

December 2018

Compliance with data protection regulation of UK Biobank's request to obtain primary care data for consented participants

On 17 October, UK Biobank and TPP wrote a letter to practices, endorsed by the Chair of the RCGP Council, asking them to agree the extraction of coded primary care data for UK Biobank participants; each of whom has given explicit consent for such information to be made available to UK Biobank. That letter (<https://www.ukbiobank.ac.uk/tpb-letter/>) provided a detailed description of the proposed process (along with links to additional material), which is also described below.

Subsequently, a few GPs have asked for confirmation (i) that this is something that UK Biobank is entitled to do; (ii) that only data on consented UK Biobank participants will be extracted; and (iii) that this process complies with data protection regulation. In addition, we have been asked how UK Biobank will address requests for assurance of the consent from participants in individual practices.

UK Biobank's participant consent

All 500,000 participants have provided UK Biobank with explicit consent to link to any health-related records (<https://www.ukbiobank.ac.uk/consent>). Any participant can withdraw at any time without giving a reason (as described on the website: <https://www.ukbiobank.ac.uk/withdrawal>). So far, however, fewer than 1,000 participants have withdrawn from the study.

UK Biobank and its funders (principally, the Medical Research Council and Wellcome Trust) were advised throughout the development of UK Biobank's information materials and consent form by, amongst others, the independent Ethics & Governance Council. This process also involved assessing participants' understanding of the consent that they were giving to UK Biobank. The study protocol has been approved by the North West Research Ethics Committee which has also formally approved UK Biobank as a Research Tissue Bank (<https://www.ukbiobank.ac.uk/rtb>).

UK Biobank already receives coded data for all of its participants in England about deaths, cancers and hospitalisations from NHS Digital/Public Health England (and similar providers for participants in Scotland and Wales) following governance review by NHS Digital (and equivalent organisations).

However, since primary care health records are not held centrally, UK Biobank is seeking these data directly from General Practices through the practice management system suppliers. All that is now required is for each practice to agree to the data extract request from TPP.

Process for extraction of primary care data

In order to ensure that primary care data are extracted only for consented UK Biobank participants who have not withdrawn, the following procedures will be followed:

- UK Biobank will provide TPP with participant identifiers (i.e. NHS number, date of birth, and gender) in an encrypted format for participants (who have not withdrawn);
- These identifiers will be matched against identifiers of patients held in the TPP practice management system. Matching is required on all three of the identifiers;

UK Biobank, 1-2 Spectrum Way, Adswold, Stockport, Cheshire SK3 0SA
Tel 0161 475 5360 Fax: 0161 475 5361 www.ukbiobank.ac.uk

- For those practices that have agreed to the extraction, TPP will run the data extraction process for the matched UK Biobank participants in their practices;
- The information extracted will comprise coded data, such as:
 - Diagnoses, symptoms, observations, referrals and associated dates
 - Prescriptions and dates prescribed
 - Lab test results and date performed
 - Immunisation records
- These coded data will be provided to UK Biobank in an encrypted format via secure transfer.

These procedures enable linkage to take place in a de-identified manner which only extracts data for consented UK Biobank participants. Practices will be able to view those patients who have had their data extracted as a result of being a consented UK Biobank participant.

The data extraction will be repeated periodically. However, as was confirmed in UK Biobank's discussions with the Information Commissioner's Office (ICO), practices only need to give their agreement once for release of these data. Practices will be able to see which of their patients have had their data extracted on each occasion.

General Data Protection Regulation (GDPR)

With the introduction of GDPR earlier this year, the legal basis on which UK Biobank continues to be entitled to obtain health record data has been communicated to all UK Biobank participants. It is summarised on the UK Biobank website (<https://www.ukbiobank.ac.uk/gdpr>).

UK Biobank's policies and procedures on the handling of identifiable and sensitive health data have been reviewed by NHS Digital which has confirmed that they meet GDPR requirements.

Following discussions with the Information Commissioner and her legal counsel, the ICO wrote to UK Biobank in April confirming that UK Biobank's approach to obtaining these primary data from general practices is entirely legitimate (<https://www.ukbiobank.ac.uk/ico>).

In particular, the ICO advised that *"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 current and incoming law"*.

With regard to the national data opt out introduced in May, participants would need to withdraw from UK Biobank in order to opt out of these data extractions. If any participant does withdraw from UK Biobank in the future their identifiers will not be used by the system supplier to extract further data and data that UK Biobank already holds will be deleted in accordance with their instructions.

Assurance of consent

It is, of course, entirely proper for a GP practice to take all reasonable steps to assure itself that UK Biobank does have the necessary lawful basis for the practice to allow the health records of individuals within their practice to be provided to UK Biobank, which is set out in our communication to participants about GDPR (<https://www.ukbiobank.ac.uk/gdpr>).

Further, UK Biobank is attaching a letter of assurance as UK Biobank's guarantee to your practice that only data from consented UK Biobank participants who have not withdrawn will be extracted.

For reasons of participant confidentiality, UK Biobank would prefer not to send the signed consent forms to practices since they contain identifiable information (and our internal processes are designed

to process de-identified information whenever possible). However, if the sight of consent forms for particular individuals is required, then we will send these to your practice via secure email.

If you do wish us to send you these consent forms or would like to discuss anything else, please get in touch with us either by phone on 0800 0276 276, or by email ukbiobank@ukbiobank.co.uk.

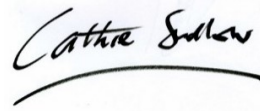
UK Biobank is already allowing researchers to generate exciting new findings about the determinants of many different conditions. Availability of primary care data will substantially increase the range of conditions that can be studied and the precision with which they can be studied.

We do very much hope, therefore, that you will agree to primary care data of consented participants in your practice being provided to UK Biobank in order to allow such research to be conducted.

Yours sincerely



Professor Sir Rory Collins, FRS FMedSci FRCP
UK Biobank Chief Executive & Principal Investigator



Professor Cathie Sudlow, DPhil FRCPE FRSE
UK Biobank Chief Scientist