
Lead Auditor
UK Biobank
Candidate Brief
July 2022

Introduction from UK Biobank's Principal Investigator/Chief Executive



Professor Sir Rory Collins

UK Biobank is scientifically unparalleled and arguably the UK's most significant scientific asset. With its unique combination of scale, depth, maturity and accessibility, more than 1,700 peer reviewed publications based on UK Biobank in 2021 alone, and an exponential increase in citations and patents, UK Biobank has

become the world's most important health resource.

Its great success is testament to a visionary collaboration between successive UK Governments and scientific research funders – most notably the MRC and Wellcome – who understood the significance of advances in genomics and that information from such a database could ultimately lead to improved diagnosis, treatment and prevention strategies for the most devastating diseases, benefiting millions of people in the UK and around the world.

Since inception, UK Biobank has also leveraged £227m of industry funding with increasing levels of interest in, and use of, UK Biobank by industry. UK Biobank is a major contributor to the advancement of modern medicine and treatment and has enabled many scientific discoveries that improve human health.

UK Biobank has a unique role to play in the Government's UK Life Sciences Vision, in both its Preconditions for Success and its Healthcare Missions, set out in June 2021. UK Biobank's role can be best understood both in terms of its ability to attract vital industry investment in UK Life Sciences and in enabling major scientific discoveries that improve public health.

The key focus of UK Biobank over the last five years has been on generating increasingly detailed genetic information on all 500,000 participants and making those data available to the international research community. The unprecedented scale, detail and quality of these data has enabled researchers to make unique discoveries about the relevance of genetics for disease.

For the next five years, our focus will shift to measuring the products of the genes. In particular, the levels of different proteins and metabolites in the blood, urine and saliva collected from participants more than ten years earlier. Completion of the initial whole body imaging of 100,000 participants, followed by repeat imaging of 60,000 of them, will add to the richness of the data available for studying biological changes that lead to the development of disease, or provide protection against it.

None of this would be possible without the altruism of the 500,000 British citizens who agreed to join the study some decades ago and the many tens of thousands of scientists around the world ensuring that their contributions deliver on the long-term vision of the funders to make improvements in human health and wellbeing that are of global significance.

Company Overview

UK Biobank is a uniquely detailed large-scale prospective study, containing genomic, lifestyle, imaging and health information from 500,000 UK participants. The resource is globally accessible to approved researchers to enable novel and important scientific discoveries that improve human health.

UK Biobank's database is unique, combining several powerful differentiators, including:

- scale (500,000 people);
- depth (detailed lifestyle information, genetic and other assay data, imaging data);
- maturity (large numbers of different health outcomes available for study, 15 years ahead of any comparable cohort study); and
- accessibility (with over 28,000 researchers worldwide already using the data).

Increasing awareness of UK Biobank is more important than ever as the database grows in value. With over 75% of all new researcher registrations coming from outside the UK, it truly is a global resource accessible to approved researchers undertaking health-related research.

UK Biobank is a distributed organisation, currently headquartered in Stockport, Greater Manchester, with four imaging centres delivering the world's largest multi-modal imaging study located in Stockport, Reading, Bristol and Newcastle. UK Biobank's epidemiological, health data teams and many of our systems are hosted at the Oxford Population Health (the Nuffield Department of Population Health, University of Oxford).

UK Research and Innovation have announced that subject to final approval, UK Biobank will receive an additional £128m of funding to support the next phase of our development. This transformative award will replace and enhance UK Biobank's infrastructure, creating a state-of-the-art facility in Manchester that will become the UK Biobank's headquarters from 2026.

UK Biobank's impact on research

With the addition of genetic sequencing data on a scale never seen before in health research, UK Biobank is one of the most significant resources for identifying target genes for drug discovery. Large scale genetic sequencing on the whole exome and whole genome of 500,000 participants is accelerating scientific discovery for human health. For example, scientists have identified rare protein-coding variants that have a large impact on complex traits, such as obesity. Individuals with a variant that suppresses protein production by the GPR75 gene expressed in the brain were observed to have significantly lower rates of BMI. The finding may lead to development of a drug that can inhibit GPR75 to offer a therapeutic strategy for treating obesity.

UK Biobank is also becoming increasingly important for the NHS and the public purse. Implementation of outputs derived from UK Biobank will result in significant savings of public expenditure, by improving prevention, early diagnosis and treatment, thereby improving population health and lowering NHS costs. For instance, the UK Biobank-derived polygenic risk score concept, allows a low-cost genotyping test to identify a substantial proportion of the population at high risk of one or more common conditions, such as heart disease, who could benefit from more effectively targeted prevention and screening strategies.

The unprecedented scale, detail and quality of UK Biobank's imaging project has enabled researchers to make unique discoveries about the development of many diseases in older age. These images are allowing scientists to study the impact of dementia risk factors on the brain and define early brain "signatures" of dementia that are providing clues to how cognitive decline and dementia start. When combined with the wealth of health data in UK Biobank, such as cognitive function tests, and genetics, this is allowing researchers the opportunity to spot dementia before symptoms appear.

A high degree of participant engagement within the cohort has enabled UK Biobank to play a vital role in helping to manage the global coronavirus pandemic. Surveillance studies during the COVID19 pandemic have increased researchers' understanding of the longer-term health impacts of coronavirus infection with over 237 COVID- related publications produced based on the UK Biobank resource.

Given the current pace of UK Biobank's development, coupled with the large increase in the number of researchers accessing the resource, there is likely to be an exponential growth in the impact of the discoveries that emerge that will be of global significance.

Overview of the Role

- Location: Park Square, 38 Bird Hall Lane, Cheadle Heath, Cheadle, SK3 0XN
- Working hours: 35 hours per week Monday – Friday
- Contract type: Permanent

To ensure through the method of auditing that UK Biobank is operating in a compliant manner, in line with governance and regulatory requirements both internally and externally. Seek to continually improve business processes for UK Biobank and our research community and to assure the effectiveness of controls, specifically relating to Quality and Information Security.

The post holder should engage with stakeholders at all levels to promote general good practice in all areas of compliance, maintaining an objective, impartial risk based approach to auditing.

UK Biobank promote onsite auditing to ensure transparency, so the post holder should expect to travel regularly, to all UK Biobank assessment centres and supplier sites where required. The role will also include a significant amount of virtual and desk based auditing, where appropriate.

Principal Duties & Responsibilities

This post holder will be responsible for the audit function within the organisation, ensuring end to end compliance with regulatory requirements, whilst encouraging and promoting UK Biobank's best practice culture.

Auditing

1. To manage and perform organisational wide internal audits across all UK Biobank sites to assure compliance against the requirements of ISO 9001, ISO 27001, ISO 20387 and additional standards deemed appropriate by the organization.
2. To manage and perform 2nd party audits on critical suppliers to assure supply chain quality management.
3. To work with the UK Biobank research community in a monitoring and measurement / engagement capacity, to provide guidance and assure best practice in terms of Quality and Information Security.
4. To act as UK Biobank's principle point of contact during regulatory assessments, for all matters relating to the audit function.

Documentation and Reporting

1. To own and maintain the audit policy and supporting documentation, ensuring the information is communicated with all stakeholders and remains up to date with regards to business and regulatory requirements.
2. To own, maintain and communicate a detailed audit schedule.
3. To document all findings and actions within the organisation's QMS software and communicate to interested parties.
4. To define and report against audit KPI's.
5. To report on the status of the audit schedule to key stakeholders.
6. To report findings to auditees and ensure a timely process for completion and close out of actions.
7. To report to the Head of Quality regularly on the status of the schedule and associated findings.

Person Specification

Essential

- Demonstrable experience in Quality and Information Security audit experience in Biobanking, Health Research or similar environment.
- Lead auditor trained in Quality and Information Security, or comparable/relevant training.
- To have experience of auditing against the requirements of ISO 9001 and ISO 27001 in the field of Biobanking, Health Research or a similar environment.
- Demonstrable ability to carry out an analytical, impartial and objective based approach to auditing.

- Ability to demonstrate strong ethics and integrity and sound judgement.
- Ability to demonstrate strong communication skills both written and verbal.
- To be personable and able to communicate with people at all levels, building good working relationships in a professional environment.
- Ability to travel regularly throughout the calendar year.
- To work effectively either alone or as part of a team.
- Proven administrative skills in a professional environment.

Desirable

- Educated to degree level within a relevant Scientific Discipline.
- Knowledge or experience of ISO 20387 International Standard for Biobanking.
- Knowledge or experience of GxP.
- Knowledge or experience of working with Quality software.
- Previous experience of working with or in line with other UKAS accreditations.

Salary and Employee Benefits

- Salary: £40,000 - £42,000 per annum depending on experience
- 26 Days Annual Leave (which increases with length of service) + Bank Holidays (including Christmas closure)
- USS salary sacrifice pension scheme (9.8% employee contribution & 21.6% employer contribution)
- Life Assurance Cover
- Enhanced maternity/paternity/adoption/shared parental leave
- Enhanced Compassionate Leave
- Enhanced Reserve Forces leave
- Enhanced company sick pay scheme
- Cycle to work scheme
- Health and wellbeing initiatives including Employee Assistance Programme (EAP)
- Eye-care scheme
- Annual Flu vaccination
- Employee discount platform scheme
- Active social committee
- Flexible work life balance policy
- Free onsite car parking
- Onsite café

How to Apply

Applications are welcome by sending a covering letter detailing how you meet the person specification requirements and CV by **5pm** to jobs@ukbiobank.ac.uk on **Friday 5th August 2022** (subject to early closure upon receipt of suitable applications).

If you require assistance in applying for the role, or attending interviews, please contact our HR department via hr@ukbiobank.ac.uk so that we can make suitable arrangements.

Our passion for diversity and equality means creating a work environment for all employees that is welcoming, respectful, engaging, and enriched with opportunities for personal and For detailed information on how we process your personal data, please review our [privacy policy](#).

In line with GDPR, we ask that you do NOT send us any information that can identify children or any of your Sensitive Personal Data (racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, data concerning health or sex life and sexual orientation, genetic and/or biometric data) in your CV and application documentation. Following this notice, any inclusion of your Sensitive Personal Data in your CV/application documentation will be understood by us as your express consent to process this information going forward. Please also remember to not mention anyone's information or details (e.g. referees) who have not previously agreed to their inclusion.

Please click on these links for further information on [Working for UK Biobank](#) and [Recruitment guidance for candidates](#)