

Genomics England Intellectual Property Policy November 2017

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1. Introduction

- 1.1 Genomics England was established as a company in 2013 to deliver the Project. The Project has the aims set out in the box below (the “Project Aims”).

Project Aims

1. **Patient benefit:** providing clinical diagnosis and, in time, new or more effective treatments for NHS patients.
2. **New scientific insights and discovery:** with the consent of patients, creating a database of 100,000 whole genome sequences linked to continually updated long term patient health and personal information for analysis by researchers.
3. **Accelerating the uptake of genomic medicine in the NHS:** working with NHSE and other partners to deliver a scalable WGS and informatics platform to enable these services to be made widely available for NHS patients. In addition, through the GeCIP, creating a mechanism to both continually improve the accuracy and reliability of information fed back to patients and add to knowledge of the genetic basis of disease.
4. **Stimulating and enhancing UK industry and investment:** by providing access to this unique data resource by industry for the purpose of developing new knowledge, methods of analysis, medicines, diagnostics and devices.
5. **Increasing public knowledge and support for genomic medicine:** delivering an ethical and transparent programme which has public trust and confidence and working with a range of partners to increase knowledge of genomics.

- 1.2 The GeCIP was set up by Genomics England to analyse and interpret the Project Dataset. In order to further the Project Aims, Genomics England may also give third parties access to the Genomics England Resources.

- 1.3 This Policy sets out Genomics England’s objectives and preferences for:-

- 1.3.1 the ownership of Intellectual Property arising out of the use of the Genomics England Resources;
- 1.3.2 the protection, management and commercialisation of patents and other Project IP;
- 1.3.3 the basis on which Genomics England will grant GeCIP Members and other collaborators (both academic and commercial) access to the Genomics England Resources;
- 1.3.4 Genomic England’s policy with regard to licensing of Project IP to GeCIP Members and other collaborators;

- 1.3.5 publication of Project Results and any other results arising out of the use of the Project Dataset, Genomics England Knowledgebase and/or Genomics England Platform; and
 - 1.3.6 achieving downstream benefits for the NHS.
- 1.4 The three Annexes to this Policy set out how Genomics England will address the objectives and preferences set out above in the following three scenarios:-
- 1.4.1 Annex 1 – Research which is carried out entirely within the GeCIP without the use of substantial assets owned by third parties and where there is no material commercial involvement, and research carried out by the GeCIP where no alternative terms have been agreed by Genomics England (Scenario 1);
 - 1.4.2 Annex 2 – Research which is carried out (i) partly within and partly outside the GeCIP; and (ii) by the GeCIP using substantial assets not owned by Genomics England, or a combination of (i) and (ii), in each case where there is no material commercial involvement (Scenario 2); and
 - 1.4.3 Annex 3 – Research which makes use of Genomics England Resources where there is a material commercial involvement (Scenario 3).
- 1.5 This Policy is part of a suite of documents, which deal with Intellectual Property within the Project. These are:-
- 1.5.1 **The DH Intellectual Property Principles for the 100,000 Genomes Project:** the DH IP Principles set out some high level principles that Genomics England’s policies must be compatible with insofar as Intellectual Property is concerned. The DH IP Principles are set out in section 2 below.
 - 1.5.2 **The GeCIP Rules:** section 10 of the GeCIP Rules sets out the Intellectual Property provisions that apply where research is conducted by GeCIP Members entirely within the GeCIP not using assets owned by third parties (described in further detail in Annex 1 to this document) and no further agreement has been agreed between Genomics England and the relevant GeCIP Domain.
 - 1.5.3 **The Genomics England Publication Policy:** this sets out the rules governing publications arising from the Project.
 - 1.5.4 **The Data Sharing Agreement** between Genomics England and each NHS Trust: this sets out the licences between the relevant Trust and Genomics England in respect of the Project Dataset. As between the relevant Trust and Genomics England, the Trust owns the clinical data and grants Genomics England a licence to use it and Genomics England owns the genomic data and grants the relevant Trust a licence to use it but only for the purpose of providing clinical care to participants. For Trust employees to use the genomic data for undertaking any research or for undertaking any

commercial development of products and services, they must become GeCIP Members.

- 1.6 This Policy, the GeCIP Rules and the Genomics England Publication Policy have been approved by the Genomics England Board and the GeCIP Board, which includes representatives from the Medical Research Council, Cancer Research UK and the Wellcome Trust. However, they are living documents, which the Genomics England Board and the GeCIP Board will review and update from time to time as required. Genomics England will review this Policy, the GeCIP Rules and the Genomics England Publication Policy in the light of experience as and when required.
- 1.7 The 100,000 Genomes Project Protocol together with the Genomics England IG Data Access and Acceptable Uses Policy set out policy regarding the governance, access and acceptable use of the Project Dataset. Under the Genomics England IG Data Access and Acceptable Uses Policy, an Access Review Committee has been formed to carry out independent examination of requests for access to the Project Dataset, with regards to the acceptable uses of the Project Dataset as outlined in the 100,000 Genomes Project Protocol and the Genomics England IG Data Access and Acceptable Uses Policy. The Access Review Committee decides whether to approve, decline, or amend requests for access to the Project Dataset.
- 1.8 The capitalised terms used in this Policy have the meanings given in section 8 of this Policy. Annexes 1, 2 and 3 are designed to be largely self-contained and so include some sections that duplicate those set out in the main body of this Policy.

2. Department of Health Principles

Department of Health's Intellectual Property Principles

1. The IP Policy should enable the achievement of the Project Aims and avoid adversely affecting public confidence in genomic medicine and the Project.
2. The Project Dataset and any IP in the Project Dataset should always remain publicly owned and controlled.
3. To the extent that it is reasonably possible, the NHS should have access to any Project Results and the Project IP for clinical use on fair and reasonable terms, reflecting the contribution of the Project Dataset to the development of the downstream Project Results and Project IP.
4. The arrangements and conditions for providing access to and use of the Project Dataset for research and development by academia and industry should be fair and reasonable so as to encourage use and access, consistent with the Project Aims.
5. To the extent that it is reasonably possible and where consistent with the other Project Aims, the management and licensing of the Project Dataset, the Project Results and the Project IP should encourage and support a competitive and diverse UK genomics industry (including SMEs).
6. IP in the Project Results should not be able to be used by the owners of such IP to restrict use of the Project Dataset by other organisations.
7. To help deliver the Project Aims and support future policy priorities, the IP Policy should enable linking of other data sets to the Project Dataset (for example, through appropriate in-licensing).
8. The IP Policy should foster collaborative approaches to accessing and working with the Project Dataset, subject to the policies on consent and confidentiality.
9. The IP Policy should not unduly restrict the timely publishing of Project Results.
10. The key elements of the IP Principles and the IP Policy should be publicly available, excluding any commercially confidential details.
11. Participants and the wider public in England should be provided with clear information about how data from the Participants will be used in accordance with the IP Policy and the policies on consent and confidentiality, together with information about other safeguards such as the Access Review Committee.
12. Any third party works that are to be used in the Project (for example, existing third party computer software) should be appropriately in-licensed and managed so as not to infringe the IP rights of others.

- 2.1 The Department of Health has set out 12 Intellectual Property Principles, which should be used to interpret and apply this Policy. These principles are set out in the box below.

3. Ownership of Project IP

- 3.1 Genomics England's approach to the ownership of Project IP, and any other Intellectual Property which arises as a result of use of or access to the Genomics England Resources, depends upon the circumstances in which such Intellectual Property arises, and the Annexes to this Policy provide a guide to Genomics England's approach in Scenario 1, Scenario 2 and Scenario 3 as described in section 1.4 above.
- 3.2 Genomics England does not seek to own any individual's genome sequences. Where this Policy refers to ownership or licensing of assets in the context of genome sequences, such references are intended as a reference to ownership or licensing of rights to data and other Intellectual Property which subsists in, claims and/or covers genome sequences.

4. Patenting Inventions in the Project Results

- 4.1 Genomics England wishes to ensure that the patenting of inventions arising out of the Project or any projects which make use of the Genomics England Resources is appropriate and socially responsible. By way of example, Genomics England will not file patent applications (and will look to discourage others from filing patent applications) for inventions arising out of the Project Results with claims:-
- 4.1.1 for isolated gene sequences containing variations;
 - 4.1.2 that are marginal;
 - 4.1.3 that are overly broad, going beyond the contribution of invention to the art;
 - 4.1.4 for hypothetical products or methods that have not been developed, unless there is a clear view as to how the product or method might be made to work and/or the patentee has a reasonable expectation that further data will be obtained to support the claims; or
 - 4.1.5 where the public interest would be best served by free and unrestricted use of the invention.

5. Benefits for the NHS

- 5.1 When Genomics England grants rights to use the Genomics England Resources or enters into a collaboration that makes use of the Genomics England Resources, Genomics England will wish to negotiate a favourable regime for the NHS to reflect the NHS's contribution to the development of the Genomics England Resources. In particular:-

- 5.1.1 where Genomics England grants rights to use the Genomics England Resources, Genomics England will wish to ensure that the NHS can have access on fair and reasonable terms to the results derived from such use of the Genomics England Resources and if applicable to use such results in the treatment of NHS patients;
- 5.1.2 where Genomics England enters into a collaboration that makes use of the Genomics England Resources, Genomics England will wish to ensure that the NHS can have access on fair and reasonable terms to the results derived from such collaboration and if applicable to use such results in the treatment of NHS patients;
- 5.1.3 if the use of the Genomics England Resources, or the results of a collaboration that makes use of the Genomics England Resources, play a significant part in the development of a product or service, then Genomics England will wish to ensure that the financial terms upon which the product or service is made available to the NHS reflect the contribution to the development of the product or service of the Genomics England Resources; and
- 5.1.4 if a new product or service is developed using the Genomics England Resources or the results of a collaboration that makes use of the Genomics England Resources, and such new product or service is trialled by the NHS then where appropriate, Genomics England will wish to ensure that the NHS can receive the new product or service at preferential prices once approved.

6. Publication

- 6.1 It is Genomics England's objective that the findings of any research arising out of the use of the Genomics England Resources, including any findings which demonstrate the utility of genomics in the treatment of patients, are published. Where such research does not include a material commercial involvement, the findings should be published in a timely fashion in accordance with the Genomics England Publication Policy e.g. via scientific journals. The Genomics England Publication Policy includes provision for reasonable delays that might be required for the purpose of filing patents.

7. Resources and standard form agreements

- 7.1 Genomics England will build the resources necessary to develop, manage and grant licences under an intellectual property portfolio. This is likely to be a combination of in-house or contracted support (e.g. a patent attorney whose job it is to be close to GeCIPs as they pursue areas of research potentially assisted by NIHR or QMUL Innovations) with a panel of patent attorney firms and a panel of experts to assist the Genomics England Board and the GeCIP.
- 7.2 Genomics England intends in due course to develop standard form agreements (i) for use when licensing out Project IP; (ii) for providing access to the Project Dataset, Genomics England Platform and Genomics England Knowledgebase; and (iii) to govern research collaborations in which Genomics England or the GeCIP are participating, in each case once it has practical experience of the issues reflected in this Policy. It is

envisaged that the standard form agreements covering research collaborations will be based upon existing model agreements such as the Lambert Agreements for pre-clinical research (see <https://www.gov.uk/guidance/university-and-business-collaboration-agreements-lambert-toolkit>) and for clinical research the Model Agreement for Non-Commercial Research in the Health Service (see <http://www.ukcrc.org/regulation-governance/model-agreements/mnca/>). Where there is a commercial involvement, it is envisaged that the standard form agreements will also be based upon the model Clinical Trial Agreement (mCTA) and model Clinical Research Organisation Clinical Trial Agreement (CRO mCTA) for clinical trials, and the model Industry Collaborative Research Agreement (mICRA) for collaborative clinical research (see <https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/standard-research-agreements.htm>).

- 7.3 Where a third party wishes to collaborate with Genomics England or the GeCIP to carry out a research project using the Genomics England Resources, Genomics England will take a flexible approach on which model agreement is used to prepare the research collaboration agreement, but considers that the model agreements referred to above would form a good basis for preparing such agreements.

8. Definitions

100,000 Genomes Project Protocol	the 100,000 Genomes Project Protocol sets out the protocol for the development, delivery, and operation of the Project and also details the patient and clinical benefits, the scientific and transformational objectives, the implementation strategy, as well as the ethical and governance frameworks required for the Project as updated from time to time. See www.genomicsengland.co.uk for further details.
Access Review Committee	the committee that carries out independent examinations of requests for access to the Project Dataset, with regards to the acceptable uses of the Project Dataset as outlined in the 100,000 Genomes Project Protocol and the Genomics England IG Data Access and Acceptable Uses Policy. The Access Review Committee decides whether to approve, decline, or amend requests for access to the Project Dataset. See www.genomicsengland.co.uk for further details.
DH IP Principles	the UK Government's Department of Health Intellectual Property Principles for the 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 Project Dataset for the purposes of carrying out research and improving the understanding and practice of clinical genomics.
GeCIP Domain	each GeCIP Domain is a UK-led consortium of researchers, clinicians and trainees approved by Genomics England to work on improving the clinical application and interpretation of the Project Dataset in a specific clinical area.
GeCIP Member	an individual admitted to the membership of the GeCIP in accordance with the GeCIP Rules.
GeCIP Rules	the rules governing the GeCIP as amended and/or updated from time to time and made available at https://www.genomicsengland.co.uk/about-gecip/for-gecip-members/documents/ .
Genomics England	Genomics England Limited, a limited liability company incorporated in England under company registration number 08493132 whose registered office is at Dawson Hall, Charterhouse Square, London, EC1M 6BQ.
Genomics England IG Data Access and Acceptable Uses Policy	Genomics England's policy regarding the governance, access and acceptable use of the Project Dataset as updated from time to time. See https://www.genomicsengland.co.uk/the-100000-genomes-project/data/ for further details.
Genomics England Knowledgebase	the database created by or on behalf of Genomics England containing (i) the knowledge and discoveries resulting from the Project and (ii) public knowledge, around the links between phenotype, disease, genes and variants.
Genomics England Platform	the systems and infrastructure developed by or on behalf of Genomics England to facilitate the Project, including without limitation Genomics England's data centre, the software applications and tools through which the Project Dataset, the Project Results and the Genomics England Knowledgebase can be accessed and analysed.

Genomics England Publication Policy	Genomics England’s policy regarding the publication of Project Results as amended and/or updated from time to time and made available at www.genomicsengland.co.uk .
Genomics England Resources	the Project Dataset, the Genomics England Knowledgebase, the Genomics England Platform and the Project Results held by Genomics England.
Intellectual Property	patents, any extensions of the exclusivity granted in connection with patents, petty patents, utility models, registered designs, trade marks, service marks, applications for any of the foregoing (including, but not limited to, continuations, continuations-in-part and divisional applications), the right to apply for and be granted any of the foregoing, rights in inventions, trade names, business names, brand names, get-up, logos, domain names and URLs, copyrights, design rights, semiconductor topography rights, database rights, publication rights, performance rights, rights in know-how, trade secrets and confidential information and all other forms of intellectual property right having equivalent or similar effect to any of the foregoing which may exist anywhere in the world.
Policy	this Genomics England Intellectual Property Policy as amended and/or updated from time to time by Genomics England.
Project	the 100,000 Genomes Project, a programme of whole genome sequencing announced by the then 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.
Project Aims	has the meaning given in section 1.1 of the main body of this Policy.
Project Dataset	any data created or derived in the course of carrying out the Project including genome sequences and clinical data from NHS patients and family members of NHS patients that participate in the Project.
Project IP	Intellectual Property that may subsist in the Project Dataset or the Project Results or is registered or applied for in respect of the Project Dataset or the Project Results.

Project Results	any innovations, inventions, discoveries, data, developments, know-how, ideas, techniques, software, algorithms, results and other outputs developed by any organisation in the course of carrying out the Project or through the use of the Project Dataset, but excluding the Project Dataset itself.
Scenario 1	research which is carried out entirely within the GeCIP without the use of substantial assets owned by third parties and where there is no material commercial involvement, and research carried out by the GeCIP where no alternative terms have been agreed by Genomics England.
Scenario 2	research which is carried out (i) partly within and partly outside the GeCIP; and (ii) by the GeCIP using substantial assets not owned by Genomics England, or a combination of (i) and (ii), in each case where there is no material commercial involvement.
Scenario 3	research which makes use of the Genomics England Resources where there is a material commercial involvement.

Annex 1

Scenario 1

Genomics England's Intellectual Property Policy for Research Entirely within the GeCIP with no Material Commercial Involvement

1. Introduction

- 1.1 This Annex sets out Genomics England's policy for Intellectual Property which arises from research which is carried out entirely within the GeCIP without the use of substantial assets owned by third parties and where there is no material commercial involvement, and research carried out by the GeCIP where no alternative terms have been agreed by Genomics England. Such a scenario is referred to in this Policy as "Scenario 1".
- 1.2 All of the GeCIP research projects will generate Intellectual Property in the narrow sense of copyright and confidential information but also, it is hoped in the broader sense of making discoveries and advancing scientific knowledge. However, whilst it is hoped much of this will be of real scientific value, it is envisaged that only in exceptional cases will the resulting Intellectual Property have substantial commercial potential.
- 1.3 The capitalised terms used in this Annex have the meanings given in section 8 of this Annex.

2. GeCIP's access to Project Dataset and Genomics England Knowledgebase

- 2.1 GeCIP Members will be given access to the Project Dataset and the Genomics England Knowledgebase free of charge. Genomics England will not make any part of the Project Dataset created by or for a particular GeCIP Domain available outside that GeCIP Domain for a period of nine months to allow for publication in accordance with the GeCIP Rules and the Genomics England Publication Policy.
- 2.2 Where a GeCIP Member, in addition to his or her GeCIP activities, is also involved in a research collaboration with a material commercial involvement which makes use of the Genomics England Resources, the GeCIP Member will be given one right of access to be used exclusively for GeCIP activities and a second right of access to be used exclusively for activities in relation to the research collaboration.

3. Ownership of Project IP arising from GeCIP-only research

- 3.1 Genomics England will own and control any Intellectual Property which arises out of work carried out entirely within the GeCIP without the use of substantial assets (e.g. data, software, results or information) owned by third parties and where there is no material commercial involvement, and will take responsibility for the patenting of inventions in the Project Results arising out of such research. The reasons for this include:-

- 3.1.1 the Project represents a significant investment by the Government;
 - 3.1.2 the Government wishes to avoid the fragmentation of ownership Intellectual Property: with individual GeCIP Members from so many different organisations collaborating on the Project, allocating ownership of Intellectual Property according to who did what would create an immensely complex, bureaucratic and potentially contentious Intellectual Property ownership structure;
 - 3.1.3 the Government does not want the allocation of ownership of Intellectual Property between multiple organisations to become a hindrance to effective co-operation;
 - 3.1.4 allocation of ownership of Intellectual Property in this way has been agreed with NHS England and through it the 65 NHS Bodies involved in the Project. Similar arrangements are in hand in respect of the devolved nations;
 - 3.1.5 industry has made it clear that they would rather deal with a single Intellectual Property owner than multiple owners; and
 - 3.1.6 the Government wishes to ensure that a socially responsible patent strategy that supports the Project Aims is pursued both in terms of encouraging the development of new products and services and supporting cases where substantial investment is needed and a single owner supports this approach.
- 3.2 Genomics England believes that the approach to Intellectual Property ownership set out above reflects the Project Aims and is more likely to deliver benefit to patients, to enable new scientific discovery and medical insights and to kick start the development of a UK genomics industry than an approach that fragments the ownership of Intellectual Property between multiple public sector bodies as is customarily the case.

4. Patenting Inventions in the Project Results

- 4.1 Genomics England wishes to ensure that the patenting of inventions arising out of the Project or any projects which make use of the Genomics England Resources is appropriate and socially responsible.
- 4.2 Genomics England will not file patent applications for inventions arising out of the Project Results with claims:-
 - 4.2.1 for isolated gene sequences containing variations;
 - 4.2.2 that are marginal;
 - 4.2.3 that are overly broad, going beyond the contribution of invention to the art;
 - 4.2.4 for hypothetical products or methods that have not been developed, unless there is a clear view as to how the product or method might be made to work

and/or Genomics England has a reasonable expectation that further data will be obtained to support the claims; or

- 4.2.5 where the public interest would be best served by free and unrestricted use of the invention.
- 4.3 If Genomics England decides not to file patent application(s) for an invention that arises out of work carried out by the GeCIP, Genomics England will permit employer(s) of the inventor(s) to file patents for such invention unless Genomics England has decided not to patent the invention for public policy reasons (which may be the case for example if Genomics England decides that the public interest would be best served by making the invention freely available for use by all rather than patenting it) in which case Genomics England will engage in a dialogue with those concerned (including the employer(s) of the inventor(s)) before reaching a final decision on patenting. Where neither Genomics England nor the employer of the inventor files patent applications for such invention(s), Genomics England will aim to publish the invention so as to prevent others from patenting the invention.

5. Genomics England's Patent Management

- 5.1 Genomics England will pursue a strategy of identifying and filing patent applications for patentable inventions that arise out of work carried out by the GeCIP if the invention constitutes a significant development to the state of the art and the resulting patents would:-
 - 5.1.1 support the Project Aims;
 - 5.1.2 provide strong protection; and
 - 5.1.3 have significant commercial potential.
- 5.2 Where Genomics England files a patent application for an invention arising out of work carried out by the GeCIP, it will endeavour to obtain patent protection in the major markets (including Europe and the United States) and will decide which other territories to cover on the basis of the likely strength of the patent, the commercial potential of the invention concerned, the likely coverage requirements of potential licensees, and the available budget for developing and maintaining its patent portfolio.
- 5.3 Genomics England will actively manage its patent portfolio by seeking licensees for its patents and by reviewing its patent portfolio on an ongoing basis, allowing patents to lapse if they have not been licenced and no longer have commercial potential.
- 5.4 Genomics England will determine its patent licensing approach on a case by case basis according to the nature of the invention but always so as to meet Genomics England's primary aims. A GeCIP Member's employer will have a right to negotiate a fair and reasonable licence for the commercialisation of GeCIP outputs created or developed in the GeCIP Domains in which the GeCIP Members that they employ participate. Genomics England will prefer licensing on a non-exclusive basis save where it is

necessary to license on an exclusive basis (e.g. an exclusive licence would be preferred where the licensee would need to make a substantial investment to develop a product or service which would bring benefit to NHS patients). Any exclusive licence granted should be approved by Genomics England's Board of directors before grant and should:-

- 5.4.1 be time limited (e.g. to the duration of the licensed patents or shorter);
 - 5.4.2 be limited to particular field(s) or purpose(s) where appropriate;
 - 5.4.3 be limited to a particular territory where appropriate;
 - 5.4.4 provide Genomics England with a veto on enforcement of licensed patents;
 - 5.4.5 provide Genomics England with retained rights to use the inventions described in the relevant patents within the Genomics England Platform and for the Project; and
 - 5.4.6 be capable of being terminated by Genomics England if the licensee does not (or ceases to) actively develop or commercialise products or services utilising the licensed patents.
- 5.5 There may be occasions when Genomics England may be asked to assign rather than license patents which arise from GeCIP-only research to a third party (e.g. where there is venture capital) and these situations will need to be addressed on a case by case basis. Assignment may be considered, for example, where commercialisation of the patents would bring benefit to NHS patients but would require substantial investment which is unlikely to be obtained unless the investor has ownership of the relevant patents. Notwithstanding any such assignment, Genomics England would seek to retain a right to use the relevant patents within the Genomics England Platform and for the Project.
- 5.6 Genomics England shall endeavour to ensure that the costs of actively filing for, managing, maintaining, defending and enforcing patents are carefully considered and justified by the expected return and achievement of the Project Aims.

6. Benefits for the NHS

- 6.1 When Genomics England grants rights under patents that arise out of work carried out by the GeCIP, Genomics England will wish to negotiate a favourable regime for the NHS to reflect the NHS's contribution to the Project. In particular:-
- 6.1.1 Genomics England will wish to ensure that the NHS can have access on fair and reasonable terms to the results of research carried out by the GeCIP and if applicable to use such results in the treatment of NHS patients;
 - 6.1.2 if the results of research carried out by the GeCIP play a significant part in the development of a product or service, then Genomics England will wish to ensure that the financial terms upon which the product or service is made

available to the NHS reflect the contribution to the development of the product or service of the Genomics England Resources; and

- 6.1.3 if a new product or service is developed as a result of research carried out within the GeCIP, and such new product or service is trialled by the NHS then where appropriate, Genomics England will wish to ensure that the NHS can receive the new product or service at preferential prices once approved.

7. Funding

- 7.1 The standard grant terms of the principal funders of medical research in the United Kingdom are not on the whole consistent with this Policy in relation to Scenario 1. However, certain of these funders have agreed that where they provide grants for research projects within Scenario 1, they will waive the Intellectual Property provisions of their standard grant terms to the extent they are inconsistent with the Intellectual Property arrangements set out in this Annex 1. Researchers should confirm the position with relevant person within the funder concerned. The document, “Making a GeCIP Research Application” sets out how we approach this.
- 7.2 If a researcher is already funded by a grant that is not allocated for a particular project, he/she should declare this at the time he/she becomes a GeCIP Member, but it will only be necessary to resolve any inconsistencies between the terms of the grant and the GeCIP Rules at the time that a research application is submitted.
- 7.3 If there is an existing project that is already funded by a grant and it is subsequently agreed that part of that project should be carried out within the GeCIP, Genomic England’s initial view is that this would most likely to fall within Scenario 2 (see Annex 2 of this Policy). Accordingly, there would be a discussion about the terms on which the GeCIP would participate in the project and part of that discussion would be in relation to Intellectual Property.

8. Definitions for Annex 1

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 Project Dataset for the purposes of carrying out research and improving the understanding and practice of clinical genomics.
GeCIP Domain	each GeCIP Domain is a UK-led consortium of researchers, clinicians and trainees approved by Genomics England to work on improving the clinical application and interpretation of the Project Dataset in a specific clinical area.
GeCIP Member	an individual admitted to the membership of the GeCIP in accordance with the GeCIP Rules.

GeCIP Rules	the rules governing the GeCIP as amended and/or updated from time to time and made available at https://www.genomicsengland.co.uk/about-gecip/for-gecip-members/documents/ .
Genomics England	Genomics England Limited, a limited liability company incorporated in England under company registration number 08493132 whose registered office is at Dawson Hall, Charterhouse Square, London, EC1M 6BQ.
Genomics England Knowledgebase	the database created by or on behalf of Genomics England containing (i) the knowledge and discoveries resulting from the Project and (ii) public knowledge, around the links between phenotype, disease, genes and variants.
Genomics England Platform	the systems and infrastructure developed by or on behalf of Genomics England to facilitate the Project, including without limitation Genomics England’s data centre, the software applications and tools through which the Project Dataset, the Project Results and the Genomics England Knowledgebase can be accessed and analysed.
Genomics England Publication Policy	Genomics England’s policy regarding the publication of Project Results as amended and/or updated from time to time and made available at www.genomicsengland.co.uk .
Genomics England Resources	the Project Dataset, the Genomics England Knowledgebase, the Genomics England Platform and the Project Results held by Genomics England.
Intellectual Property	patents, any extensions of the exclusivity granted in connection with patents, petty patents, utility models, registered designs, trade marks, service marks, applications for any of the foregoing (including, but not limited to, continuations, continuations-in-part and divisional applications), the right to apply for and be granted any of the foregoing, rights in inventions, trade names, business names, brand names, get-up, logos, domain names and URLs, copyrights, design rights, semiconductor topography rights, database rights, publication rights, performance rights, rights in know-how, trade secrets and confidential information and all other forms of intellectual property right having equivalent or similar effect to any of the foregoing which may exist anywhere in the world.
Policy	the Genomics England Intellectual Property Policy as amended and/or updated from time to time by Genomics England.
Project	the 100,000 Genomes Project, a programme of whole genome sequencing announced by the then 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.

Project Aims	has the meaning given in section 1.1 of the main body of the Policy.
Project Dataset	any data created or derived in the course of carrying out the Project including genome sequences and clinical data from NHS patients and family members of NHS patients that participate in the Project.
Project IP	Intellectual Property that may subsist in the Project Dataset or the Project Results or is registered or applied for in respect of the Project Dataset or the Project Results.
Project Results	any innovations, inventions, discoveries, data, developments, know-how, ideas, techniques, software, algorithms, results and other outputs developed by any organisation in the course of carrying out the Project or through the use of the Project Dataset, but excluding the Project Dataset itself.
Scenario 1	research which is carried out entirely within the GeCIP without the use of substantial assets owned by third parties and where there is no material commercial involvement, and research carried out by the GeCIP where no alternative terms have been agreed by Genomics England.
Scenario 2	research which is carried out (i) partly within and partly outside the GeCIP; and (ii) by the GeCIP using substantial assets not owned by Genomics England, or a combination of (i) and (ii), in each case where there is no material commercial involvement.
Scenario 3	research which makes use of the Genomics England Resources where there is a material commercial involvement.

Annex 2

Scenario 2

Genomics England's Intellectual Property Policy for External GeCIP Collaborations with no Material Commercial Involvement

1. Introduction

1.1 This Annex sets out Genomics England's policy for Intellectual Property arising from research which is carried out:-

1.1.1 partly within and partly outside the GeCIP and where there is no material commercial involvement; and/or

1.1.2 within the GeCIP using substantial asset(s) (e.g. data or software) not owned by Genomics England and where there is no material commercial involvement;

and research which involves a combination of the activities described in subsections 1.1.1 and 1.1.2 above. These scenarios are referred to in this Policy as "Scenario 2".

1.2 An example of a non-material commercial involvement might be where a commercial entity contributes materials or funding to the collaboration but does not have a preferential right or option to use or patent the results of the collaboration.

1.3 All of the GeCIP research projects will generate Intellectual Property in the narrow sense of copyright and confidential information but also, it is hoped in the broader sense of making discoveries and advancing scientific knowledge. However, whilst it is hoped much of this will be of real scientific value, it is envisaged that only in exceptional cases will the resulting Intellectual Property have substantial commercial potential.

1.4 Where Intellectual Property with substantial commercial potential does arise, Genomics England wishes to ensure that the organisation participating in the research that is best placed to protect, manage and secure commercialisation of that Intellectual Property is given the rights to do so.

1.5 The capitalised terms used in this Annex have the meanings given in section 11 of this Annex.

2. Ownership of Intellectual Property arising from research carried out partly within and partly outside the GeCIP and where there is no material commercial involvement

2.1 This section 2 sets out the approach Genomics England will take when deciding how ownership of Intellectual Property should be allocated where research is carried out

partly within and partly outside the GeCIP and where there is no material commercial involvement.

2.2 Ownership of Intellectual Property arising out of research collaborations can be allocated in one or more of the ways set out below:-

2.2.1 one party can own all of the arising Intellectual Property and grant the other collaborators appropriate licences;

2.2.2 all of the arising Intellectual Property can be jointly owned by the collaborators;

2.2.3 each party can own the arising Intellectual Property that its personnel generate. Where arising Intellectual Property is generated jointly (e.g. where employees of two or more collaborators are inventors on the same patent) then that arising Intellectual Property could be jointly owned or allocated in another way;

2.2.4 ownership of arising Intellectual Property can be allocated according to the technical field it falls into. For example, in a collaboration between a pharmaceutical company and developer of inhalation devices to develop a new asthma product, the parties might agree that pharmaceutical company will own any arising Intellectual Property that relates primarily to pharmaceutical compound and the inhaler company will own any arising Intellectual Property that relates primarily to the inhaler device. Any arising Intellectual Property that relates to both technical fields could be jointly owned or allocated in another way;

2.2.5 ownership of arising Intellectual Property can be allocated according to whether it constitutes an improvement to a party's background Intellectual Property. In cases where arising Intellectual Property does not represent an improvement to any party's background or constitutes an improvement to more than one party's background then that item of arising Intellectual Property could be jointly owned or allocated in another way.

2.3 The appropriate basis on which to allocate the ownership of Intellectual Property arising from research collaborations under Scenario 2 will depend upon the nature and circumstances of the collaboration. Genomics England does not have a particular preference provided its interests as described below are addressed.

2.4 In general, where Genomics England participates in a project which involves a DNA sequencing element, and Genomics England (or its sequencing provider) carries out the sequencing, Genomics England would prefer to own and control the data which arises out of the sequencing. The reasons for this include:-

2.4.1 the Government wishes to avoid the fragmentation of ownership of Intellectual Property;

- 2.4.2 the Government does not want the allocation of Intellectual Property between multiple organisations to become a hindrance to effective co-operation; and
- 2.4.3 the Government wishes to ensure that a socially responsible patent strategy that supports the Project Aims is pursued both in terms of encouraging the development of new products and services and supporting cases where substantial investment is needed and a single owner supports this approach.
- 2.5 In general, if items (such as data, software, results or information) resulting from the collaboration are to be incorporated into the Genomics England Platform, Project Dataset and/or Genomics England Knowledgebase, Genomics England would prefer to own the rights in such items. This is particularly the case (i) where as part of the collaboration, Genomics England (or its sequencing provider) is generating whole genome sequences that are to become part of the Project Dataset and (ii) where the collaboration gives rise to improvements that are specific to the Genomics England Platform (e.g. improved workflow procedures). However, in other cases, Genomics England may consider other arrangements such as co-ownership or a licence meeting the licence requirements set out in section 4.2 below.
- 2.6 As a general rule, Genomics England would wish to avoid joint ownership of results but may consider it in particular circumstances where joint ownership would be appropriate given the interests of Genomics England and the other participants in the collaboration.
- 2.7 In general, Genomics England would not seek to acquire ownership in any Intellectual Property developed by the collaborators outside the collaboration unless, in exceptional circumstances, it is agreed that certain whole genome sequences contributed by a collaborator are to be incorporated into the Project Dataset.
- 2.8 Other considerations that may influence Genomics England's approach to the allocation of Intellectual Property ownership for a particular collaboration are as follows:-
- 2.8.1 the relative importance/value of the contribution of the Genomics England Resources and Genomics England to the collaboration as compared with the contributions being made by the other collaborators. The greater the relative contribution of the Genomics England Resources and Genomics England to the collaboration, the more likely it is that Genomics England would wish to have ownership of the results;
- 2.8.2 the extent to which the results of work carried out by the GeCIP in the collaboration are severable from the results from the rest of the collaboration. If Genomics England's contribution to the collaboration is relatively discrete such that Genomics England could own the rights arising out of GeCIP's contribution to the collaboration then it may be appropriate for Genomics England to own the results of the GeCIP work;

- 2.8.3 which of the collaborators is best placed to ensure the results of the collaboration are made available and utilised for the public benefit;
- 2.8.4 Genomics England wishes to ensure that there is a socially responsible patent strategy for inventions that arise out of research using the Genomics England Resources;
- 2.8.5 Genomics England wishes to ensure that the findings from collaborations arising out of use of the Genomics England Resources are published (e.g. via scientific journals); and
- 2.8.6 if in fact most of the work on the project is to be carried out by the GeCIP using the Project Dataset and only minor aspects are to be carried out outside the GeCIP then it may be more appropriate for ownership of Intellectual Property to be allocated in accordance with the arrangements that apply to Scenario 1 (see Annex 1 of the Policy).

3. Ownership of Intellectual Property arising from research carried out by the GeCIP using substantial assets not owned by Genomics England and where there is no material commercial involvement

- 3.1 Examples of substantial assets that might be brought into Genomics England's data centre for research carried out by the GeCIP include software and collections of tissue samples, whole genome sequences, phenotypic data, genomic data and multiomic data that are not created as part of the Project itself.
- 3.2 Genomics England's general approach to ownership of Intellectual Property where an external asset is brought into GeCIP research is set out below but will vary on a case by case basis according to the nature of the external asset and the surrounding circumstances:-
 - 3.2.1 Before any external asset is brought into or used in the GeCIP, Genomics England must agree to such use and there must be agreement between Genomics England and the owner of the asset on how any improvements to, developments of and results derived from the external asset will be owned and licensed.
 - 3.2.2 Save in the exceptional circumstances described in section 3.2.3 below, Genomics England will not seek to obtain ownership of the original external asset that is brought into the GeCIP. If the external asset is to be incorporated into the Genomics England Platform, Project Dataset and/or Genomics England Knowledgebase, Genomics England will look to receive a licence in relation to the external asset meeting the licence requirements set out in section 4.2 below. If the external asset is not going to be incorporated into the Genomics England Platform, Project Dataset and/or Genomics England Knowledgebase, Genomics England will look to receive a licence but only to the extent such licence is necessary to enable use of any resulting improvements, developments and results in connection with the Genomics England Platform, Project Dataset and/or Genomics England Knowledgebase.

- 3.2.3 If the external asset is a collection of whole genome sequences that are to be incorporated into the Project Dataset, then Genomics England's preference would be to own the rights in such collection if the collection was created using UK public funds. However, Genomics England may consider other arrangements such as co-ownership or a licence meeting the licence requirements set out in section 4.2 below.
- 3.2.4 Genomics England envisages that in most cases it would be appropriate for both Genomics England and the owner of the external asset to have the right to use and license the use of improvements and results arising out of the use or development of the external asset.
- 3.2.5 If the results arising out of use or development of the external asset by the GeCIP are to be incorporated into the Genomics England Platform, Project Dataset and/or Genomics England Knowledgebase then Genomics England's preference would be to own the rights in such results. However, Genomics England may consider other arrangements such as co-ownership or a licence meeting the licence requirements set out in section 4.2 below.
- 3.2.6 If the use of the external asset by the GeCIP results in improvements to that external asset then in general, Genomics England would agree that that the owner of the external asset could own the improvements. However, Genomics England may ask for a licence to use the improved external asset meeting the requirements set out in section 4.2 below if it would benefit the Genomics England Platform.
- 3.2.7 As a general rule, Genomics England would wish to avoid joint ownership of results but may consider joint ownership in particular circumstances where it would be appropriate given the respective interests of Genomics England and the owner of the external asset (for example, where a collection of whole genome sequences is to be incorporated into the Project Dataset but for contractual reasons the original owner needs to retain an ownership interest).
- 3.2.8 The publication of the results arising out of use or development of the external asset by the GeCIP should be published in accordance with the Genomics England Publication Policy.
- 3.3 Where the external asset is just an initial concept or idea and most of the substantial work will be carried out within the GeCIP using the Genomics England Platform then it may be more appropriate for ownership of Intellectual Property to be allocated in accordance with the arrangements that apply to Scenario 1 (see Annex 1 of this Policy).
- 3.4 The following examples describe research that would be categorised within Scenario 2 and set out Genomics England's expectations as regards the allocation of ownership of Intellectual Property:-

- 3.4.1 A collaborator is to collect tissue samples and phenotypic data from a cohort of patients. As part of a research collaboration, Genomics England is to sequence the tissue samples and then carry out a preliminary analysis of the sequence data using the Genomics England Platform. Other collaborators would then look to identify significant variations. In this case, Genomics England would be looking to:-
- own the rights in the sequence data;
 - have a licence meeting the requirements set out in section 4.2 below in relation to the phenotypic data;
 - include any results from the analysis in the Genomics England Knowledgebase; and
 - ensure that the results and the collaboration are published (e.g. via a scientific journal).
- 3.4.2 A research collaboration is to test a new treatment for a particular cancer on a cohort of patients having a particular genetic variation. Genomics England's role in the collaboration is to identify a cohort of patients with that cancer who have the genetic variation concerned. Genomics England would not have any further involvement in the collaboration. In this case, Genomics England would be looking to ensure:-
- that the results of the collaboration are published (e.g. via a scientific journal);
 - that Genomics England has a licence meeting the requirements set out section 4.2 to include the conclusions of the collaboration in the Genomics England Knowledgebase; and
 - that Genomics England is remunerated by means of a right to receive a fair and reasonable share of any revenue that results from the new treatment having regard to the contribution that use of the Genomics England Resources made to the development of such products or services.
- 3.4.3 The GeCIP wishes to use a software algorithm not owned by Genomics England to verify and improve the algorithm's performance using the Project Dataset. In such case, Genomics England may agree that it is appropriate for the owner of the software to retain ownership of the software algorithm and any improvements to it but the results generated by use of the software algorithm on the Project Dataset should be owned by Genomics England. Genomics England may also ask for a licence to use the improved software algorithm in the Genomics England Platform.
- 3.4.4 The GeCIP wishes to use a collection of whole genome sequences and associated phenotypic data for a cohort that is not owned by Genomics

England and it is intended that the collection should form part of the Project Dataset or Genomics England Knowledgebase and be hosted on the Genomics England Platform and then be analysed in conjunction with the rest of the Project Dataset. As the external data will be integrated into the Project Dataset and Genomics England Knowledgebase and Genomics England will be covering the costs of storage and analysis, Genomics England would wish to own the external data but may agree to co-ownership if it is necessary for the originator to retain an ownership interest.

4. Licence Requirements – Intellectual Property licensed to Genomics England

- 4.1 If items (such as data, software, results or information) are incorporated into the Genomics England Resources and are licenced to Genomics England, Genomics England would wish to avoid having inconsistent licence terms for the different items. For example, if 50 different collections of phenotypic data are licensed to Genomics England and are incorporated into the Project Dataset and/or Genomics England Knowledgebase, Genomics England would not wish to have 50 different, inconsistent sets of licence terms each with their own restrictions on the use of each collection as this would make it impractical for Genomics England to make the collections available to users of the Genomics England Resources.
- 4.2 Accordingly, if items (such as data, software, results or information) are to be incorporated into the Genomics England Resources and Genomics England is to receive a licence in respect of such items, then the licence should meet all of the following requirements:-
- 4.2.1 the licence may be exclusive, non-exclusive or sole;
 - 4.2.2 a one-off up-front licence fee could be paid (if agreed by Genomics England) but otherwise the licence should be royalty free;
 - 4.2.3 the licence should be perpetual and irrevocable as it could be difficult to track some licensed items once incorporated into the Genomics England Resources and subsequently remove them once the licence had come to an end. Also from a scientific perspective it would be undesirable to delete data upon which important findings had been made;
 - 4.2.4 the licence should permit the licensed items to be kept by or on behalf of Genomics England at least in the UK;
 - 4.2.5 the licence should permit derivatives of the licensed items to be made and the licensed items to be incorporated in other works;
 - 4.2.6 the licence should permit use of the licensed items as part of the Genomics England Resources by Genomics England and any persons authorised by Genomics England anywhere in the world for healthcare and other purposes consistent with the Project Aims;

- 4.2.7 the licence should be assignable to any successor in function of Genomics England; and
 - 4.2.8 the licence should permit Genomics England to grant sub-licences.
- 4.3 If items (such as data, software, results or information) are to be incorporated into the Genomics England Resources and a licence meeting all the requirements set out in section 4.2 is not offered then Genomics England would be looking to obtain an ownership interest in the Intellectual Property instead.

5. Patenting Inventions in the Project Results

- 5.1 Regardless of which party owns the Project IP, Genomics England wishes to ensure that the patenting of inventions arising out of the Project or any projects which make use of the Genomics England Resources is appropriate and socially responsible. By way of example, Genomics England will not file patent applications (and will look to discourage others from filing patent applications) for inventions arising out of the Project Results with claims:-
- 5.1.1 for isolated gene sequences containing variations;
 - 5.1.2 that are marginal;
 - 5.1.3 that are overly broad, going beyond the contribution of invention to the art;
 - 5.1.4 for hypothetical products or methods that have not been developed, unless there is a clear view as to how the product or method might be made to work and/or the patentee has a reasonable expectation that further data will be obtained to support the claims; or
 - 5.1.5 where the public interest would be best served by free and unrestricted use of the invention.

6. Genomics England's Patent Management

- 6.1 Where Genomics England owns or co-owns Project IP, Genomics England will pursue a strategy of identifying and filing patent applications for patentable inventions that arise out of research conducted under Scenario 2 if the invention constitutes a significant development to the state of the art and the resulting patents would:-
- 6.1.1 support the Project Aims;
 - 6.1.2 provide strong protection; and
 - 6.1.3 have significant commercial potential.
- 6.2 Where Genomics England files a patent application for an invention that arises out of research conducted under Scenario 2, it will endeavour to obtain patent protection in the major markets (including Europe and the United States) and will decide which other territories to cover on the basis of the likely strength of the patent, the

commercial potential of the invention concerned, the likely coverage requirements of potential licensees, and the available budget for developing and maintaining its patent portfolio.

- 6.3 Genomics England will actively manage its patent portfolio by seeking licensees for its patents and by reviewing its patent portfolio on an ongoing basis, allowing patents to lapse if they have not been licensed and no longer have commercial potential.
- 6.4 There may be occasions when Genomics England may be asked to assign rather than license a patent which arises from research under Scenario 2 to a third party (e.g. where there is venture capital) and these situations will need to be addressed on a case by case basis. Assignment may be considered, for example, where commercialisation of the patents would bring benefit to NHS patients but would require substantial investment which is unlikely to be obtained unless the investor has ownership of the relevant patents. Notwithstanding such assignment, Genomics England would seek to retain a right to use the relevant patents within the Genomics England Platform and for the Project.
- 6.5 Genomics England shall endeavour to ensure that the costs of actively filing for, managing, maintaining, defending and enforcing patents arising from research under Scenario 2 are carefully considered and justified by the expected return and achievement of the Project Aims.

7. Benefits for the NHS

- 7.1 When Genomics England grants rights to use the Genomics England Resources or enters into a collaboration that makes use of the Genomics England Resources, Genomics England will wish to negotiate a favourable regime for the NHS to reflect the NHS's contribution to the development of the Genomics England Resources. In particular:-
 - 7.1.1 where Genomics England grants rights to use the Genomics England Resources, Genomics England will wish to ensure that the NHS can have access on fair and reasonable terms to the results derived from such use of the Genomics England Resources and if applicable to use such results in the treatment of NHS patients;
 - 7.1.2 where Genomics England enters into a collaboration that makes use of the Genomics England Resources, Genomics England will wish to ensure that the NHS can have access on fair and reasonable terms to the results derived from such collaboration and if applicable to use such results in the treatment of NHS patients;
 - 7.1.3 if the use of the Genomics England Resources, or the results of a collaboration that makes use of the Genomics England Resources, play a significant part in the development of a product or service, then Genomics England will wish to ensure that the financial terms upon which the product or service is made available to the NHS reflect the contribution to the development of the product or service of the Genomics England Resources; and

- 7.1.4 if a new product or service is developed using the Genomics England Resources or the results of a collaboration that makes use of the Genomics England Resources, and such new product or service is trialled by the NHS then where appropriate, Genomics England will wish to ensure that the NHS can receive the new product or service at preferential prices once approved.

8. Funding

- 8.1 Where research funded by non-commercial funders falls under Scenario 2, Genomics England will seek to reach agreement on the ownership of Intellectual Property arising out of such research in accordance with the document, “Making a GeCIP Research Application”.
- 8.2 Scenario 2 is very flexible. However, it is possible that a determination in respect of Scenario 2 may not be consistent with the research funders grant conditions. Certain of these funders have agreed that where they provide grants for research projects within Scenario 2, they will waive the Intellectual Property provisions of their standard grant terms to the extent they are inconsistent with the Intellectual Property arrangements set out in this Annex 2. Researchers should confirm the position with relevant person within the funder concerned.
- 8.3 Where complex funding arrangements involving multiple funders are envisaged, researchers should discuss these in advance with Genomics England

9. Standard Form Agreements

- 9.1 Genomics England intends in due course to develop standard form agreements (i) for use when licensing out Project IP; (ii) for providing access to the Project Dataset, Genomics England Platform and Genomics England Knowledgebase; and (iii) to govern research collaborations in which Genomics England or the GeCIP are participating, in each case once it has practical experience of the issues reflected in this Policy.
- 9.2 It is envisaged that the standard form agreements covering research collaborations will be based upon existing model agreements such as the Lambert Agreements for pre-clinical research (see <https://www.gov.uk/guidance/university-and-business-collaboration-agreements-lambert-toolkit>), and for clinical research the Model Agreement for Non-Commercial Research in the Health Service (see <http://www.ukcrc.org/regulation-governance/model-agreements/mnca/>).
- 9.3 Where a third party wishes to collaborate with Genomics England or the GeCIP to carry out a research project using the Genomics England Resources, Genomics England will take a flexible approach on which model agreement is used to prepare the research collaboration agreement, but considers that the model agreements referred to above would form a good basis for preparing such agreements.

10. Definitions for Annex 2

GeCIP	the Genomics England Clinical Interpretation Partnership which is the collective term for the community of individual researchers, NHS
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clinical disease experts and NHS healthcare professional and trainees who are given free access to the Project Dataset for the purposes of carrying out research and improving the understanding and practice of clinical genomics.

Genomics England	Genomics England Limited, a limited liability company incorporated in England under company registration number 08493132 whose registered office is at Dawson Hall, Charterhouse Square, London, EC1M 6BQ.
Genomics England Knowledgebase	the database created by or on behalf of Genomics England containing (i) the knowledge and discoveries resulting from the Project and (ii) public knowledge, around the links between phenotype, disease, genes and variants.
Genomics England Platform	the systems and infrastructure developed by or on behalf of Genomics England to facilitate the Project, including without limitation Genomics England's data centre, the software applications and tools through which the Project Dataset, the Project Results and the Genomics England Knowledgebase can be accessed and analysed.
Genomics England Publication Policy	Genomics England's policy regarding the publication of Project Results as amended and/or updated from time to time and made available at www.genomicsengland.co.uk .
Genomics England Resources	the Project Dataset, the Genomics England Knowledgebase, the Genomics England Platform and the Project Results held by Genomics England.
Intellectual Property	patents, any extensions of the exclusivity granted in connection with patents, petty patents, utility models, registered designs, trade marks, service marks, applications for any of the foregoing (including, but not limited to, continuations, continuations-in-part and divisional applications), the right to apply for and be granted any of the foregoing, rights in inventions, trade names, business names, brand names, get-up, logos, domain names and URLs, copyrights, design rights, semiconductor topography rights, database rights, publication rights, performance rights, rights in know-how, trade secrets and confidential information and all other forms of intellectual property right having equivalent or similar effect to any of the foregoing which may exist anywhere in the world.
Policy	the Genomics England Intellectual Property Policy as amended and/or updated from time to time by Genomics England.
Project	the 100,000 Genomes Project, a programme of whole genome sequencing announced by the then 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.

Project Aims	has the meaning given in section 1.1 of the main body of the Policy.
Project Dataset	any data created or derived in the course of carrying out the Project including genome sequences and clinical data from NHS patients and family members of NHS patients that participate in the Project.
Project IP	Intellectual Property that may subsist in the Project Dataset or the Project Results or is registered or applied for in respect of the Project Dataset or the Project Results.
Project Results	any innovations, inventions, discoveries, data, developments, know-how, ideas, techniques, software, algorithms, results and other outputs developed by any organisation in the course of carrying out the Project or through the use of the Project Dataset, but excluding the Project Dataset itself.
Scenario 1	research which is carried out entirely within the GeCIP without the use of substantial assets owned by third parties and where there is no material commercial involvement, and research carried out by the GeCIP where no alternative terms have been agreed by Genomics England.
Scenario 2	research which is carried out (i) partly within and partly outside the GeCIP; and (ii) by the GeCIP using substantial assets not owned by Genomics England, or a combination of (i) and (ii), in each case where there is no material commercial involvement.
Scenario 3	research which makes use of the Genomics England Resources where there is a material commercial involvement.

Annex 3

Scenario 3

Genomics England's Intellectual Property Policy for Research with a Material Commercial Involvement

1. Introduction

- 1.1 This Annex sets out Genomics England's policy for Intellectual Property arising from research which makes use of the Genomics England Resources where there is a

material commercial involvement. Such a scenario is referred to in this Policy as “Scenario 3”.

- 1.2 The capitalised terms used in this Annex have the meanings given in section 11 of this Annex.

2. Research with a material commercial involvement

- 2.1 Research with a material commercial involvement may take a number of different forms. Examples of research with a material commercial involvement include:-

- 2.1.1 where a commercial entity is granted access to the Genomics England Resources in order to enable it to carry out research of its own;

- 2.1.2 collaborations where a commercial entity is granted access to the Genomics England Resources in order to enable it to carry out research in collaboration with other commercial entities or academic entities, including Genomics England or GeCIP Members (any such GeCIP Member collaborating with a commercial entity will be doing so independently and not in his or her capacity as a GeCIP Member);

- 2.1.3 clinical trials with a commercial sponsor which make use of the Genomics England Resources; and

- 2.1.4 academic led industry partnerships which make use of the Genomics England Resources.

3. Access to the Genomics England Resources for preliminary review

- 3.1 Before deciding whether to carry out research that will make use of the Genomics England Resources, researchers may wish to review the Genomics England Resources to check their extent and attributes in order to assess whether they would be of assistance in the research project. Subject to approval by the Access Review Committee, Genomics England will offer researchers access to the Genomics England Resources for the sole purpose of enabling them to assess the extent and attributes of the Genomics England Resources in order to assess whether they would be of assistance in the research project. Those granted access on this basis must not use the Genomics England Resources for research.

4. Access to use the Genomics England Resources for research

- 4.1 Genomics England will license access to or use of the Genomics England Resources to appropriate commercial entities for research purposes subject to such research being approved by the Access Review Committee in accordance with the 100,000 Genomes Project Protocol and the Genomics England IG Data Access and Acceptable Uses Policy.

- 4.2 Genomics England will apply a fee for service model for commercial entities. It is noted that setting fair and reasonable financial terms is difficult, particularly at a time when the nature and value of the product or service that may arise out of the research is not known. However, it is anticipated that within a fee for service regime, there will be a spectrum of charging models (upfront/royalty/revenue share) depending on how the Intellectual Property arising out of such research is to be owned (e.g. by Genomics England or by the commercial party or jointly owned by Genomics England and the commercial party) and if owned by the commercial party, whether Genomics England and/or the NHS will have any licence under the Intellectual Property rights or preferential pricing. In general, the wider the rights that are sought by the commercial party, the higher the charge will be (commensurate with ensuring that the data is widely used).
- 4.3 It is important that any fees for access to or use of the Genomics England Resources, whether charged upfront or in the form of royalties or revenue share for downstream products and services, do not result in a significant proportion of relevant researchers in commercial organisations deciding not to access the Genomics England Resources. This should be balanced with the benefits of capitalising on the large public investment in the Project, and seeking a reasonable financial return for the UK Government which could be re-invested to further the Project Aims. However, income generation is not a primary goal of Genomics England and, in the context of the Project Aim “Stimulating and enhancing UK industry and investment”, generation of revenue is less important than the stimulation of UK industry and investment.

5. Ownership of Intellectual Property

- 5.1 Genomics England takes a very flexible approach as to how Intellectual Property arising out of commercial use of the Genomics England Resources should be dealt with. The appropriate basis on which to allocate the ownership of such Intellectual Property will depend upon the nature and circumstances of the research and will take into account various factors including:-
- 5.1.1 the relative value of the contributions made by the Genomics England Resources, Genomics England personnel and the other participants in the research;
 - 5.1.2 the extent to which the results of the research are agreed to be incorporated into the Project Dataset, Genomics England Knowledgebase and/or Genomics England Platform;
 - 5.1.3 the scientific importance of the research; and
 - 5.1.4 the likelihood of a downstream benefit to patients.
- 5.2 Ownership of Intellectual Property arising out of research collaborations can be allocated in one or more of the ways set out below:-
- 5.2.1 one party can own all of the arising Intellectual Property and grant the other collaborators appropriate licences;

- 5.2.2 all of the arising Intellectual Property can be jointly owned by the collaborators;
 - 5.2.3 each party can own the arising Intellectual Property that its personnel generate. Where arising Intellectual Property is generated jointly (e.g. where employees of two or more collaborators are inventors on the same patent) then that arising Intellectual Property could be jointly owned or allocated in another way;
 - 5.2.4 ownership of arising Intellectual Property can be allocated according to the technical field it falls into. For example, in a collaboration between a pharmaceutical company and developer of inhalation devices to develop a new asthma product, the parties might agree that pharmaceutical company will own any arising Intellectual Property that relates primarily to pharmaceutical compound and the inhaler company will own any arising Intellectual Property that relates primarily to the inhaler device. Any arising Intellectual Property that relates to both technical fields could be jointly owned or allocated in another way; or
 - 5.2.5 ownership of arising Intellectual Property can be allocated according to whether it constitutes an improvement to a party's background Intellectual Property. In cases where arising Intellectual Property does not represent an improvement to any party's background or constitutes an improvement to more than one party's background then that item of arising Intellectual Property could be jointly owned or allocated in another way.
- 5.3 In general, if items (such as data, software, results or information) resulting from the research are to be incorporated into the Genomics England Platform, Project Dataset and/or Genomics England Knowledgebase, Genomics England would prefer to own the rights in such items. This is particularly the case (i) where as part of the research, Genomics England (or its sequencing provider) is generating whole genome sequences that are to become part of the Project Dataset and (ii) where the research gives rise to improvements that are specific to the Genomics England Platform (e.g. improved workflow procedures). However, in other cases, Genomics England will consider other arrangements such as co-ownership or a licence meeting the licence requirements set out in section 8 below.
- 5.4 As a general rule, Genomics England would wish to avoid joint ownership of results but may consider it in particular circumstances where joint ownership would be appropriate given the interests of Genomics England and any other participants in the research.
- 5.5 In general, Genomics England would not seek to acquire ownership in any Intellectual Property developed by collaborators outside a research collaboration unless, in exceptional circumstances, it is agreed that certain whole genome sequences contributed by a collaborator are to be incorporated into the Project Dataset.

- 5.6 Other considerations that may influence Genomics England’s approach to the allocation of Intellectual Property ownership are as follows. These are intended to be for guidance purposes only, and Genomics England is willing to discuss the Intellectual Property ownership position on a case by case basis:-
- 5.6.1 the relative importance/value of the contribution of the Genomics England Resources and Genomics England to the research as compared with the contributions being made by other parties. The greater the relative contribution of the Genomics England Resources and Genomics England, the more likely it is that Genomics England would wish to have ownership of the results;
 - 5.6.2 the extent to which the results of work carried out by Genomics England are severable from the results from the rest of the research. If Genomics England’s contribution to the research is relatively discrete such that Genomics England could own the rights arising out of its contribution to the research then it may be appropriate for Genomics England to own the results of such work;
 - 5.6.3 which party is best placed to ensure the results of the research are made available and utilised for the public benefit; and
 - 5.6.4 the extent to which payment is being made to Genomics England for access to or use of the Genomics England Resources.

6. Patenting Inventions in the Project Results

- 6.1 Regardless of which party owns the Project IP, Genomics England wishes to ensure that the patenting of inventions arising out of any projects which make use of the Genomics England Resources and any access to or use of the Genomics England Resources is appropriate and socially responsible. By way of example, Genomics England will not file patent applications for inventions arising out of the Project Results with claims:-
- 6.1.1 for isolated gene sequences containing variations;
 - 6.1.2 that are marginal;
 - 6.1.3 that are overly broad, going beyond the contribution of invention to the art;
 - 6.1.4 for hypothetical products or methods that have not been developed, unless there is a clear view as to how the product or method might be made to work and/or the patentee has a reasonable expectation that further data will be obtained to support the claims; or
 - 6.1.5 where the public interest would be best served by free and unrestricted use of the invention.

6.2 However, the principles set out above will be applied flexibly by Genomics England depending on the nature and circumstances of the research arrangement. For example, Genomics England will take into account various factors including: (i) the relative value of the contributions made by the Genomics England Resources, Genomics England personnel and the other participants in the research; (ii) the extent to which the results of the research are agreed to be incorporated into the Project Dataset, Genomics England Knowledgebase and/or Genomics England Platform; (iii) the scientific importance of the research; and (iv) the likelihood of a downstream benefit to patients.

7. Benefits for the NHS

7.1 Where it is agreed that a commercial entity should own Intellectual Property arising from research involving access to/use of the Genomics England Resources, Genomics England is interested in exploring the access which the NHS could have to such Intellectual Property should the NHS seek such access, and on what terms. In particular:-

7.1.1 where Genomics England grants rights to access or use the Genomics England Resources for research, Genomics England will wish to ensure that the NHS can have access on fair and reasonable terms to the results derived from such research and if applicable to use such results in the treatment of NHS patients;

7.1.2 where Genomics England enters into a collaboration that makes use of the Genomics England Resources, Genomics England will wish to ensure that the NHS can have access on fair and reasonable terms to the results derived from such collaboration and if applicable to use such results in the treatment of NHS patients;

7.1.3 if the use of the Genomics England Resources, or the results of research that makes use of the Genomics England Resources, play a significant part in the development of a product or service, then Genomics England will wish to ensure that the financial terms upon which the product or service is made available to the NHS reflect the contribution to the development of the product or service of the Genomics England Resources; and

7.1.4 if a new product or service is developed using the Genomics England Resources or the results of research that makes use of the Genomics England Resources, and such new product or service is trialled by the NHS then where appropriate, Genomics England will wish to ensure that the NHS can receive the new product or service at preferential prices once approved.

8. Licence Requirements – Intellectual Property licensed to Genomics England

8.1 If Intellectual Property arising out of access to or use of the Genomics England Resources is to be owned by a commercial entity, and the parties have agreed that such Intellectual Property should be licensed to Genomics England, Genomics England has certain licensing preferences as set out in this section 8.

- 8.2 If items (such as data, software, results or information) are incorporated into the Genomics England Resources and are licensed to Genomics England, Genomics England would wish to avoid having inconsistent licence terms for the different items. For example, if 50 different collections of phenotypic data are licensed to Genomics England are incorporated into the Project Dataset and/or Genomics England Knowledgebase, Genomics England would not wish to have 50 different, inconsistent sets of licence terms each with their own restrictions on the use of each collection as this would make it impractical for Genomics England to make the collections available to users of the Genomics England Resources.
- 8.3 Accordingly, if items (such as data, software, results or information) are to be incorporated into the Genomics England Resources and Genomics England is to receive a licence in respect of such items, then Genomics England prefers that the licence meets the following requirements:-
- 8.3.1 the licence may be exclusive, non-exclusive or sole;
 - 8.3.2 a one-off up-front licence fee could be paid (if agreed by Genomics England) but otherwise the licence should be royalty-free;
 - 8.3.3 the licence should be perpetual and irrevocable as it could be difficult to track some licensed items once incorporated into the Genomics England Resources and subsequently remove them once the licence had come to an end. Also from a scientific perspective it would be undesirable to delete data upon which important findings had been made;
 - 8.3.4 the licence should permit the licensed items to be kept by or on behalf of Genomics England at least in the UK;
 - 8.3.5 the licence should permit derivatives of the licensed items to be made and the licensed items to be incorporated in other works;
 - 8.3.6 the licence should permit use of the licensed items as part of the Genomics England Resources by Genomics England and any persons authorised by Genomics England anywhere in the world for healthcare and other purposes consistent with the Project Aims;
 - 8.3.7 the licence should be assignable to any successor in function of Genomics England; and
 - 8.3.8 the licence should permit Genomics England to grant sub-licences.

9. Standard Form Agreements

- 9.1 Genomics England intends in due course to develop standard form agreements (i) for use when licensing out Project IP; (ii) for providing access to the Project Dataset, Genomics England Platform and Genomics England Knowledgebase; and (iii) to govern research collaborations in which Genomics England or the GeCIP are participating, in each case once it has practical experience of the issues reflected in this Policy. It is

envisaged that the standard form agreements covering research collaborations will be based upon existing model agreements such as the Lambert Agreements for pre-clinical research (see <https://www.gov.uk/guidance/university-and-business-collaboration-agreements-lambert-toolkit>), the model Clinical Trial Agreement (mCTA) and model Clinical Research Organisation Clinical Trial Agreement (CRO mCTA) for clinical trials, and the model Industry Collaborative Research Agreement (mICRA) for collaborative clinical research (see <https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/standard-research-agreements.htm>).

- 9.2 Where a third party wishes to carry out a research project using the Genomics England Resources, Genomics England will take a flexible approach on which template is used to prepare the relevant agreement, but suggests that the standard form agreements set out above would form a good basis for preparing such agreements.

10. Publication

- 10.1 It is Genomics England's objective that the findings of any research arising out of the use of the Genomics England Resources, including any findings which demonstrate the utility of genomics in the treatment of patients, are published.

- 10.2 However, where commercial entities carry out research using the Genomics England Resources, Genomics England recognises the need to be flexible around publication and will take into account various factors including: (i) the relative value of the contributions made by the Genomics England Resources, Genomics England personnel and the other participants in the research; (ii) the extent to which the results of the research are agreed to be incorporated into the Project Dataset, Genomics England Knowledgebase and/or Genomics England Platform; (iii) the scientific importance of the research; and (iv) the likelihood of a downstream benefit to patients.

11. Definitions for Annex 3

100,000 Genomes Project Protocol the 100,000 Genomes Project Protocol sets out the protocol for the development, delivery, and operation of the Project and also details the patient and clinical benefits, the scientific and transformational objectives, the implementation strategy, as well as the ethical and governance frameworks required for the Project as updated from time to time. See www.genomicsengland.co.uk for further details.

Access Review Committee the committee that carries out independent examinations of requests for access to the Project Dataset, with regards to the acceptable uses of the Project Dataset as outlined in the 100,000 Genomes Project Protocol and the Genomics England IG Data Access and Acceptable Uses Policy. The Access Review Committee decides whether to approve, decline, or amend requests for access to the Project Dataset. See www.genomicsengland.co.uk for further details.

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 Project Dataset for the purposes of carrying out research and improving the understanding and practice of clinical genomics.
GeCIP Member	an individual admitted to the membership of the GeCIP in accordance with the GeCIP Rules.
GeCIP Rules	the rules governing the GeCIP as amended and/or updated from time to time and made available at https://www.genomicsengland.co.uk/about-gecip/for-gecip-members/documents/ .
Genomics England	Genomics England Limited, a limited liability company incorporated in England under company registration number 08493132 whose registered office is at Dawson Hall, Charterhouse Square, London, EC1M 6BQ.
Genomics England IG Data Access and Acceptable Uses Policy	Genomics England’s policy regarding the governance, access and acceptable use of the Project Dataset as updated from time to time. See https://www.genomicsengland.co.uk/the-100000-genomes-project/data/ for further details.
Genomics England Knowledgebase	the database created by or on behalf of Genomics England containing (i) the knowledge and discoveries resulting from the Project and (ii) public knowledge, around the links between phenotype, disease, genes and variants.
Genomics England Platform	the systems and infrastructure developed by or on behalf of Genomics England to facilitate the Project, including without limitation Genomics England’s data centre, the software applications and tools through which the Project Dataset, the Project Results and the Genomics England Knowledgebase can be accessed and analysed.
Genomics England Resources	the Project Dataset, the Genomics England Knowledgebase, the Genomics England Platform and the Project Results held by Genomics England.
Intellectual Property	patents, any extensions of the exclusivity granted in connection with patents, petty patents, utility models, registered designs, trade marks, service marks, applications for any of the foregoing (including, but not limited to, continuations, continuations-in-part and divisional applications), the right to apply for and be granted any of the foregoing, rights in inventions, trade names, business names, brand names, get-up, logos, domain names and URLs, copyrights, design

rights, semiconductor topography rights, database rights, publication rights, performance rights, rights in know-how, trade secrets and confidential information and all other forms of intellectual property right having equivalent or similar effect to any of the foregoing which may exist anywhere in the world.

Policy	the Genomics England Intellectual Property Policy as amended and/or updated from time to time by Genomics England.
Project Aims	has the meaning given in section 1.1 of the main body of the Policy.
Project Dataset	any data created or derived in the course of carrying out the Project including genome sequences and clinical data from NHS patients and family members of NHS patients that participate in the Project.
Project IP	Intellectual Property that may subsist in the Project Dataset or the Project Results or is registered or applied for in respect of the Project Dataset or the Project Results.
Project Results	any innovations, inventions, discoveries, data, developments, know-how, ideas, techniques, software, algorithms, results and other outputs developed by any organisation in the course of carrying out the Project or through the use of the Project Dataset, but excluding the Project Dataset itself.
Scenario 1	research which is carried out entirely within the GeCIP without the use of substantial assets owned by third parties and where there is no material commercial involvement, and research carried out by the GeCIP where no alternative terms have been agreed by Genomics England.
Scenario 2	research which is carried out (i) partly within and partly outside the GeCIP; and (ii) by the GeCIP using substantial assets not owned by Genomics England, or a combination of (i) and (ii), in each case where there is no material commercial involvement.
Scenario 3	research which makes use of the Genomics England Resources where there is a material commercial involvement.