

# FAQs on applying and accessing UK Biobank data

This document contains answers to FAQs from researchers. Please read our <u>UK Biobank Access Policy and Procedures</u> before registering via the UK Biobank Access Management System (AMS).

For assistance you can visit the UK Biobank Community.

# **Registration**

- What do I do if I am affiliated with more than one institute? You can add all your current affiliations to a single registration in AMS, listing your personal institute email address for each of them.
- Who can register for access to the UK Biobank Resource? The Resource is available to all bona fide researchers for all types of health-related research which is in the public interest.
- What is the cost of Registration? There is no cost to register.
- I am trying to register but the system will not let me progress. What should I do? If the mandatory fields have been completed please contact the Access Management Team for assistance.
- **Can I register on behalf of someone else?** No. The email address used to register must be your personal institute email address.
- I have submitted my Registration. What happens next? We aim to review all registrations within 10 working days, but this may be longer if additional information is required.
- **My account is locked, what do I do?** Follow the process for "What happens if I forget my password?" below.
- What happens if I forget my password? Click the 'Forgot your password?' link on the AMS Log in Page. Enter your username and the system will send you an email with a reset password link.
- **Can I change my password?** Yes. You can use the 'Human Icon' <sup>1</sup> button at the top right corner of the Home Page after logging into AMS – select 'Change password'.
- **Do I need to re-register if I change email address and/or move to a different Institute?** No. You can click Profile after logging in to AMS to change the details in your registration. You can add or edit institute details.
- My institute address has changed how do I update my contact details? Contact details can be updated via the 'Profile' tab on your AMS Home Page. Your email address is set as your User Name by default. If you change institute you can add details of your new institute (including your personal institute email address) in your Profile tab.

# **Applications**

- Will UK Biobank respond to questions regarding the Resource before application? Yes. UK Biobank is happy to respond to general questions, such as whether a research project is feasible using the resource, although in some cases an application is required to answer specific queries.
- Am I required to collaborate with UK Biobank in order to access the Resource? No.
- Do I need to be based in the UK to access the Resource? No. The Resource is available to all bona fide researchers regardless of their location.
- **Can I apply on behalf of another researcher?** No. Researchers need to apply on their own behalf. If you submit an application you automatically become the Applicant PI and are required to sign the Material Transfer Agreement (MTA).
- Who do I need to include as collaborators? You need to list all researchers who will have direct access to the UK Biobank data. Researchers who are involved in a project (e.g., as coauthors on publications) but will not access the data do not need to be named on the application.
- Can I remove collaborators from my Application? Yes. Collaborators listed in an application can be added or removed by the Applicant PI.
- I am changing institute do you need to know? Yes. Please add the new Institute to the Profile tab on your AMS Home Page. The Access Management Team will need to verify any new Institute added.
- Can I transfer my Application to a new Applicant Principal Investigator (PI)?

Yes. Please contact the Access Management Team for guidance. The proposed new Applicant PI must be registered with UK Biobank, named on the application and a new MTA will need to be executed.

- What information is required to submit an Application?
  - Application Form tab:
    - A1: Project title (200 characters)
    - A2: A brief lay summary of the research you intend to undertake (4000 characters)
    - A3: Up to six keywords that describe the intended research
    - A4a: Confirmation that you intend to conduct health-related research
    - A4b: Confirmation that you intend to use UK Biobank data to perform research in the public interest
    - A5a: Is your intended research output potentially considered contentious?
    - A6: Declaration of conflicts of interest (2000 characters)
    - B1: Selection of data tier
  - Collaborators tab:
    - Please select Institute where you will be conducting the project
    - Add collaborators at your institute only researchers who are already registered and approved can be added
    - Add collaborators at another institute
    - Materials Transfer Agreement information:
      - Institute name to appear on legal document
      - Select contact at this Institute
- Is there a limit to the amount of data and/or samples that I can request access to? No. Although the request must be appropriate to your application.
- How do I make a request to re-contact participants?

Please contact the Access Management Team to discuss your re-contact request.

- I submitted an Application but have not received a response. Why is this? The Access Management Team escalates all applications for review by our epidemiologists within 10 working days of submission. We will respond with their feedback as soon as possible.
- **My Application has been declined. Can I appeal?** Yes. You have the right to request reconsideration. Requests must be submitted in writing within 3 months of the Application being declined, and will be placed before the Access Committee (AC) which will review your appeal at its next guarterly meeting.

## **Payment**

- How much does it cost? Please see our <u>Costs</u> section for more information.
- How do I make payment? The Application fee can be paid online by the Applicant PI or you can generate and download an invoice and arrange to pay by BACS.
- **Do I have to pay VAT?** UK Biobank is obliged to charge VAT on access charges. See our <u>VAT note</u> for information.
- **Do you accept payment in any currency (e.g. Euro)?** Payments must be in pounds sterling (GBP) taking bank charges into account.

# Approval, Licensing and Ethics

- **Do I need to obtain ethics approval?** Not usually. UK Biobank has obtained Research Tissue Bank (RTB) approval from its ethics committee that covers the majority of proposed uses of the Resource, so researchers do not typically need to obtain separate ethics approval. Please refer to the UK Biobank <u>Access</u> <u>Procedures.</u>
- What is the UK Biobank Research Ethics Committee (REC) approval number? The REC reference for UK Biobank is 16/NW/0274.
- Do I need to obtain ethics approval to re-contact participants? Yes. Requests for re-contact require separate approval from a Research Ethics Committee.
- Do I require a Human Tissue Authority (HTA) Licence? UK Biobank possesses a HTA Licence, so a separate licence is not required by researchers who receive samples from the Resource, provided that:
  - $\circ$   $\;$  Residual samples are destroyed or returned at the end of the project; and
  - Applicants do not transfer samples to a third party without prior UK Biobank approval.

# **Property Rights**

Who owns UK Biobank data and samples?

UK Biobank is the owner of the Intellectual Property Rights of the data and samples contained in the Resource. Successful applicants are granted a limited, revocable, worldwide, royalty-free, non-exclusive licence (but not ownership rights) to use samples for a <u>permitted purpose</u> only.

Subject to the licence-back provisions set out in the Access Procedures, the Intellectual Property Rights in the Results Data deriving from use of the Resource for the <u>permitted</u> <u>purpose</u> will belong to the Applicant.

• Does UK Biobank have any financial claim over any inventions developed by researchers using the Resource?

UK Biobank will remain the owner of the data and samples, but will have no financial claim over any inventions that are developed by researchers as a result of accessing the Resource (unless they are used to restrict health-related research or access to healthcare unreasonably).

UK Biobank will require a copy of any patents whose claims cover, or are intended to cover, an Applicant Generated Invention\* within two months of their publication. \* Applicant-Generated Invention: an invention developed by the Applicant as a result of carrying out the Approved Research Project.

• Is UK Biobank a research institute?

UK Biobank is a research resource not a research institute. UK Biobank's purpose is described in the <u>Ethics and Governance Framework</u> as to: "build a major resource that can support a diverse range of research intended to improve the prevention, diagnosis and treatment of illness and the promotion of health throughout society".

# Data and/or Sample release and additional requests

- When will I have access to data and/or samples? Access will be granted when:
  - UK Biobank has formally approved the Application;
  - All charges have been paid in full;
  - A Material Transfer Agreement has been signed and returned then executed by UK Biobank.

#### Can I amend the Material Transfer Agreement (MTA)?

No. The MTA is non-negotiable. It has been designed and written by UK Biobank in collaboration with funders, stakeholders and the independent UK Biobank Ethics & Governance Council. It does not seek to apply punitive restrictions on researchers but must safeguard the Resource and the data participants have provided.

#### • How long would I have access to the data/samples? Data/sample use is granted for an initial period of 36 months. Usage is for the duration of the project. Reasonable extension requests made in AMS will be considered by UK Biobank. Extensions are subject to a charge.

- How do I request additional data items that were not included in my original dataset? You can request to change to a higher data tier in the Requests tab of your project. Charges will apply to any project moving to a higher tier.
- Is it possible to conduct additional research on the dataset? A dataset must only be used to conduct research which has been approved. Further research may require a separate application to the Resource. Please contact the Access Management Team for guidance.
- How does UK Biobank ensure participant anonymity? Each dataset is provided with a unique participant identifier so that researchers cannot link their datasets. Researchers are also obliged to NOT seek to identify participants, as stipulated in the signed MTA. Penalties may be imposed on researchers and / or their institutes who seek to do this.

# Publications and return of results

- **Do I need to publish my findings?** Yes. You are obliged to publish your findings in a peer-reviewed journal or on an open source publication site.
- Do I need to acknowledge UK Biobank in my publication?

Yes. For information of the acknowledgements required by UK Biobank and by our data linkage providers please visit our <u>Manage Your Project</u> page.

- Do I need to provide UK Biobank with conference abstracts and publications? Yes. Please provide all written reports (e.g. meeting abstracts, on-line reports, publications) to UK Biobank via AMS or email at least 2 weeks before their expected public release date. This is solely for tracking how results are being disseminated (our approval is not required) and to provide general information to participants who have provided samples and data.
- Does UK Biobank need to know about potentially controversial results? Yes. Please let us know if you think a report is likely to provoke controversy or attract significant public attention, so we can be prepared for possible media enquiries and, when necessary, inform participants.
- Is it acceptable to use UK Biobank images in a journal manuscript? Please contact the Access Team for approval to reproduce images in a manuscript. If permission is granted, please include the caption "Reproduced by kind permission of UK Biobank".

#### How do I return my results?

You must return your results to UK Biobank (i.e. the final analytical dataset plus statistical methods and tools used to create any derived data-fields). Please also tell us which, if any, derived data might be useful to share with other researchers so we can incorporate them into the Resource. Please see our <u>Return of Results User Guide</u> for further information.

• Will participants and the public be kept informed about how the Resource is used? Yes. The UK Biobank website provides information about all approved Applications in and remains in touch with participants via its newsletter and participant events.

### **Complaints**

• How do I make a formal complaint?

A complaint form is available from UK Biobank. Please email <u>access@ukbiobank.ac.uk</u> and UK Biobank will respond within 3 working days.

### **Feedback**

#### How do I provide feedback?

*UK Biobank welcomes feedback from researchers. The Access Management Team seeks feedback after registration approval and at certain points in the application process. Researchers can also submit feedback by emailing <u>access@ukbiobank.ac.uk</u>.* 

### **Useful Information**

• What are the contact details for UK Biobank?

If you have registered with UK Biobank please visit the <u>UK Biobank Community</u> where you can find online support and raise a ticket if required. If you are not currently registered the email address for the Access Management Team is <u>access@ukbiobank.ac.uk</u>. Our postal address is: UK Biobank Coordinating Centre, Units 1-4 Spectrum Way, Adswood, Stockport, Cheshire SK3 0SA, United Kingdom.

• I have applied to access the Resource. Do I have the right to see what information UK Biobank holds about me?

Yes. You have the right to request a copy of the information UK Biobank holds about you and can request to have any inaccuracies in the information corrected. Any such requests should be made in writing to UK Biobank or email to <u>access@ukbiobank.ac.uk.</u>