Genomics England Intellectual Property Policy

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Contents

1 Introduction

1.1 Genomics England was established as a company in 2013 to deliver the 100,000 Genomes Project (the Project, 100KGP). The Project has four main aims (the Project Aims):

1.1.1 to bring benefit to NHS patients;

1.1.2 to create an ethical and transparent programme based on consent;

1.1.3 to enable new scientific discovery and medical insights; and

1.1.4 to kick start the development of a UK genomics industry.

1.2 This document (Intellectual Property Policy) sets out Genomics England's policy for:

1.2.1 the ownership of intellectual property within the GeCIP;

1.2.2 the protection, management and commercialisation of patents and other intellectual property arising out of the 100,000 Genomes Project including the GeCIP; and

1.2.3 the basis on which Genomics England will grant access to the dataset to GeCIP Members and Genomic England's licensing policy with regard to GeCIP Members.

1.3 This Intellectual Property Policy is part of a suite of documents, which deal with intellectual property (IP) within the Project. These are:

1.3.1 *The DH Intellectual Property Principles for the 100, 000 Genomes Project* (IP Principles): this sets out some high level principles that all the other documents must be compatible with insofar as IP is concerned. In the case of any inconsistency between the IP Principles and the other documents the Intellectual Property Principles will prevail;

1.3.2 *The GeCIP Rules*: section 10 sets out the IP rules that apply where research is conducted by GeCIP Members entirely within the GeCIP not using assets owned by third parties (described as Scenario 1 in this document) and no further agreement has been agreed between Genomics England and the relevant domain. Ownership of IP rights arising out of access to the Project data and/or know-how:

1.3.2.1 in circumstances in which research is carried out entirely within the GeCIP but using substantive asset(s) that are not owned by Genomics England (Scenario 2);

1.3.2.2 in circumstances in which a research collaboration is carried out partly within the GeCIP and partly outside the GeCIP and there is no material commercial involvement in the collaboration (Scenario 3); or

1.3.2.3 where there is material commercial involvement in the research collaboration,

will be negotiable on the basis set out in the Annex;

1.3.3 *The Genomics England Publication Policy*: this sets out the rules governing publications arising from the Project.

1.3.4 *The Data Sharing Agreement* between Genomics England each NHS Trust: this sets out the licences between the relevant Trust and Genomics England in respect of the project data. 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 members of GeCIP.

1.4 The IP Policy, the GeCIP Rules and the Publication Policy have been approved by the Genomics England Board and the GeCIP Board, which comprises MRC, Wellcome Trust and CRUK. 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 commits to a review of the IP Policy, GeCIP Rules and the Publication Policy in the light of experience at least on annual basis.

2 Ownership of IP within the GeCIP

2.1 Genomics England should own and control any IP rights that arise out of work carried out by the GeCIP in circumstances in which research is carried out entirely within the GeCIP not using assets (eg data, software, results or information) owned by third parties (other situations are described in the Annex). The reasons for this include:

2.1.1 The 100,000 Genomes Project represents a significant investment by the Government;

2.1.2 The Government wishes to avoid the fragmentation of intellectual property: with individual GeCIP members from so many different organisations collaborating on the Project, allocating ownership of IP rights according to who did what would create an immensely complex, bureaucratic and potentially contentious IP ownership structure;

2.1.3 The Government does not want the allocation of intellectual property rights between multiple organisations to become a hindrance to effective co-operation;

2.1.4 Control of IP 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;

2.1.5 Industry has made it clear that they would rather deal with a single IP owner rather than multiple owners; and

2.1.6 The Government wishes to ensure that a socially responsible patent strategy that supports the Project's aims is pursued both in terms of encouraging the development of new products and services and supporting cases where high investment is needed and a single owner supports this approach.

2.2 Genomics England believes that approach 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 IP between multiple public sector bodies as is customarily the case.

2.3 For clarity, 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 IP which subsists in, claims and/or covers genome sequences.

3 Patents

3.1 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 where such inventions:-

3.1.1 support Genomics England's primary aims;

3.1.2 constitute a significant development;

3.1.3 would give rise to strong patents; and

3.1.4 have significant commercial potential.

3.2 Genomics England will not file patent applications with claims:-

3.2.1 for isolated gene sequences containing variations;

3.2.2 that are marginal;

3.2.3 that are overly broad, going beyond the contribution of invention to the art;

3.2.4 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

3.2.5 where Genomics England considers the public interest would be best served by publication and subsequent market competition for supply.

3.3 If Genomics England decides not to file patent application(s) for an invention that arises out of work carried out by the GeCIP:-

3.3.1 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; and

3.3.2 Genomics England will ensure that the invention is published so as to prevent others from patenting the invention.

3.4 Where Genomics England decides to file patent applications for an invention, Genomics England will endeavour to obtain patent protection in the major markets (including Europe and the United States) but 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 Genomics England's patent portfolio.

3.5 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.

3.6 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 be:-

3.6.1 time limited (e.g. to the duration of the licensed patents or shorter);

3.6.2 limited to particular field(s) or purpose(s) where appropriate;

3.6.3 limited to a particular territory where appropriate;

3.6.4 provide Genomics England with a veto on enforcement of the licensed patents; and

3.6.5 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.

3.7 There may be occasions when Genomics England may be asked to sell rather than license a patent 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.

3.8 Genomics England will endeavour to negotiate a favourable regime for the NHS when granting patent licences. In particular, if a product or service is developed using inventions, data, know-how and/or discoveries that arose out of the Project, then the financial terms upon which the product or service is made available to the NHS should reflect the contribution of such inventions, data, know-how and/or discoveries to the development of the product or service. Genomics England's patent licences could also require licensees to sublicense the patent to the NHS on fair and reasonable terms, where use is sought by the NHS. In some cases, it may be appropriate to enter into an arrangement with a licensee whereby a new product or service developed using inventions, data, know-how and/or discoveries that arose out of the Project is trialled by the NHS and in return the NHS receives the new product or service at preferential prices once approved.

3.9 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.

4 Other IP

4.1 The principal other items that Genomics England will license access to are the raw data and knowledge base arising out of the Project and stored in its data centre. If tools/algorithms/software are developed in the course of the Project and Genomics England owns the rights in them, Genomics England may decide to licence access to them.

4.2 When licensing access to the raw data and knowledge base and these other items to commercial entities, Genomics England will have regard to negotiating licence conditions which include a favourable regime for the NHS for any downstream inventions developed by the licensee as a result of the access. To the extent reasonably possible, the financial terms upon which a downstream product or service is made available to the NHS should reflect the contribution of such access to the development of the product or service, as described above for patent licences (paragraph 3.8). Again, Genomics England's licences to the raw data and knowledge base could require licensees to licence any downstream products or services

developed by the licensee to the NHS on fair and reasonable terms, where use is sought by the NHS.

4.3 Genomics England will apply a fee for service model to licensing access to its data and knowledgebase rather than an open access 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 access is not known. The outcomes of the GENE consortium industry trial will assist Genomics England in determining which industry engagement strategies are viable. However, it is anticipated that within a fee for service regime, there will be a spectrum of charging models (upfront/royalty) depending on how the IP rights arising out of such access are to be owned (e.g. by Genomics England or by the licensee or jointly owned by Genomics England and the licensee) and if owned by the licensee, whether Genomics England and/or the NHS will have any licence under the IP rights or preferential pricing. In general, the wider the rights that are sought by the licensee, the higher the charge will be (commensurate with ensuring that the data is widely used).

4.4 It is important that any fees for access to the data and knowledgebase, whether charged upfront or in the form of royalties for downstream products and services, do not result in a significant proportion of relevant researchers in commercial organisations deciding not to access the data and knowledgebase. This should be balanced with the benefits of capitalising on the large public investment in the Project, and seeking a reasonable financial return for government which could be re-invested to further the Project goals. However, income generation is not a primary goal of the Project and in the context of the fourth project aim (to kick start the development of a UK genomics industry), generation of revenue is less important than the generation of industrial activity.

5 GeCIP – access and licensing requirements

5.1 Members of the GeCIP will be given access to the Genomics England Dataset and the Genomics England Knowledgebase free of charge. There will also be a nine month moratorium regarding data pertaining to a Domain to allow publication in accordance with the GeCIP Rules and the Genomics England Publication Policy. However, as described above, the IP rights arising out of any work carried out by the GeCIP will be owned by Genomics England save as described in the Annex.

5.2 There is no preclusion to licensing of the rights to develop an invention to universities or the NHS employer of an invention and Genomics England will do so on terms that are fair and reasonable to the relevant university or NHS employer having regard to the contribution to the development of the intellectual property and the plans to commercialise the invention. It follows that where it is decided to charge at all, Genomics England is likely to favour royalties over upfront licence fees.

5.3 As a general policy:

5.3.1 licences granted by Genomics England over GeCIP results to GeCIP Institutions will be non-exclusive unless it would be in the public interest for an exclusive licence to be granted (which for example may be the case where commercialisation of the relevant GeCIP results would bring benefit to NHS patients but would require substantial investment which is unlikely to be obtained unless the investor has an exclusive licence); and

5.3.2 it is not envisaged that Genomics England will assign GeCIP results to GeCIP Institutions other than in exceptional circumstances (which for example may be the case where commercialisation of the GeCIP results 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 intellectual property).

5.4 If Genomics England agrees to grant a GeCIP Institution an exclusive licence or agrees to assign to the Institution any of the GeCIP results then Genomics England would seek to retain a right to use the relevant GeCIP results within the GeCIP Platform and for the Programme.

6 Resources and standard documents

6.1 Genomics England will build resources to support this policy. 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 Board/GENE/GeCIP.

6.2 Genomics England intends to develop standard documents in due course once it has practical experience of the issues reflected in this Policy, which shall set out terms applicable to the ownership and use of intellectual property.

7 Funding grants

7.1 It is understood that the GeCIP Funders standard grant terms are not consistent with Genomics England's IP policy in relation to Scenario 1. If there is an existing project that is already funded by a grant from a GeCIP Funder and part of that project is to be carried out subsequently within the GeCIP, Genomic England's initial view is that this would most likely to fall within Scenario 3. 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.

7.2 It is also understood that the case may arise where an individual or group of researchers are already in receipt of grant from a GeCIP Funder and that funding is not allocated for a particular project as such. If such an individual or group of researchers wished to become members of the GeCIP, it would first be necessary to resolve any

inconsistencies between the terms of the grant and the GeCIP Rules. The Domains within the GeCIP consist of individuals from a number of different institutions. It would not be workable to have inconsistent IP provisions applicable to different participants within the same Domain.

7.3 When the GeCIP Funders provide grants for research projects that will involve work being carried out by the GeCIP for the Project, Genomics England understands that the relevant GeCIP Funders will in most cases, and where possible, seek to waive the IP provisions of the Funder's standard grant terms, which are inconsistent with the IP arrangements set out in the GeCIP Rules and/or the GeCIP Participation Agreement, whereupon the IP provisions of the GeCIP Rules and/or the GeCIP Participation Agreement will prevail. Researchers should check with the relevant department within the GeCIP Funder concerned.

Annex

1. **Introduction**

1.1 The GeCIP Rules and GeCIP Participation Agreements contain provisions relating to the ownership and use of results and intellectual property arising from research carried out in circumstances in which research is carried out entirely within the GeCIP not using assets owned by third parties (in particular, when research is carried out using data obtained by Genomics England for the Project) or in circumstances where no alternative terms have been entered into with Genomics England. Such a scenario is referred to in this Policy as "Scenario 1".

1.2 This Annex applies to the two scenarios described below:

1.2.1 **Scenario 2:** circumstances in which research is carried out entirely within the GeCIP but using substantive asset(s) that are not owned by Genomics England.

1.2.2 **Scenario 3:** circumstances in which a research collaboration is carried out partly within the GeCIP and partly outside the GeCIP and there is no material commercial involvement in the collaboration.

2. **Scenario 2: Research carried out entirely within the GeCIP but using substantive asset(s) that are not owned by Genomics England**

2.1 Examples of substantive 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 not required to be provided under the GMC Contract as part of the Project.

2.2 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:-

2.2.1 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.

2.2.2 Save in the exceptional circumstances described in 2.2.3 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 GeCIP Platform (as defined in the Participation Agreement) or becomes part of the 100KGP dataset, Genomics England will look to receive a licence in relation to the external asset meeting the licence requirements set out in section 5.2 below. If the external asset is not going to be incorporated into the GeCIP Platform or become part of the 100KGP dataset, 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 the GeCIP Platform.

2.2.3 If the external asset is a collection of whole genome sequences that are to be incorporated into the dataset held on the GeCIP Platform or become part of the 100KGP 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 5.2 below.

2.2.4 If the results arising out of use or development of the external asset by the GeCIP are to be incorporated into the GeCIP Platform 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 5.2 below.

2.2.5 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 5.2 below if it would benefit the GeCIP Platform.

2.2.6 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 are to be incorporated into the 100KGP dataset but for contractual reasons the original owner needs to retain an ownership interest.

2.2.7 The publication of the GeCIP Results is subject to Genomics England's Publication Policy.

2.2.8 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 such improvements, developments and results.

2.3 By way of example only, the following circumstances would be within Scenario 2-

2.3.1 *The external asset is a software algorithm and the GeCIP work is to verify and improve the algorithm's performance using the Genomics England 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 Genomics England's dataset should be owned by Genomics England. Genomics England may also ask for a licence to use the improved software algorithm in the GeCIP Platform.*

2.3.2 *The external asset is a collection of whole genome sequences and associated phenotypic data for a cohort and it is intended that the collection should form part of the 100KGP dataset and be hosted on the GeCIP Platform and then be analysed in conjunction with the rest of the 100KGP dataset. As the external data will be integrated into the GeCIP Platform Genomics England 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.*

2.3.3 *Where the external asset is just an initial concept or idea and most of the substantive work will be carried out within the GeCIP using the GeCIP 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.*

3. Scenario 3: Research collaboration carried out partly within the GeCIP and partly outside the GeCIP

3.1 This section 3 sets out the approach Genomics England will take when deciding how ownership of intellectual property should be allocated where the work carried out within the GeCIP forms only part of the work being carried out as part of broader research collaboration and no commercial entities have a material involvement.

3.2 Ownership of intellectual property arising out of research collaborations can be allocated in one or more of the ways set out below:-

3.2.1 one party can own all of the arising intellectual property and grant the other collaborators appropriate licences;

3.2.2 all of the arising intellectual property can be jointly owned by the collaborators;

3.2.3 each party can own the arising IP 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;

3.2.4 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;

3.2.5 ownership of arising intellectual property can be allocated according to whether it constitutes an improvement to a parties 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.

3.3 The appropriate basis on which to allocate the ownership of arising intellectual property 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.

3.4 In general, if items (such as data, software, results or information) resulting from the collaboration are to be incorporated into the GeCIP Platform or become part of the 100KGP dataset, 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 contractor) are generating whole genome sequences that are to be incorporated into the GeCIP Platform or become part of the 100KGP dataset and (ii) where the collaboration gives rise to improvements that are specific to the GeCIP 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 5 below.

3.5 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.

3.6 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 GeCIP Platform.

3.7 Other considerations that may influence Genomics England's approach to the allocation of IP ownership for a particular collaboration are as follows:-

3.7.1 The relative importance/value of the contribution of the GeCIP Platform to the collaboration as compared with the contributions being made by the other collaborators. The greater the relative contribution of the GeCIP Platform to the collaboration, the more likely it is that Genomics England would wish to have ownership of the results.

3.7.2 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 discreet 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.

3.7.3 Which of the collaborators is best placed to ensure the results of the collaboration are made available and utilised for the public benefit.

3.7.4 As set out in Genomics England IP Policy October 2015, Genomics England wishes to ensure that there is a socially responsible patent strategy for inventions that arise out of the GeCIP Platform.

3.7.5 Genomics England would wish to ensure that the findings from the collaboration arising out of use of the GeCIP Platform are published (e.g. via scientific journals).

3.7.6 If in fact most of the work on the project is to be carried out by the GeCIP using the 100KGP dataset and only minor aspects are to be carried out outside the GeCIP then it may be more appropriate for ownership of IP to be allocated in accordance with the arrangements that apply to Scenario 1.

3.8 By way of example only, the following circumstances would be within Scenario 3:-

3.8.1 *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 GeCIP Platform. Other collaborators would then look to identify significant variations. In this case, Genomics England would be looking to (i) own the rights in the sequence data (ii) to have a licence meeting the requirements set out in section 5.2 below in relation to the phenotypic data and (ii) to include any results from the analysis in the Genomics England knowledgebase, and (iii) ensure that the results and the collaboration are published (e.g. via a scientific journal).*

3.8.2 *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 (i) that the results of the collaboration are published (e.g. via a scientific journal) and (ii) that Genomics England has a licence meeting the requirements set out section 5 to include the conclusions of the collaboration in the Genomics England knowledgebase. Genomics England would look to be remunerated by a royalty. If there was a material commercial involvement then section 4 would apply*.

4. Research collaborations with material commercial involvement

4.1 The GeCIP has been set up to carry out non-commercial academic research. It is not envisaged that the GeCIP would become involved in research collaborations where commercial entities have a material involvement. An example of a material involvement is where a commercial entity has a preferential right or option to patent or commercialise the results of the collaboration. An example of a non-material involvement might be where the 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. Clinical trials with a commercial sponsor and academic led industry partnerships are likely to be regarded as research collaborations with material commercial involvement and therefore considered under this section 4.

4.2 If the GeCIP Platform is to be used in a research collaboration where commercial entities have a material involvement, Genomics England would take much the same approach to the allocation of ownership of IP as is set out in section 3 for Scenario 3 although other allocations are possible. An additional consideration that Genomics England would take into account is the extent to which payment is being made to

Genomics England for use of the GeCIP Platform. Genomics England will be keen to encourage that (i) there be a socially responsible patent strategy for any inventions arising out of use of the GeCIP Platform (ii) the findings from the collaboration arising out of use of the GeCIP Platform are published (e.g. via scientific journals) and (iii) the interests of UK tax payers (who funded the GeCIP Platform) are fairly reflected in any financial arrangements.

4.3 Where a GeCIP Member, in addition to his or her GeCIP activities, is also involved in a research collaboration with material commercial involvement that makes use of the GeCIP Platform, 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 with material commercial involvement.

5. Licence Requirements

5.1 If items (such as data, software, results or information) that are integrated into the GeCIP Platform 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 GeCIP Platform, 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 GeCIP Platform.

5.2 Accordingly, if items (such as data, software, results or information) are to be incorporated into the GeCIP Platform and Genomics England is to receive a licence in respect of such items then the licence should meet all of the following requirements:

5.2.1 the licence may be exclusive, non-exclusive or sole;

5.2.2 a one-off up-front licence fee could be paid (if agreed by Genomics England) but otherwise the licence should be royalty free;

5.2.3 the licence should be perpetual and irrevocable as it could be difficult to track some licensed items once incorporated into the GeCIP Platform 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;

5.2.4 the licence should permit the licensed items to be kept by or on behalf of Genomics England at least in the UK;

5.2.5 the licence should permit derivatives of the licensed items to be made and the licensed items to be incorporated in other works;

5.2.6 the licence should permit use of the licensed items as part of the GeCIP Platform by Genomics England and any persons authorised by Genomics England anywhere in the world for healthcare and other purposes consistent with the principal aims of the 100,000 Genomes Project;

5.2.7 the licence should be assignable to any successor in function of Genomics England;

5.2.8 the licence should permit Genomics England to grant sub-licences.

5.3 If items (such as data, software, results or information) are to be incorporated into the GeCIP Platform and a licence meeting all the requirements set out in section 5.2 is not offered then Genomics England would be looking to obtain an ownership interest in the IP instead.

6. Determination and Consequences of the application of Scenarios 2 and 3

6.1. Introduction

6.1.1. All of the GeCIP research projects will generate IP 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 IP have substantial commercial potential. With this in mind, this section 6 provides guidance as to how Genomics England will consider research applications which are within Scenarios 2 and 3.

6.1.2. Where IP with substantial commercial potential does arise, Genomics England wishes to ensure that the institution that is best placed to protect, manage and secure commercialisation of that IP is given the rights to do so.

6.2. Completing the GeCIP Research Application

6.2.1. Those persons registering a project in the Genomics England research registry ("Lead Researchers") are reminded that each researcher who is a member of a Domain should declare in the relevant research application whether there is pre-existing funding in place that they wish to apply to the research project in question and/or if there is any background IP they wish to bring to the project. If no declaration of pre-existing funding or background IP is made in the relevant research application then Genomics England will proceed on the basis that there is no such funding or no such background IP. If Lead Researchers later become aware that existing funding or background IP are being employed, they will communicate with Genomics England to rectify their disclosure.

6.2.2. Lead Researchers should be aware that the GeCIP has been set up to carry out non-commercial research and so no commercial funding should be utilised in the research to be carried out under the research application. Researchers who wish to use commercial funding for research in the GeCIP should speak to the Commercial Lead within Genomics England before making the research application.

6.2.3. Where a researcher has in place a grant, sponsorship, endowment or other funding arrangement relating to the research project within such researcher's employing institution then this should be declared in the research application. If a researcher has such grant, sponsorship, endowment or other funding arrangement from a non-commercial source, that of itself will not be viewed by Genomics England as removing an application from Scenario 1.

6.2.4. To enable Genomics England to determine whether a research application is within Scenario 1, Scenario 2 or Scenario 3, each research application should also identify (i) any assets that do not form part of the GeCIP Platform and are not owned by Genomics England but which will be used to carry out the research (e.g. software, tissue samples, whole genome sequences, phenotypic data, genomic data and multiomic data not required to be provided under the GMC Contract as part of the 100KGP) and (ii) whether any of the research to be carried out under the research proposal will be carried out outside the GeCIP Platform. In each case, any such asset(s) not owned by Genomics England and/or research carried out outside the GeCIP will need to be considered to be material in the context of the research which is the subject of the research application to take the research application outside Scenario 1.

6.2.5. Where the Lead Researcher considers that Scenario 2 or 3 applies to the research application, the Lead Researcher may also indicate in the research application the Lead Researcher's preferred approach as regards the ownership and licencing of IP arising out of the research, after internal discussions with their research office and technology transfer offices.

6.3. **Non-commercial Funding**

6.3.1. Genomics England has agreed the Genomics England Intellectual Property Policy with Cancer Research UK ("CRUK"), the Medical Research Council ("MRC") and Wellcome Trust ("Wellcome"). Research applications that are solely funded by MRC and/or Wellcome will fall under Scenario 1.

6.3.2. Research applications supported by CRUK or other non-commercial funders with whom Genomics England has not yet agreed the Genomics England Intellectual Property Policy will fall under Scenarios 2, 3 or potentially under the scenario described in Section 4 of this Annex. If the support from other non-commercial funders is material to the research application, Genomics England

may seek to reach agreement on ownership and licencing of IP arising out of the research with that funder prior to the approval of the relevant research application.

6.3.3. Lead Researchers are advised to avoid complex funding arrangements involving multiple funders for a single research project. Genomics England is likely to reject such applications particularly where they appear constructed simply to avoid the conclusion that Scenario 1 applies.

6.4. **Genomics England Determination**

6.4.1. On receipt of a research application Genomics England will determine which Scenario Genomics England considers is applicable to the application and Genomics England's determination regarding ownership and licensing of IP arising out of the research and will notify the Lead Researcher of its determination.

6.4.2. If Genomics England determines that the research application is within Scenarios 2 or Scenario 3, Genomics England will write to the Lead Researcher and their respective university in the form of the letter set out at Appendix 2.

6.4.3. Should GeCIP members consider in due course that IP with substantial commercial potential is likely to arise from the research then it will be the responsibility of the researchers to notify the Office of the Genomics England Chief Scientist in writing in which event Genomics England will enter into an agreement with the relevant institutions to reflect its determination regarding ownership and licensing of such IP.

Appendix 1

Addition to GeCIP Research Application Form

This Form is to be completed by the Lead Researchers at application stage. In case the Lead Researchers become aware of any change in the information submitted, they should contact Genomics England to rectify it as soon as possible, and for Genomics England to review the new scenario.

Intellectual Property Requirements[1]
Relevant Scenario: Please explain which IP scenario (described in the Genomics England Intellectual Property Policy) best describes your research application: • Scenario 1: research is carried out entirely within the GeCIP Platform not using substantive assets owned by third parties (e.g. research is carried out on the GeCIP Platform using data obtained by Genomics England for the 100KGP) • Scenario 2: research is carried out entirely within the GeCIP Platform but using substantive asset(s) that are not owned by Genomics England (for example software, tissue samples, whole genome sequences, phenotypic data, genomic data and multiomic data not required to be provided under the GMC Contract as part of the 100KGP) • Scenario 3: a research collaboration is carried out partly within the GeCIP Platform and partly outside the GeCIP Platform and there is no material commercial involvement in the collaboration For the purposes of this application form, the GeCIP Platform means Genomics England's IT systems used to store, provide access to and facilitate analysis of the dataset of whole genome sequences arising out of the 100,000 Genomes Project, additional data and annotations, including the analytical tools and GeCIP knowledge base made available through Genomics England's IT systems.
Scenario 2: Please provide the following information: • list any funding including any grant, sponsorship, endowment or other funding arrangement that will be utilised in the research project; • if the terms applicable to such funding include provisions that affect ownership and/or licensing of results and/or IP arising out of research project, attach a copy of

[1] Please refer to the Annex to the Intellectual Property Policy.

such terms;

- identify if there are researchers outside GeCIP involved in the conduct of the research project;
- describe the substantive assets (other than the GeCIP Platform) that will be used in the research project;
- identify if there are third parties involved in the funding;
- identify the owner(s) of such asset(s);
- agreements governing use of the asset(s);
- **optional at the application stage and to be confirmed with the Lead Researchers' Institution:**
    - set out the proposed ownership of IP in improvements to such asset(s);
    - set out the proposed ownership of IP in results derived from use of such asset(s);
    - set out the proposed licensing of IP in improvements to such asset(s) and in the results derived from use of such asset(s);
    - set out any proposed royalties payable to Genomics England in relation to commercialisation of (i) improvements to such asset(s), and (ii) in results derived from use of such asset(s); and
    - summarise why you consider the arrangements set out above are reasonable in the circumstances.

Scenario 3:

Please provide the following information:

- describe the overall arrangements for the research project;
- identify the individual researchers (other than GeCIP) who will participate in the research project;
- identify the employers of such individual researchers;
- list any external funding including any grant, sponsorship, endowment or other funding arrangement utilised in the research project;

- if the terms applicable to such funding include provisions that affect ownership and/or licensing of results and/or IP arising out of research project, attach a copy of such provisions;
- provide a copy of any agreements or where confidential a summary of the relevant terms of any agreements setting out the arrangements that are applicable to the research project;
- describe the aspects of the research project that will be carried out using the GeCIP Platform;
- describe the aspects of the research project that will be carried out outside the GeCIP Platform;
- describe the material assets (other than the GeCIP Platform) that will be used in the research project;
- **optional at the application stage and to be confirmed with the Lead Researchers' Institution:**
    - set out the proposed ownership of IP arising out of the research project (including improvements to the asset(s));
    - set out the proposed licensing of IP arising out of the research project;
    - set out any proposed royalties payable to Genomics England in relation to commercialisation of IP arising out of the research project (including improvements to the asset(s)); and
    - summarise why you consider the arrangements set out above are reasonable in the circumstances.

Appendix 2

Letter to Lead Researcher

[Name]
c/o QMUL
Dawson Hall
Charterhouse Square
London EC1M 6BQ
0207 882 5922

[Lead Researcher]

[date]

Dear [Lead Researcher]

[Application] – Determination of Intellectual Property Issues

We refer to your application [reference][dated]. Having reviewed your application I have set out below our determination regarding ownership and licensing of results and intellectual property arising from the research project described in your application.

Applicable Scenario

The application referred to above falls under Scenario [2/3] as described in the Genomics England Intellectual Property Policy.

Ownership of IP

[***To be completed***]

Licensing Terms

[***To be completed***]

Royalties

[***To be completed***]

Further Written Agreement

It is agreed that in the event that the results and/or intellectual property arising out of the research project described in your application have substantial commercial potential, Genomics England and the institutions that employ the researchers in your Domain will enter into a formal agreement to implement the ownership and, licensing and royalty provisions outlined above.

If [***Insert name of institution***] is in agreement with the above please sign the enclosed copy of this letter where indicated and return it to me at the above address.

Yours sincerely,

[NAME]
[POSITION]
[email]

We agree to the above terms and conditions.

Signed by……..

Dated……..
For and on behalf of [*Insert name of institution*]