Deputy Chief Scientist, Director of Bioinformatics and Genomics England Publication Committee.

8. Responsibilities

Responsibility for the enactment of this policy lies with the Publication authors, the GeCIP team Lead, GeCIP team and the Genomics England Publication Committee.

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9. Abbreviations / 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 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);
GeCIP team	the Genomics England staff members responsible for coordination and administration of research activities utilising Genomics England data;
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 from Genomics England data;
Science team	comprises staff members who report to the Genomics England Chief Scientist, including the GeCIP team.

10. Appendices

Appendix 1. Terms of Reference for the Publication Committee (amended 14/11/2018)

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 Genomics England Science Team on matters of publication, including those by users utilising Genomics England data.

“PC Secretariat” shall mean the Genomics England’s Chief Scientist or their nominee.

“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 the Genomics England Chief Scientist. The first Chair of the PC is Professor Sir John Bell.

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As of November 2018 the members of the PC are:

- (a) Professor Patrick Maxwell,
- (b) Professor David Lomas,
- (c) Dr Tom Hudson,
- (d) Dr David Bick,
- (e) Professor Stephen Holgate,
- (f) Professor Parveen Kumar,
- (g) Dame Kay Davies, and
- (h) Professor Chris Day.

Only members of the PC, the PC Secretariat and one or more representatives from the GeCIP team shall have the right to attend meetings. However, other individuals such as the Genomics England Chair, Genomics England CEO 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 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 policies and guidance relating to publication are complied with;
- (c) members are familiar with the sections of the 100,000 Genomes Project Protocol relating to uses of the data and the complementary GeCIP 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 Ethics Advisory Committee and Science Advisory Committee are consulted where appropriate.

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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.

PC Secretariat

The PC Secretariat shall be called to mediate issues regarding Publications including matters relating, but not limited to; authorship and patentability and ensure that:

- a) minutes and agendas are drawn up with the help of the Chair;
- b) action points made by the PC are recorded including those actionable within Genomics England or requests for further information from the Author;
- c) in relation to each Request submitted to the PC, the meeting which discusses it must result in a statement resolving the issue and setting out a justification, or requesting further information to enable such a decision to be reached;
- d) members are updated with a list of publications resulting from analyses of the 100,000 Genome Project dataset by the PC Secretariat and of important developments within Genomics England via regular communications;
- e) an up-to-date list of members and expert contributors including their expenses and duration of membership (if applicable) is maintained;
- f) attendees/members are supported as needed in becoming familiar with any relevant internal documents.

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 who will be advised by the GeCIP team.

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

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with an agenda of items to be discussed, shall be forwarded to each member of the PC and any other person invited 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. 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, may be assigned the same outcome by executive decision of the Secretariat and subsequently the Committee will be informed 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 the outcome to the publication request (below). 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.

Duties

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

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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:

- (a) the Genomics England Intellectual Property Policy that sets out the conditions under which subject matter is likely to be protected; the relative contribution of authors whether they be employed by Genomics England or otherwise;
- (b) 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 GeCIP team on its proceedings and any recommendations made after each meeting;
- (b) Be entitled to report advice to the Board, 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 in its current format.
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.

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Other Matters

The PC shall, once a year or as deemed necessary by the GeCIP team 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:

- (a) commission any reports, surveys or information which it deems necessary to help fulfil its obligations;
- (b) 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 Genomics England Science Team.

- (a) In the first instance, where the Caldicott Guardian and the Genomics England Science Team 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 sub-committee of the Board, comprising external members (who do not form part of the PC or the Genomics England Science Team) 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

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Policy, other relevant policies and supporting documents and these Terms of Reference.

The sub-committee of the Board referred to above 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.

Signed by: Dated..... 20....