

Frequently Asked Questions

Answers to questions about request for primary care data of UK Biobank participants who have given explicit consent

[The current version of this note with embedded links is available at <http://www.ukbiobank.ac.uk/gp-faq>]

What is UK Biobank?

UK Biobank is a prominent research resource which is supported by the NHS and funded primarily by the Medical Research Council and Wellcome Trust, along with the British Heart Foundation and Cancer Research UK. UK Biobank is following the health of 500,000 adults from England, Wales and Scotland who agreed to join the project between 2006 and 2010. It is being used for a wide range of health research that is in the public interest (for example, polygenic risk predictors for heart disease, cancer and other conditions; genetic and non-genetic causes of cognitive decline and dementia).

Further information about the ways in which UK Biobank is increasing knowledge about the causes of many different conditions, and ways to prevent and treat them, is available at: <https://www.ukbiobank.ac.uk>

How do I know which of my patients are UK Biobank participants?

Unless a patient has mentioned their participation to you directly, it is unlikely that you would know which of them is in the study. Consequently, enclosed with this letter is a list of identifiers for those UK Biobank participants who NHS Digital has told us are registered with your practice. However, although we can guarantee that all the individuals on this list are consented UK Biobank participants, the practice registration may not be up-to-date (e.g. if a patient has moved to another practice).

Do I need to contact each patient to confirm their consent before agreeing to a practice extract?

UK Biobank's view is that it not necessary to check with each UK Biobank participant registered at your practice as we already have their explicit written consent, and health-related data are already being provided on that basis by NHS Digital. Moreover, although it may represent standard practice when dealing with requests that may have an impact on the patient

(e.g. for health insurance), there would be no impact on the participant as a result of providing these data to UK Biobank.

How do I know the consent is still valid?

As indicated in the information materials provided to potential participants before they agreed to join UK Biobank, consent was provided for the lifetime of the project:

<https://www.ukbiobank.ac.uk/participant-information-leaflet>

We recently wrote (in May 2018) to all of the UK Biobank participants to let them know our legal basis for holding their data under the new GDPR data protection legislation: <https://www.ukbiobank.ac.uk/gdpr>

We remain in regular contact with the participants via annual newsletters that inform the participants about what is being done with their data:

<https://www.ukbiobank.ac.uk/newsletters>

In addition, we regularly invite participants to take part in enhancement projects (e.g. web-based questionnaires; wearing activity monitors; attending imaging assessments), and to attend meetings that are held all over the country in order to hear about progress with the project:

<https://www.ukbiobank.ac.uk/participant-events>

Participants can withdraw from UK Biobank at any time, without giving any reason, although only about 1000 participants have so far chosen to withdraw. The options for withdrawal are shown at:

<https://www.ukbiobank.ac.uk/withdrawal>

Finally, prior to beginning this primary care data linkage project, we spoke with the Information Commissioner Elizabeth Denham, and the subsequent reply from the ICO's Legal Counsel (<https://www.ukbiobank.ac.uk/ico>) confirmed that our consent is compliant with the GDPR:

"The consents given by the participants to UK Biobank provide the GPs with comfort that their disclosure of these patient records to UK Biobank is in accordance with the current and incoming law."

How is the extraction being undertaken and how do I know it is secure?

UK Biobank is working closely with the GP systems suppliers – including EMIS Health (EMIS Web) and TPP (SystmOne) – to manage the extract in

a secure, scalable and sustainable way. UK Biobank is communicating directly with each and every one of the 8,000 GP practices across England that are covered by these system suppliers to set out the purpose of the data extract, provide evidence of the consent from participants, and give assurances that the extract only involves patients registered at a practice that have explicitly consented to participate in the UK Biobank study.

UK Biobank is able to ensure that only data which relates to UK Biobank participants are extracted by the GP system supplier by providing the participants' identifiers (NHS number, date of birth and gender) in an encrypted format via secure transfer for precise matching to relevant records only. Only the matched participant records from a practice will be extracted and provided to UK Biobank in an encrypted format via secure transfer. Only information that does not identify participants is provided to approved researchers undertaking health-related research that is in the public interest.

What information would be extracted from our GP practice records if we give our agreement?

The information extracted from the health records of consented participants would comprise coded data only about the patient's health and well-being, and interactions with the practice, including:

- Coded diagnoses, symptoms, observations, referrals and associated dates
- Prescriptions and dates prescribed
- Lab test results and date of test
- Immunisation records

The data extraction is not focussed on any particular condition as UK Biobank is a resource for a wide variety of research into all types of health outcomes. No identifiable information about any person who works in the practice or sees the patient would be extracted. Further information on the data fields to be extracted is available at:

<http://www.ukbiobank.ac.uk/general-practice-extract>

Am I required to do a Data Privacy Impact Assessment (DPIA) prior to agreeing to this extraction?

The RCGP/BMA Joint IT committee recommends that practices carry out a DPIA for this data extraction process. The Committee reminds GP practices that the GDPR allows for DPIAs to be shared and adopted by others.

UK Biobank has created an exemplar DPIA which has been prepared as a suggested format to help GP practices readily incorporate the relevant information about UK Biobank into a DPIA form (although it is for each GP practice to conduct its own DPIA assessment). The Joint IT Committee considers this exemplar to be comprehensive and capable of being simply adopted by GP practices.

The UK Biobank form can be downloaded here:

<http://www.ukbiobank.ac.uk/general-practice-dpia>

It takes into account the following points relating to UK Biobank and the proposed extraction:

- All UK Biobank participants have explicitly consented to the processing and secure sharing of all of their medical and other health-related data with UK Biobank for health-related research;
- The processing is necessary to support their participation in UK Biobank in order that their health outcomes can be linked to all of the other data that they have provided;
- UK Biobank only ever uses linked healthcare data (as already provided to us on deaths, cancers and hospitalisations) for the purposes of developing and improving its research resource;
- UK Biobank does not release identifiable data to researchers or other parties in any circumstances (other than for the purposes of obtaining updates of health outcome data, as in this case); and
- Practices may wish to add UK Biobank to their Privacy Notice as a named research entity with which they share data, and to display a notice to that effect in their practice.

The Information Commissioner's Office also provides guidance on conducting a DPIA:

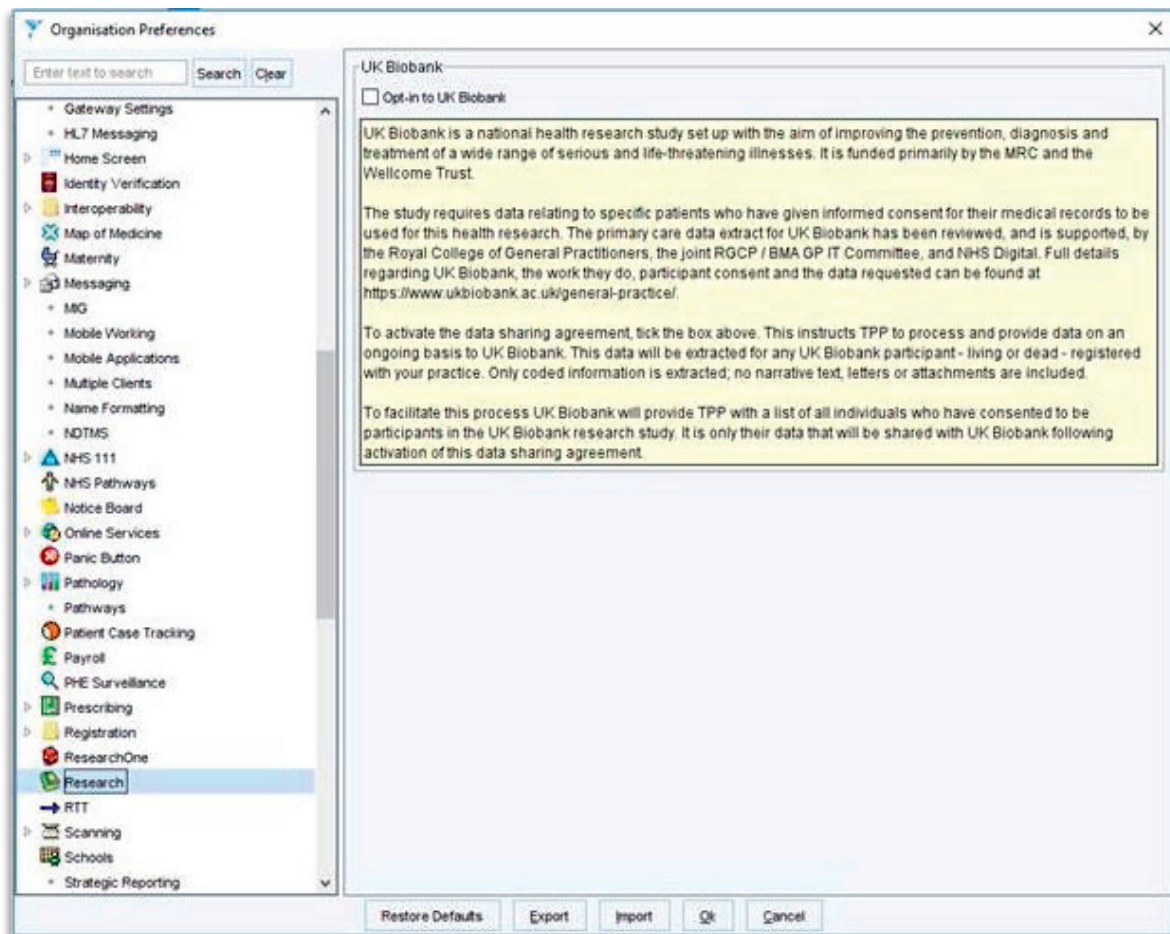
<https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/data-protection-impact-assessments-dpias/how-do-we-do-a-dpia/#how2>

How do I enable the data extraction to take place?

This is easily done by accessing the data sharing agreement section of your practice management system and agreeing to the UK Biobank Data Sharing Agreement. The screenshots below show how this works for TPP and for EMIS practices.


For TPP:

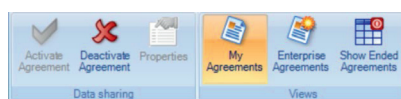
- The “Data Sharing Agreement” is located under the “Research” element of the “Organisation Preferences” panel within SystmOne, and is available to the GP practice administrator.
- To activate the Agreement, a GP practice simply needs to read the brief summary and then to tick the checkbox marked “Opt-in to UK Biobank” (as shown in the screen capture below).





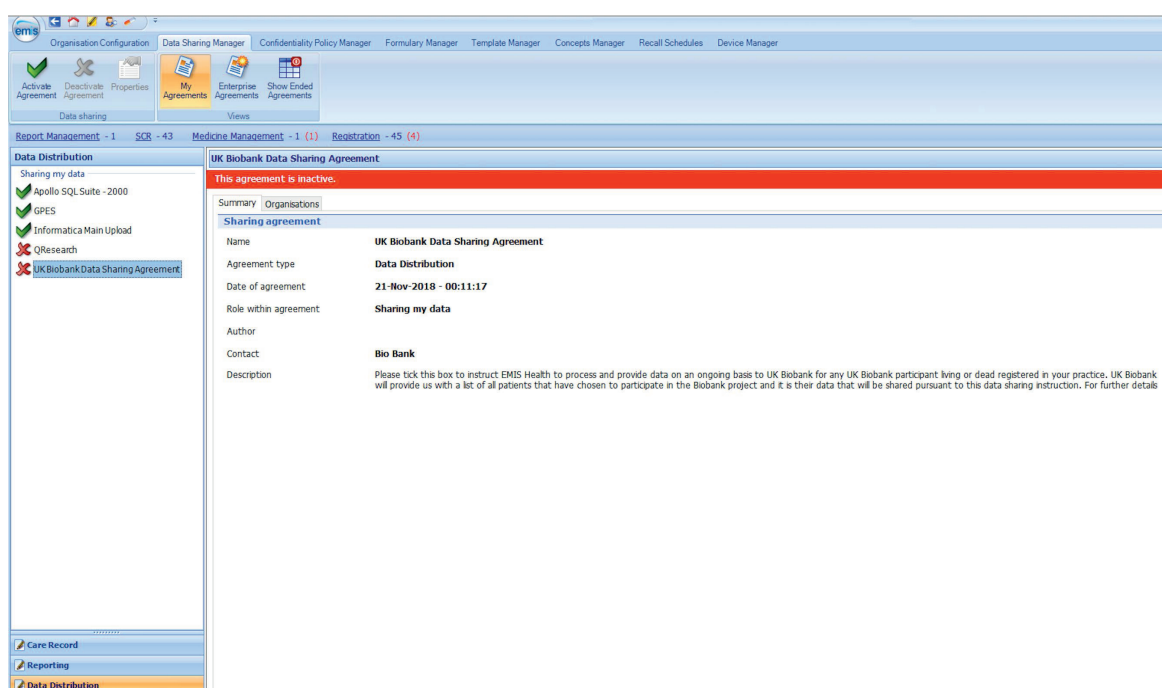
For EMIS:

- The “Data Sharing Agreement” is located under the “Data Sharing Manager” and is available to a GP practice administrator with RBAC activity B0109 in their role profile.

- Click on , point to "Configuration" and then select "Data Sharing Manager". On the ribbon, if not already selected, click on "My Agreements" (as shown below).



- In the "My Agreements" panel, click on the "Data Distribution" tab (as shown below).
- Active agreements are displayed with a green tick  and those that have not yet been activated are displayed with a red cross . Select the "UK Biobank Data Sharing Agreement".



- To activate the Agreement, a GP practice simply needs to read the brief summary and then to click on "Activate Agreement" in the ribbon (as shown below).

