

Dear []

Information about the new General Data Protection Regulation (GDPR)

You may have heard that Britain's data protection law is changing. Indeed, it is likely that you will already have received information about it from other organisations as this is required by the law.

In order to help you understand what the General Data Protection Regulation (GDPR) means for your involvement in UK Biobank, we have summarised the key points in this letter (while, as is required, providing further details in the enclosed note).

The GDPR replaces existing data protection legislation on 25 May 2018. UK Biobank has undertaken a detailed review and concluded that it already complies with the GDPR. There are three key facts that are of direct relevance to you as a participant in UK Biobank. There is:

- **no action** that you need to take or any response that you need to provide;
- **no change** in the way that we will process, store and use your data; and
- **no change** *in the basis of your participation in UK Biobank.*

Your continued participation remains as described in the Information Leaflet that we sent to you at the start, and in the consent form that you signed at your first visit to an assessment centre. For example, you have the right to withdraw from UK Biobank at any time without giving a reason, although I very much hope that you will not do so since your data (and that of the other 500,000 participants) is allowing ground-breaking health research to be performed.

We apologise for contacting you if you have previously asked not to receive any further information or contact from us. Unfortunately, the new law requires us to do so on this occasion. If you have any questions about the GDPR related to UK Biobank then we would be delighted to answer them. You can contact me directly at rory@ukbiobank.ac.uk or by calling or writing to UK Biobank using the details provided at the end of the summary document enclosed.

Yours sincerely



Professor Sir Rory Collins
UK Biobank Principal Investigator
& Chief Executive Officer

Information notice for UK Biobank participants: the General Data Protection Regulation (GDPR)

The purpose of this note is to draw your attention to certain parts of the GDPR about which we are required to tell you by the legislation. (Whenever we refer to the "old law" we mean the Data Protection Act 1998, and whenever we refer to the "new law" we mean the GDPR.)

We should like to assure you that we will only process, store and use your data in a manner that is consistent with the basis on which you joined UK Biobank (as described in the information materials and consent form; available at www.ukbiobank.ac.uk/resources. In particular, your information will continue to be made available only to bona fide researchers undertaking health research that is in the public good.)

UK Biobank's lawful basis for processing your data

A legal requirement of the GDPR is that we tell you about the legal basis on which UK Biobank will process your personal data. This includes information about you (like your name and address), the information that you told us about (such as answers to questions about your lifestyle), and information that we have received from others (such as your health records).

Because of the health-related nature of the personal information that you have provided to us, there are two lawful bases for our processing of it, which are referred to in the legislation as "**legitimate interests**" and "**consent**". UK Biobank believes that both of these are valid reasons for processing your data and, as is required by the law, we have set our reasoning below.

Legitimate interests

Legitimate interests are defined in the GDPR as "*processing which is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child*".

In this case, UK Biobank is defined as the "data controller". In the GDPR, there is a 3-step test to demonstrate "legitimate interests" which we have set out as a series of questions and answers:

Purpose test: what are UK Biobank's legitimate interests?

- *What is UK Biobank trying to achieve?* Our objective is to set up and manage a major international research resource for health-related research that is in the public interest.
- *Who benefits from UK Biobank's processing?* Patients and the wider public benefit from the advances made in the prevention, diagnosis and treatment of disease.
- *How significant/important are these benefits?* UK Biobank is now one of the largest and most used health research resources in the world. Over 6,000 institutions are registered with us and over 1,000 health-related research applications have been approved.

Necessity test: is the processing necessary for the legitimate interests?

- *Is processing personal data a reasonable way to achieve the objective?* Without the personal data provided voluntarily by you and the other participants, UK Biobank would not exist.
- *Is there another less obtrusive way to meet our purposes?* Your data are stored in a way that makes it extremely difficult even for UK Biobank to re-identify you. Only a very few individuals within UK Biobank are allowed to do so (and they are strictly monitored) in order that further information about you can be added. Data provided to researchers have personal identifiers removed so that

an individual participant cannot be identified. There are no circumstances in which your data can be processed in a manner that could have an adverse impact on you.

Balancing test: UK Biobank has to weigh up the participant's interests.

- *Would participants expect UK Biobank to use their data this way? Yes; this is what we set out in the information materials provided to participants and in the consent form each of them signed.*
- *How likely would a participant be to object? In our view, this is very unlikely. During the past 10 years since participants joined UK Biobank during 2006-10, fewer than 800 of the 500,000 participants have withdrawn from the study and asked that we delete all of their information.*

For completeness, we should add that there is a further requirement under the GDPR for processing "special categories of data" and this includes data concerning an individual's health. This requirement can be satisfied if the processing is necessary "for reasons of public interest in the area of public health or for archiving purposes in the public interest, scientific or historical research purposes". The GDPR specifies that "research purposes" include "studies conducted in the public interest in the area of public health". We consider that UK Biobank's activities fall squarely within this requirement.

Consent

Each person who joined UK Biobank provided their explicit consent for us to collect, store and make available information about them (including data from genetic and other assays of the samples that were collected) for health-related research, and for their health to be followed over many years through medical and other health-related records, as well as by being re-contacted by UK Biobank.

Under the GDPR, explicit consent needs to satisfy each of the following 6 criteria:

- *Freely given:* your consent was not provided as a precondition for a service or a benefit;
- *Presented separately from other information:* a separate consent form from the information materials was provided which all participants signed (see: www.bit.ly/ukbiobankconsentform);
- *Based on properly explained information:* all participants were provided with the relevant information materials which described how UK Biobank would use their information to support health-related research that is in the public interest (see: www.bit.ly/ukbiobankinformationleaflet);
- *Could be refused and easily withdrawn:* all participants volunteered to join UK Biobank after having the chance to review the information materials and ask any questions that they had, and any participant can withdraw for any reason at any time (see: www.ukbiobank.ac.uk/withdrawal);
- *Provided for specific purposes:* there was a set of separate points on the consent form related to specific purposes to which participants had to agree before signing the form;
- *Named third party controllers relying on the consent:* UK Biobank does not provide data to researchers which can be used to identify participants. Instead, personal identifiers are removed from the data provided to researchers and UK Biobank's legal agreement with these researchers requires them to restrict their use of the data for their approved research and not to try to identify any participant. This means that, for the purposes of the GDPR, it is no longer "personal" data and so this criterion is not relevant.

The National Data Opt Out

The national data opt out programme becomes live on 25th May 2018 <https://digital.nhs.uk/services/national-data-opt-out-programme>. This enables any individual in the UK to notify the NHS that they only want their personal data to be used for their own health care purposes. However, if any UK Biobank participant elects to use the opt-out this will not exclude them from UK Biobank. In order to withdraw from UK Biobank, any participant has to withdraw by notifying UK Biobank in the normal way.

New rights under the GDPR

The GDPR introduces certain new rights for individuals which were not part of the old law, but these new rights do not change your relationship with UK Biobank. These rights fall into two categories:

- *Rights of access:* All participants joined UK Biobank on the explicit understanding (as described in the information leaflet and consent form) that there would be no feedback of any information that was discovered about them from using their data. The reason for taking this “no feedback” approach was that it was considered likely that providing feedback would prevent or impair the research purposes of UK Biobank. Both the old law and the GDPR have provisions which allow research projects (like UK Biobank) not to provide participants with their data.
- *Rights to restrict processing, to be forgotten, erasure and withdrawal:* these rights are covered by your ability to withdraw from UK Biobank at any time for any reason (although we very much hope that you choose not to exercise that right so that your data can continue to be used to help researchers study the causes, prevention and treatment of many different diseases).

Participants also have the right to contact the UK’s data protection authority – the [Information Commissioner’s Office \(ICO\)](#) – if they have any concerns about UK Biobank’s use of personal data and/or UK Biobank’s approach to data protection and the GDPR.

Protecting your data

UK Biobank stores all your data securely and to the highest industry and professional standards. It undertakes regular testing of its IT systems to ensure that they are robust. UK Biobank also commissions external experts to test the security of our systems.

Before UK Biobank provides data to researchers, we first remove all the personal identifiers so that individual participants cannot be identified. In addition, your data are only provided to researchers on the execution of a legal agreement prohibiting the researcher from trying to identify a participant.

Only UK Biobank has access to participants’ data with the personal identifiers (which is necessary in order to allow us to add more information about each participant as it becomes available) and we restrict the number of individuals within UK Biobank who have access to these personal identifiers.

Retention of Data

UK Biobank will store participants’ data for as long as it has a legitimate interest in doing so. The UK Biobank project is a long-term study and participants’ data will be kept for the duration of the project as set out in the [consent](#) provided by each participant who joined UK Biobank. However, should a participant wish to leave UK Biobank they can do so at any time: [Withdrawing from UK Biobank](#)

Data Protection Officer

We have appointed a Data Protection Officer (DPO) who can be contacted with any questions or concerns relating to UK Biobank's approach to data protection and the GDPR. Please write to the DPO using dpo@ukbiobank.ac.uk or via the post: FAO: The Data Protection Officer, UK Biobank, Units 1-2 Spectrum Way, Adswold, Stockport, SK3 0SA.

Summary

We hope that you have found this note informative and useful. If you have any questions about the way in which UK Biobank is complying with the new law, please do not hesitate to contact us.

Call us: UK Biobank Freephone 0800 0276 276 8am-6pm Monday-Friday, 8am-4pm Saturdays.
Write to us: UK Biobank, Participant Resource Centre, Division of Population Medicine, Cardiff University, 5th Floor, Neuadd Meirionnydd, Heath Park, Cardiff, CF14 4YS
Email us: Rory@ukbiobank.ac.uk