



Department  
of Health

# Intellectual Property Principles for 100,000 Genomes Project

## 1 Introduction

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

- to bring benefit to NHS patients
- to create an ethical and transparent programme based on consent
- to enable new scientific discovery and medical insights
- to kick start the development of a UK genomics industry

The Department of Health – with the Secretary of State for Health the sole shareholder in Genomics England – is the organisation responsible for funding and stewardship of the Project. The Department of Health should ensure that the Project's intellectual property (IP) policy (IP Policy) is designed in a way to enable the achievement of these four key aims.

The Ethics Working Group established by Chief Medical Officer in 2013 to advise on the priorities for the 100,000 Genomes Project stated:

*A clear policy will be required on commercialisation, detailing the extent of data sharing, IP, exclusivity, feedback requirements, how commercial researchers will interact with clinicians and academic researchers, and what oversight will be put in place to ensure that any commercialisation is in the public interest and brings benefits to the NHS.*

These IP Principles should be used to interpret and apply the IP Policy, related policies, access agreements and licences. These IP Principles and the IP Policy should be reviewed and updated as necessary at the completion of relevant interim Project milestones (including the conclusion of the industry trial) and before the Project ends in 2017, to ensure they remain consistent with the achievement of the Project Aims.

In this document the following terms have the following meanings:-

|                                |   |
|--------------------------------|---|
| <b>Access Review Committee</b> | An advisory committee to the Genomics England Board of which the Chair and members are independent of Genomics England. Membership is composed of at least two participant representatives. The role of this committee is to review requests to access data within the Project. |
| <b>Participants</b>            | NHS patients and family members of NHS patients that participate in the Project.  |
| <b>Project Data</b>            | Any data created or derived in the course of carrying out the Project including genome sequences and clinical data from Participants.   |
| <b>Project IP</b>              | Intellectual property rights that may subsist in the Project Data or the Project Results or are registered or applied for in respect of the Project Data 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 Data, but excluding the Project Data itself.

## 2 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 Data and any IP in the Project Data 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 Data 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 Data 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 Data, 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 Data 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 Data (for example, through appropriate in-licencing).
8. The IP Policy should foster collaborative approaches to accessing and working with the Project Data, 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.