



## **UK BIOBANK**

### **ACCESS PROCEDURES**

Application and review procedures for access to the UK Biobank Resource

Version 2.1

(July 2022)

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## GLOSSARY

*The following terms are used throughout these Access Procedures and are equivalent to the definitions in the Material Transfer Agreement, although the term “researcher” refers generically to any researcher authorised by UK Biobank to access the Resource (a research institute or an individual researcher belonging to a research institute).*

**Affiliate:** any company or other entity that is directly or indirectly Controlling, Controlled by or under common Control with an Applicant Institution or Collaborator Institution (which includes if such Institution is a company, a subsidiary or parent or holding company of such Institution, or a subsidiary of such parent or holding company) for so long as such Control exists. Please see the definition of ‘Control’ in the MTA for further information. For the avoidance of doubt, an Affiliate is a company which is part of the same corporate group as the Applicant or Collaborator (and is working on the Approved Research Project with the Applicant or Collaborator).

**Application:** the application by the Applicant PI and their Applicant Institution to UK Biobank for access to the UK Biobank Resource in relation to an Approved Research Project.

**Applicant or Applicant Institution:** the organization (e.g. University, company or other identifiable legal entity) making the Application for access in respect of the Approved Research Project and by which an Applicant PI is employed or otherwise contractually attached.

**Applicant PI:** the principal investigator of an Approved Research Project at an Applicant Institution.

**Applicant Researcher:** a researcher at the Applicant who is working with the Applicant PI on the Approved Research Project.

**Approved Research Project:** the research project which has been approved by UK Biobank (specifically including any conditions or stipulations made by UK Biobank) in accordance with the Access Procedures.

**Collaborator or Collaborator Institution:** the organization (e.g. University, company or other identifiable legal entity) which employs the Lead Collaborator who is collaborating with the Applicant PI on an Approved Research Project.

**Collaborator Researcher:** a researcher who is working with the Lead Collaborator at a Collaborator Institution on the Approved Research Project.

**Lead Collaborator:** the lead investigator at a Collaborator Institution.

**Participant(s):** the individuals who participate in UK Biobank.

**Participant Level Data:** the personal data of Participants contained within UK Biobank data/samples and any data generated by a researcher.

**Permitted Purpose:** the conduct of the Approved Research Project in accordance with the MTA, the approved project scope and timeframe as agreed with UK Biobank.

## SUMMARY

### 2022 Update

UK Biobank opened for access in March 2012 and access to the Resource was subject to version 1 of the Access Procedures. Since 2012, UK Biobank has been the beneficiary of a number of a very significant enhancements to the Resource. It is now one of the leading biomedical research resources in the world.

This updated version of the Access Procedures (version 2) has been introduced in order to capture the changes and updates in UK Biobank's access practice and is designed to operate in conjunction with the new Material Transfer Agreement ("**MTA**") (available [here](#)) and the revised Access Fees (for more information on Access Fees, please click [here](#)).

This version 2 is similar in content and structure to version 1 (which can still be found [here](#)) but it is drafted as a stand-alone document (so it is not necessary to cross refer to version 1). By way of introduction to this version 2 ***it should be emphasised that UK Biobank's underlying access policy is fundamentally unchanged*** and:

- in areas where UK Biobank's approach is unchanged, this version uses the same text (or very similar text) as in version 1 of the Access Procedures;
- in other areas, UK Biobank's access process has been clarified, streamlined or simplified; and
- finally, there are some areas (notably data protection) where the landscape is more complicated than it was 10 years ago and this is reflected in the text of this version.

### Key Principles

The Summary in version 1 contained eight bullet points setting out the key principles of the Access Procedures. These key principles are unchanged and are repeated below:

- The Resource is available to all bona fide researchers for all types of health-related research that is in the public interest, without preferential or exclusive access for any person. All researchers, whether in universities, charities, government agencies or commercial companies, and whether based in the UK or abroad, will be subject to the same application process and approval criteria.
- Applications to use the Resource will be checked to ensure that research proposals are consistent with these Access Procedures, the Ethics & Governance Framework ("**EGF**"), and the consent (to take part in UK Biobank) that was provided by the Participants (including having relevant scientific and ethics approval).
- Access to the biological samples that are limited and depletable will be carefully controlled and coordinated. The quantity of sample that is required will be judged against the potential benefits of the research project, with advice from appropriate experts as required.
- Safeguards will be maintained to help ensure the anonymity and confidentiality of Participants' data and samples. Researchers will enter a legal agreement with UK Biobank not to make any attempt to identify Participants, and data and/or samples provided to researchers from the Resource will not identify any particular Participant (i.e. they will be "de-identified").

- Researchers will have to pay for access to the Resource on a cost-recovery basis for their proposed research, with a fixed charge for initiating the application review process and a variable charge depending on how many samples, tests and/or data are required for the research project.<sup>1</sup>
- UK Biobank will remain the owner of the database and samples, but will have no claim over any inventions that are developed by researchers using the Resource (unless they are used to restrict health-related research or access to health-care unreasonably).
- Researchers granted access to the Resource will be required to publish their findings and return their results to UK Biobank so that they are available for other researchers to use for health-related research that is in the public interest.
- UK Biobank will seek active engagement with Participants, researchers and society in general throughout the Resource's lifetime (which is intended to be some decades), in particular regarding the research that is being conducted on it and the research findings that emerge.

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<sup>1</sup> The Access Fees were revised on 1 April 2021 and the fees charged depend on the how many samples, tests and/or data are required for a research project. Please see section A5 below for more information.

## **A OVERVIEW OF THE ACCESS PROCEDURES**

### **A1 Background to the UK Biobank Resource**

A1.1 The UK Biobank Resource and the scientific rationale behind it are described in detail [here](#).

A1.2 The consent of each Participant (to take part in UK Biobank) remains the cornerstone of UK Biobank's activities. Although consent is not the principal lawful basis which UK Biobank uses for data protection purposes, UK Biobank considers that the informed Participant consent itself – taken in the context of the recruitment process, the informational materials, the EGF and subsequent communications – sets out the framework within which UK Biobank operates. The relevant documentation is available [here](#).

A1.3 The EGF, which consolidated the material in the consent form and the informational materials, will be updated in due course to reflect current practice (as per this version of the Access Procedures), and will be available on UK Biobank's website.

### **A2 Access Policy**

A2.1 The objective of UK Biobank's access policy is to provide fair, consistent and transparent access to the Resource in order to ***promote health-related research by bona fide researchers that is in the public interest*** (and this is the access test which has been and will continue to be applied to all applications).

A2.2 UK Biobank applies the same access test and makes no distinction between Applicants, in terms of process, application review and/or contracting (in other words the same MTA applies), regardless of whether they are:

- i) from the UK or abroad; and/or
- ii) from charitable, academic, governmental or commercial entities.

A2.3 The specific objective of these Access Procedures is to maximise access to the samples and data, while ensuring that such access and usage is consistent with the undertakings given to the Participants and the wider public interest (including complying with the prevailing law and upholding respect for human rights).

A2.4 UK Biobank made several undertakings to Participants in relation to access to the Resource. In summary, UK Biobank agreed that it would:

- i) ensure that any uses of the Resource are consistent with its stated aims;
- ii) protect Participants' anonymity and confidentiality;
- iii) ensure that all research projects have relevant scientific and ethics approval (see B5 (Ethical review) below for more information); and
- iv) make information publicly available about the uses of the UK Biobank Resource.

A2.5 UK Biobank believes that these Access Procedures are clear and transparent and have been (and will continue to be) implemented in a manner which is proportionate, accountable and fair. The Access Procedures provide a framework for addressing and determining access issues. They deliberately **do not** prescribe what will be done in each and every circumstance because UK Biobank cannot (and would be unwise to try to) predict the nature of access requests that it will receive over

the long-term. Built into the Access Procedures is sufficient flexibility to address both the expected and the unexpected, including the ability to update them with suitable guidance (based on a published precedent-based approach) and revise them periodically in the light of practical experience.

- A2.6 The functioning of these Access Procedures will be kept under review by the Access Sub-Committee and the UK Biobank team. Input from the Participants, researchers, funders, the Ethics Advisory Committee (“EAC”) and other interested parties will also be taken into account.

### **A3 Researcher responsibilities**

- A3.1 Researchers must comply with their obligations set out in the MTA at all times.
- A3.2 An important part of these obligations is for the researcher to submit annual reports, publish their findings and return their results in a timely manner (see B7 and B8 below). If researchers fail to do so, then their opportunities to obtain additional data, data updates, access to the Resource may be directly impaired. UK Biobank does remind researchers of their obligations, but UK Biobank’s view is that ultimately it is the responsibility of the researcher to discharge their obligations compliantly and punctually.
- A3.3 It is also the responsibility of the researcher (and not UK Biobank) to manage their own research project, including the selection of the methodology and statistical methods which should be used. For example, a decision whether to take account of potential sources of bias and/or confounding is a matter for the researcher to determine (not for UK Biobank to proscribe).
- A3.4 For more information about researcher key responsibilities, please see the Researcher Responsibilities Guidance document available [here](#).

### **A4 Communication**

- A4.1 UK Biobank maintains an active dialogue with Participants, researchers and the public at large. With respect to its Participants, UK Biobank responds to individual queries and questions, releases regular newsletters (both periodic and item-based) and holds regular and well-attended participant meetings (both online and in person).
- A4.2 Summaries of [approved applications](#) and [subsequent publications](#) are also made available on the website.
- A4.3 UK Biobank is involved in a number of discussions relating to medical research in the UK and abroad – such as access to primary care data for research purposes – and, where appropriate, it is an active participant in and contributor to such debates.

### **A5 Access Fees**

- A5.1 UK Biobank charges researchers to access the UK Biobank Resource on a cost-recovery basis.
- A5.2 The Access Fees were [revised](#) on 1 April 2021 to reflect the extent and quantity of data within the Resource, the internal costs of servicing applications and the requests for further data or data updates required by researchers during the course of an Approved Research Project. UK Biobank reserves the right to amend these fees from time to time.
- A5.3 The Access Fees are standardised for all data applications. Sample and re-contact applications attract additional bespoke costs depending on the requirements for sample extraction, processing,

and administrative burdens, which are assessed on a cost-recovery basis (inclusive of any overheads) on a case by case basis.

A5.4 The position with VAT, which is added to invoices (where appropriate) is available [here](#).

## **B FACTORS AFFECTING ACCESS**

### **B1 Scope of applications**

- B1.1 The scope of a research project is required to be definable. An application to study anything about everything will not be successful.
- B1.2 Nevertheless, UK Biobank is comfortable with relatively broad research objectives (as long as they are definable) and an application does not have to have a specific hypothesis: i.e., UK Biobank permits hypothesis-generating applications (which may in turn lead to a researcher identifying and testing a particular hypothesis).
- B1.3 UK Biobank does review and consider granting extensions to the project scope (as opposed to the project duration which is covered in B6 below) of any application, as long as the extended project scope is consistent with the original research project and/or the project scope has not already been extended on multiple occasions so that it is no longer consistent with the original research project.
- B1.4 All communications between researchers and UK Biobank must be done using the Access Management System (“AMS”) and/or email to the Access Team ([access@ukbiobank.ac.uk](mailto:access@ukbiobank.ac.uk)). Communications using hard copy or fax are not accepted.

### **B2 No preferential or exclusive access**

- B2.1 UK Biobank does not grant preferential access to any researcher. Researchers who provide funding to generate or derive data from the Resource (e.g. assays of samples; analyses of images) may request and be granted a 9 month preferred access period to use the derived data (for analysis purposes) linked to all of the other available UK Biobank data before these data will be made available for other researchers to use. See B10 below for further information.
- B2.2 There are no restrictions on the number of researchers who can be provided with the same or overlapping data that are already contained within the Resource.
- B2.3 UK Biobank applies a standard set of criteria (subject to ongoing review and amendment by the Access Sub-Committee) to the assessment of all applications, including the compatibility of the research project with the purposes of UK Biobank; the feasibility of the research project; and the facilities for managing data and/or samples.
- B2.4 The level of scrutiny used to assess applications is related to the nature and scale of the research project (as set out in B2.3), and taking into account other factors such as whether there may be contentious issues involved.
- B2.5 The requirements for sample access and re-contact applications (of which the latter requires separate ethical clearance) are more stringent and are set out [here](#). Please also see B10 and B11 below for more information.

### **B3 Registration and the application process**

- B3.1 All researchers are required to register online with UK Biobank and, in addition, all Applicants must submit an application, pay Access Fees and sign the MTA in order to access the UK Biobank Resource.
- B3.2 Please see section C below for further information about the registration and application process.

## **B4 Applicants, Collaborators and Affiliates**

**B4.1** The legal body who is responsible to UK Biobank under the MTA is the Applicant Institution. Further, the Applicant Institution is responsible for the:

- i) conduct of the Applicant PI;
- ii) the Applicant Researchers (of the Applicant Institution, including the Applicant PI) working on the Approved Research Project;
- iii) any third-party processors engaged by the Applicant Institution for the purposes of the Approved Research Project in accordance with the terms of the MTA; and
- iv) any Affiliates working on the Approved Research Project in accordance with the terms of the MTA.

The Applicant PI is required to acknowledge the contents of the MTA but UK Biobank does not impose any direct contractual responsibility on the Applicant PI.

**B4.2** An Applicant Institution can add a Collaborator Institution to their Application (or Approved Research Project) at any time, subject to the Collaborator Institution:

- i) registering their researcher(s) with UK Biobank and becoming a registered researcher;
- ii) completing and executing the MTA; and
- iii) paying the Additional Institution Access Fee (which is the legal responsibility of the Applicant Institution but either the Applicant or the Collaborator may pay).

A Collaborator Institution is responsible for the conduct of the Lead Collaborator and all Collaborator Researchers involved in the Approved Research Project.

The Applicant Institution is not responsible for the conduct of the Collaborator Institution, the Lead Collaborator or Collaborator Researchers other than to ensure that the Collaborator Institution is conducting collaborative research with the Applicant PI and that this is within the scope of the Permitted Purpose of the Approved Research Project.

**B4.3** There is no formal limit on the number of Collaborator Institutions which may be added to an application, however, UK Biobank would emphasise two points:

- i) Collaborator Institutions must be researchers actively involved in the relevant research project for the Permitted Purpose, not just organisations seeking to access data which is being generated by the Approved Research Project (as this would constitute preferential access); and
- ii) in this context, UK Biobank would consider that a large number of Collaborator Institutions (for example, in the region of 10 or more, or where it is not immediately obvious that the individual Collaborator Institutions are each bringing some specific differentiated expertise) on a particular application might give rise to the presumption that no relevant research was being conducted by one or more of the Collaborator Institution(s) (given the practical difficulties of managing research projects with a large number of Collaborator Institutions).

**B4.4** Relevant Affiliates (of either the Applicant Institution or the Collaborator Institution) can work on an Approved Research Project with the Applicant or the Collaborator. The Applicant Institution or Collaborator Institution must inform UK Biobank of the names of any Affiliates which will be working

on their Approved Research Project. All Affiliate Researchers must be added to the Application/project. All Affiliates must also be named, by the Applicant Institution or Collaborator Institution as appropriate, on the annual report forms.

## **B5 Ethical review**

B5.1 UK Biobank is registered as a Research Tissue Bank (more information is available [here](#)). This means that all data and sample applications may use this ethical clearance to conduct their research. Separate Research Ethics Committee (“REC”) or other ethical clearance is not required nor needed.

B5.2 Nevertheless, (third party) re-contact applications do require separate REC clearance. This separate REC application will need to be made by the Applicant and UK Biobank (as set out in more detail in the re-contact procedures). Please see B11 (re-contact applications) below.

## **B6 Project duration**

B6.1 Originally, UK Biobank required researchers to specify how long they considered that their research project would take and in turn this was used to set the project duration. UK Biobank now operates the following approach:

- i) all applications are granted a minimum 3-year period for their Approved Research Project; and
- ii) this time period may be extended by the Applicant (with the agreement of UK Biobank) during the final year of the Approved Research Project in one (1) year increments (for a minimum period of one (1) year, a period of two (2) years or for a maximum period of three (3) years), subject to payment of the required Access Fees, compliance with UK Biobank’s MTA, the reporting and security requirements and the conduct of ongoing research.

B6.2 For the avoidance of doubt, the extensions set out above in B6.1 can be applied cumulatively (subject to applicable Access Fees) so that, for example, an extension of 3 years may be granted to take the Approved Research Project duration from three (3) years to six (6) years, and this may then be extended by a further three (3) years to nine (9) years, and so on.

B6.3 UK Biobank requires all researchers to endeavour to complete their research in a timely fashion. All researchers have an obligation to notify UK Biobank promptly on the completion of their research, even if the Approved Research Project is completed prior to the initial 3-year period.

## **B7 Annual project report and confirmation form**

B7.1 UK Biobank requires all Applicant PIs and Lead Investigators at Collaborator Institutions to complete their respective annual report forms (available on AMS and [here](#)). These forms require confirmation of the following:

- i) the details of Affiliates and third-party processors who are working on the Approved Research Project with the Applicant or Collaborator; and
- ii) the Applicant or Collaborator’s compliance with the terms of the MTA and the security requirements.

B7.2 In addition to the above, the Applicant’s annual project report form also requires the Applicant PI to provide UK Biobank with project updates, their plans for the next 12 months and details of any research output including publications, conference abstracts, websites, patents and location of GWAS summary statistics.

B7.3 Since 2021, the default position is that if these annual report forms are outstanding then the ability of a researcher to download further data (either in terms of new data fields or updates of existing data fields) or access existing data via the Research Analysis Platform (“RAP”) may be impeded or halted. UK Biobank also reserves the right to terminate the researcher’s MTA and research project and/or decline future applications by the researcher if their annual report form is outstanding for an unreasonable period of time.

B7.4 For more information about UK Biobank’s key requirements for researchers in relation to annual report forms, please see the Researcher Responsibilities Guidance document available [here](#).

## **B8 Publication of findings, summary datasets and return of results**

B8.1 The Applicant is required to use all reasonable endeavours to publish the findings of any research deriving from the Resource in an academic journal or via an open source publication site as soon as practically possible and in any event within 6 months after the completion date of the Approved Research Project.

B8.2 The Applicant is required to use all reasonable endeavours to publish a commensurate level of findings within the first 3 years of the Approved Research Project. Where this is not possible, the Applicant shall provide UK Biobank with a reasonable explanation (which can be provided in the annual project report) as to why such action was not possible and an estimation of when a publication can be expected.

B8.3 Approval of publications is not required from UK Biobank, but the Applicant PI ***must provide a copy of any report of its findings and/or any press release to UK Biobank at least 2 weeks before their expected date of first public presentation or publication in any format*** (e.g. meeting abstract, on-line report, pre-print server, and journal).

B8.4 The Applicant PI is also required to advise UK Biobank in advance if any report or press release is reasonably likely to provoke controversy or otherwise attract significant public attention.

B8.5 All publications of findings using the UK Biobank Resource are required to include the following credit, typically within the acknowledgement section, and it is also a requirement that the term “UK Biobank” is incorporated within the title and/or the abstract:

*“This research has been conducted using the UK Biobank Resource under application number [     ].”*

The credit to UK Biobank should be linked, wherever possible, to reference search tools (such as PubMed and MEDLINE).

B8.7 ***Within the earlier of 6 months of publication or 12 months of when the Approved Research Project was completed, the Applicant PI is required to provide the results data behind them, for inclusion in the Resource in such detail and format as UK Biobank reasonably requires.***

B8.8 UK Biobank acknowledges that many publications require the publication of summary data tables alongside the main article. UK Biobank supports this approach but would note that such summary data table should not include any Participant Level Data. The summary data should also be returned to UK Biobank as part of the results data.

B8.9 For more information about UK Biobank’s key requirements for researchers in relation to publication, acknowledgement and return of results, please see the Researcher Responsibilities Guidance document available [here](#).

## **B9 Use of third-party processors**

- B9.1 UK Biobank does permit the use of third-party processors – for whom the researcher is fully responsible – to undertake discrete elements of data computation and analysis, subject to complying with the published provisions in the MTA on third-party processors.
- B9.2 For the avoidance of doubt, a third-party processor is not a researcher (either as a Collaborator or an Affiliate) – as this would require registration as a researcher with UK Biobank – and thus UK Biobank would not expect to find (for example) such third-party processors named as authors or co-authors on research papers.
- B9.3 For more information about UK Biobank’s policy on cloud storage of UK Biobank data, please see B16 below.

## **B10 Sample application and the preferred access period**

- B10.1 Applications that request access to the biological samples are subject to the same criteria as those for data, but in addition the Applicant needs to demonstrate compliance with the sample release policy (available [here](#)). This sets out more stringent criteria as the samples are considered to be a depletable resource (whereas the data are not). All applications for samples are considered by the Access Sub-Committee.
- B10.2 UK Biobank originally envisaged that it might conduct case-control calls for particular diseases. However, UK Biobank has revised its approach – and no longer intends to put out such calls – with the rationale for this change also set out in the sample release policy.
- B10.3 If an Applicant conducts a sample assay – in the manner agreed between the Applicant and UK Biobank – then, if requested by the researcher and agreed by UK Biobank, the Applicant will be entitled to a 9-month period of exclusive access over the assay data (referred to as the ‘preferred access period’). After careful deliberation, UK Biobank considers that 9 months is a reasonable preferred access period.
- B10.4 The process of an approved sample assay is (in general terms) as follows:
- i) Pilot: A pilot or test phase may be required, using UK Biobank or other samples, to ensure the performance characteristics of the assay is as expected;
  - ii) Tranching: Depending on the timeframe of the assay – particularly where the assay will take a reasonable period to complete – tranching of the return of assay data is desirable. For example, if a metabolomic assay was conducted on 500,000 samples over a scheduled period of 3 years, then the data return might be in tranches of 5 tranches of 100,000 for example (this is one of the matters which is discussed and agreed between the Applicant and UK Biobank, and forms part of the MTA). The preferred access period applies to each relevant tranche;
  - iii) QC metrics: When a tranche of data is returned back to UK Biobank and is deemed to have passed all the relevant QC metrics, then the Applicant applies for the linking code to be released (and this must be done promptly within a month of completion of the return of the assay data). The release of the linking code – which enables the Applicant to link the assay data to the rest of the UK Biobank dataset – commences on the start of the relevant preferred access period; and
  - iv) Availability: At the end of the preferred access period, the assay data are made available by UK Biobank to all researchers through Showcase.

B10.5 Preferred access periods of 9-month duration are also available to researchers who fund enhancements that result in other types of additional data generation (such as cardiac rhythm data, accelerometry measurements or repeat imaging scans).

B10.6 In addition to the normal Access Fees, UK Biobank will charge incremental fees to the Applicant for its direct (such as sample extraction) and indirect costs (such as central overheads) of enabling the sample assay or enhancement.

## **B11 Re-contact applications**

B11.1 UK Biobank assesses re-contact applications in accordance with the re-contact procedures available [here](#). As stated above, an application by UK Biobank and the Applicant will need to be made to UK Biobank's REC.

B11.2 Re-contact applications are always assessed by UK Biobank's Access Sub-Committee and are subject to the same criteria as those for data applications as well the additional criteria for re-contact. UK Biobank regards re-contact as a de-facto depletable resource (akin to samples) in that UK Biobank Participants have a certain reasonable level of expectation about limited re-contact, but this is not inexhaustible.

B11.3 For a re-contact application to proceed:

- i) UK Biobank will make the first re-contact;
- ii) UK Biobank will have the right to comment upon and approve all materials (information forms and consent forms) of the re-contact project;
- iii) UK Biobank will require a suitable data sharing agreement with the Applicant (over and above the MTA); and
- iv) (similarly to sample applications) UK Biobank will charge the necessary incremental fees to recovery its direct and indirect costs of the re-contact application.

## **B12 Intellectual Property**

B12.1 UK Biobank's approach to Intellectual Property Rights (IPR) is unchanged. It is structured on the basis that it seeks to encourage use of the Resource for health-related purposes by bona fide researchers. To this end, UK Biobank will retain ownership of its rights in the Resource (so that it is available to all other approved researchers), while at the same time facilitating the development of clinical advances (e.g. diagnostics and treatments) arising from its use.

B12.2 UK Biobank is the owner of the property in the database and the samples (which will be added to, and updated, throughout the life of the Resource) and retains all the intrinsic IPRs in the data in the Resource (notably database rights and copyright).

B12.3 Researchers are granted limited licences (but not any ownership rights) to use the data and samples to conduct the Approved Research Project for a particular period of time. These rights are not assignable nor transferable, and nor is there any ability to sub-license.

B12.4 In terms of data generated by the researcher this falls into the following categories:

- i) assay data, the data generated by the Applicant pursuant to the pre-agreed assay (for sample/assay applications only);
- ii) findings, the findings generated by the Applicant;

- iii) results data, the data and methodology (for example the SAS/R/Stata scripts) which underlie the findings and which would enable another competent researcher to generate the findings; and
- iv) other data, all other data generated by the researchers, which is not findings, results data or assay data.

B12.5 In summary, the findings, results data and other data are all owned by the researcher subject to the licence back below:

- i) findings are required to be published;
- ii) results data are required to be returned to UK Biobank; and
- iii) other data are not required to be returned to UK Biobank.

B12.6 The findings, results data and other data are owned by the researcher, subject to the requirement to grant a non-exclusive licence back to UK Biobank for its use on an irrevocable, perpetual, worldwide, fully paid-up, royalty-free, fully sub-licensable basis (so that other researchers may use and review the results data).

B12.7 The results data includes summary data and derived variables – these include not just simple metrics like BMI but also derived phenotypes (for example dynamic volume analysis of the cardiac chambers) – as these are of considerable use to other researchers.

B12.8 In terms of assay data (derived from sample/assay applications), UK Biobank and the Applicant jointly own all IPRs in any and all of the assay data, subject to the following restrictions:

- i) UK Biobank will not transfer or distribute the assay data to a third party (including other researchers) until the expiration of the relevant preferred access period; and/or
- ii) the Applicant may use the assay data for the Permitted Purpose only.

B12.9 UK Biobank will have no claim over inventions and associated IPRs that are developed by researchers as a result of using the Resource, unless such IPRs are used to restrict health-related research and/or access to health-care unreasonably.

B12.10 UK Biobank does not intend to use this right to appropriate third party inventions, but does not expect naturally-occurring genetic sequences, biomarkers, proteins or biochemical processes to be made the exclusive preserve of one party. In this context, UK Biobank does not seek to restrict applications for the protection of IPRs, rather their use in an **unreasonably restrictive** manner.

B12.11 In the event that conduct is considered **unreasonably restrictive** by UK Biobank, it reserves the right to require that a licence of such rights is granted back to UK Biobank on an irrevocable, perpetual, worldwide, fully paid-up, royalty-free, fully sub-licensable basis so that other researchers who are granted access to use the Resource can exercise such rights to the extent necessary to conduct their research project. Of note is that this is not a step that UK Biobank has had to invoke over the past 9 years.

### **B13 De-identification of Participant Level Data**

B13.1 Each Participant who agreed to join the UK Biobank project received a clear assurance (and their consent to take part was provided on this basis) that all of their personal information would be held

in strict confidence with careful controls, and that identifiable information about them would not be available to anyone outside of UK Biobank.

- B13.2 All technical and legal measures that are available to UK Biobank are used to help ensure that each Participant's identity remains confidential. In particular, secure IT industry standard methods and regular external penetration testing are used to protect the main systems and database from accidental access or intentional abuse.
- B13.3 Identifying information is retained by UK Biobank to allow it to make contact with Participants when required and to enable linkage with their health-related records (although much of the linkage activity is undertaken without any identifying information being exchanged). The level of access that is allowed to a small number of staff within UK Biobank is controlled by unique usernames and passwords; and restricted and audited on the basis of their need to carry out particular duties.
- B13.4 UK Biobank makes as much (de-identified) data as possible publicly available on its Showcase database in grouped and summary format (i.e. no data are displayed at an individual Participant level), so that potential research users can evaluate what the Resource contains before applying to use it. This includes summaries of the questionnaire and physical measurement data and the types of biological samples collected, along with the numbers of Participants in various groupings of the data variables.
- B13.5 UK Biobank goes to significant lengths to de-identify all the data it releases to researchers, by removing direct and indirect identifiers, such that (even taking into account publicly available information) it should not be possible for a researcher to be able to re-identify a Participant. This is set out in more detail in the de-identification protocol [here](#).
- B13.6 Each Participant is assigned a unique identifier known as a PID, which is a randomly generated number (algorithmically derived) and cannot be reverse engineered by third parties. The PID is stored with both the identifiable Participant data and with the de-identified Participant data and acts as the "primary key" to link the information together. The data released to researchers is de-identified and is assigned unique, project-specific encoded identifiers known as the EID. Each EID is a number algorithmically generated by UK Biobank specifically for a particular research application. The link between a) the identifiable Participant data and the PID, and in turn b) the PID and EID is securely stored by UK Biobank. The EID can be reversed by UK Biobank but not by the researcher. The reason for this is that otherwise results and derived variables generated by researchers (which are of considerable utility to UK Biobank and to other researchers) could not be linked back at a Participant level. This is why UK Biobank does not fully anonymise the data as that would prevent such linkage.
- B13.7 Further, the MTA (available [here](#)) includes a strict prohibition on researchers identifying or trying to identify any Participant. In the case of inadvertent identification, researchers are required to report this immediately to UK Biobank and not to disclose it further or make any attempt to contact the individual.
- B13.8 UK Biobank does not require researchers – although researchers can if they wish – to make a formal application for data relating to selected types of Participant, and can request (indeed the majority of researchers do) access to the data for the whole Resource. UK Biobank responds promptly to questions about the Resource prior to submission of applications and during the course of considering them.

## **B14 Data protection**

B14.1 One of the areas where UK Biobank's Access Procedures have become more complicated is in the area of data protection: this is as a direct function of changes in data protection regulation in the UK and abroad. UK Biobank would emphasise two things:

- i) it has been the recipient of extensive expert advice and input in this area; and
- ii) it has sought to address the prevailing regime in a manner it considers most practical and least bureaucratic for researchers.

B14.2 Under the original data protection regime, as long as the UK Biobank data were appropriately de-identified - with no realistic prospect of re-identification occurring – then the data provided by UK Biobank was not considered personal data and thus the transfer of data to researchers was not (legally speaking) subject to the data protection regime. Nevertheless, UK Biobank's contractual clauses (in the old MTA) effectively imposed standards on researchers to treat UK Biobank data to the same standard as if it were personal data.

B14.3 The situation under the UK GDPR is more complex and whether or not UK Biobank is providing personal data to researchers is now significantly less clear cut. UK Biobank considers that it is possible that some UK Biobank data (in particular, more detailed data such as Whole Genome Sequencing data) may be considered by some regulatory authorities to contain personal data. As such, the data protection clauses have been re-framed on the basis that the UK Biobank data supplied to researchers is *personal data*.

B14.4 Personal data, as defined in the UK GDPR, means any information relating to an identified or identifiable natural person. An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as an identification number or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

### *The prevailing law*

B14.5 The UK Data Protection Act 2018 (DPA) sets out the framework for data protection law in the UK. It came into effect on 25 May 2018. It sits alongside the UK GDPR, and impacts on how the UK GDPR applies in the UK.

B14.6 The EU GDPR is the General Data Protection Regulation (EU) 2016/679. It sets out the key principles, rights and obligations for the processing of personal data. It came into effect on 25 May 2018. As a European Regulation, it originally had direct effect in UK law and automatically applied in the UK until the end of the Brexit transition period. The GDPR now forms part of UK law under the European Union (Withdrawal) Act 2018, with some technical changes to make it work effectively in a UK context. It is now referred to as the "UK GDPR".

B14.7 In addition, specific EU Exit Regulations (aka Brexit) amend the GDPR, the DPA and other privacy regulations so that these laws can continue to work properly in a context where the UK is no longer an EU Member State.

### *Controllers and processors*

B14.8 In the UK GDPR there are two principle categorisations of an organisation using personal data: namely controllers or processors. A controller determines the purposes and means of the processing of personal data. UK Biobank is a controller of the UK Biobank data. A processor processes personal data on behalf of the controller. The processor must act on the instructions of

the controller and does not have the discretion to determine the purposes and means of processing of the personal data.

- B14.9 UK Biobank considers that a researcher is a separate and independent controller (not a processor) of the Participant Level Data. Although the scope of the research project is approved by UK Biobank, the researcher (rather than UK Biobank) determines the specific purposes and means of the processing by which the Participant Level Data are used by the researcher in order to conduct its Approved Research Project.
- B14.10 As the researcher needs to conduct the research (and not UK Biobank), they must determine the means and purposes of the processing in relation to the Participant Level Data. They are not under the instruction of UK Biobank, and thus they are acting as a separate and independent controller – not as a processor – in the context of a research project.
- B14.11 Even though the researcher is a separate and independent data controller of the Participant Level Data – it is not a joint controller with UK Biobank. The researcher’s use and processing of the Participant Level Data must be strictly in accordance with the Approved Research Project, Permitted Purpose and the provisions of the new MTA.
- B14.12 As such, UK Biobank requires the researcher to treat UK Biobank data as if the researcher is a separate and independent controller of the UK Biobank data and as if the UK Biobank data is personal data. The specific requirements on the researcher contained in the new MTA are a direct function of these requirements.
- B14.13 The relevant provisions in the new MTA are necessary in order for the parties to adhere to the prevailing legislation in the UK (which is the UK GDPR and the Data Protection Act 2018). Compliance with these provisions enables UK Biobank to provide the data to the researcher.

#### *Lawful basis for processing*

- B14.14 Every data controller requires a lawful basis to process personal data under the UK GDPR: UK Biobank is no exception. Consent is an important part of the research process and UK Biobank sought explicit consent (which consent covers the confidentiality requirements) from all of its Participants in order to participate in UK Biobank. However, consent to participate in research is not the same as consent being the lawful basis for processing personal data under the UK GDPR. Therefore, when processing the Participant Level Data that forms the UK Biobank Resource, UK Biobank relies on legitimate interests as set out in Article 6(1)(f) and (due to the “special category” data) Article 9(2)(j) of the UK GDPR.
- B14.15 Notwithstanding UK Biobank’s reliance (for data protection purposes) on legitimate interests and for reasons of public interest as its lawful basis for processing Participant Level Data, it should be expressly noted that UK Biobank would not do anything with Participant Level Data which was not within the bounds of the original participant consent, as that is the basis on which Participants were recruited. For example, it does not affect the ability of a Participant to withdraw from UK Biobank for any reason at any time.

#### *Data Protection Officer*

- B14.16 UK Biobank has 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 UK GDPR. Please write to the DPO using [dpo@ukbiobank.ac.uk](mailto:dpo@ukbiobank.ac.uk) or via post: The Data Protection Officer, UK Biobank, Units 1-2 Spectrum Way, Adswood, Stockport, SK3 0SA.

### *International transfers of data*

- B14.17 The UK GDPR restricts transfers of personal data outside of the UK, unless the rights of the individuals in respect of their personal data are protected in another compliant way. There are limited circumstances in which personal data relating to UK data subjects (i.e., the Participant Level Data) can be transferred outside of the UK.
- B14.18 In accordance with the UK GDPR, there are two mechanisms by which UK Biobank will permit transfers of the Participant Level Data to researchers located outside of the UK: (i) to researchers located in a country covered by an "adequacy regulation" or (ii) in accordance with approved standard contractual clause, such as EU Standard Contractual Clauses or the International Data Transfer Addendum to the EU Commission issued by the UK Information Commissioner ("**UK Addendum**"):
- i) *Adequacy Regulations*: adequacy determinations are made by the UK government and currently the territories covered are the EEA, EU or EEA institutions, bodies, offices or agencies, Andorra, Argentina, Canada (commercial organisations), Faroe Islands, Gibraltar, Guernsey, Isle of Man, Israel, Jersey, New Zealand, Japan (private sector organisations), Switzerland or Uruguay. These territories may be updated by the UK Government from time to time both to add or remove territories from the relevant list. If the researcher is located in a territory covered by an adequacy regulation then the transfer of personal data from the UK to these countries is permitted and no further action is required.
  - ii) *EU Standard Contractual Clauses/UK Addendum*: If the researcher is not located in one of the listed countries then approved standard clauses will automatically apply to any such transfer. Historically, the standard clauses were the Controller-to-Controller EU Standard Contractual Clauses and this is what UK Biobank has applied to date. Due to the UK leaving the EU, the UK Information Commissioner's Office ("**ICO**") has produced a separate set of standard clauses, called the UK Addendum, and these will be deemed to be incorporated (as necessary) into the new version of the MTA issued from the end of July 2022 onwards. The new clause provides for the mechanism for this incorporation and no further action – other than familiarisation with the UK Addendum by the researcher – is required.

In UK Biobank's view, the EU Standard Contractual Clauses and the UK Addendum create broadly comparable obligations on the researcher, although the researcher is advised to review the relevant obligations and seek their own advice and counsel.

Researchers currently using the EU Standard Contractual Clauses – under the ICO's transitional provisions (available [here](#)) - are permitted to continue to use these clauses until 21 March 2024. For research projects which may extend beyond 21 March 2024 and are currently using the EU Standard Contractual Clauses, UK Biobank will issue a further announcement at the end of 2023 which will provide for an automatic change from the EU Standard Contractual Clauses to the UK Addendum.

It should be noted that neither the EU Standard Contractual Clauses nor the UK Addendum are negotiable and automatically invalidated by any change. The EU Standard Contractual Clauses and the UK Addendum incorporated into the MTA are available [here](#) and [here](#). Where they apply, the researcher must familiarise themselves with these obligations. To the extent that the UK GDPR applies to the researcher as a controller, more information can be found on the UK Information Commissioner's Office website [here](#) and [here](#).

## **B15 Contact with Participants**

- B15.1 Any and all contact with individual Participants must only ever be undertaken by UK Biobank.
- B15.2 There is no realistic prospect that a researcher would be contacted directly by a UK Biobank Participant. However, should this happen (or appear to happen, as a researcher has no means of establishing whether an individual is or is not a Participant and is in any event prohibited to trying to re-identify or contact Participants), the researcher should not engage with the Participant and instead refer the enquiry promptly to UK Biobank.

## **B16 Data security and cloud policy**

- B16.1 UK Biobank has an obligation to its participants (and under the UK GDPR) to ensure that UK Biobank data and samples are stored, retrieved and used securely, with appropriate organisational and technical measures in place. UK Biobank must also take reasonable steps to ensure that the data and samples it shares continue to be protected with adequate security.
- B16.2 Therefore, UK Biobank expects researchers to implement the security measures set out in the new MTA (available [here](#)) as a minimum to ensure that the data provided by UK Biobank to researchers are stored, processed and used in a secure and compliant manner with appropriate measures in place to restrict access only to authorised users and to protect from unauthorised access by internal and external parties.
- B16.3 Cloud storage of UK Biobank data is permitted as long as the researcher remains fully responsible for the UK Biobank data and the cloud storage is compliant with the provisions of the MTA.

## **B17 Research Analysis Platform and downloading data**

- B17.1 The Research Analysis Platform (“**RAP**”) is a cloud-based platform, developed by UK Biobank in conjunction with the platform provider, providing a research environment that will allow researchers to access UK Biobank’s data without the need to download the data. It provides access to storage and compute resources that allows researchers to undertake their analyses within the platform.
- B17.2 The RAP contains several tools to allow analysis across the various modalities within the UK Biobank datasets. Further details about the RAP are available [here](#).
- B17.3 Researchers are not obliged to but may (if they wish) publicise their code, example notebooks or tools so that they can be used freely by other researchers within the RAP. Further, when a researcher has completed their analysis, there is an option to return data via the RAP directly to UK Biobank.
- B17.4 For researchers undertaking an Approved Research Project, there is no additional charge by UK Biobank to access the RAP. However, whilst there is no upfront charge to researchers using the RAP, the great majority of activities will incur a fee (payable to the platform provider), for example there are fees for storage of uploaded or derived data, compute and analysis (dependent on instance type) and egress charges.
- B17.5 Please also note that every researcher who uses the RAP will have to accept certain standard terms and conditions of usage with the platform provider which are available [here](#).
- B17.6 Although much of the UK Biobank data are still available for download, UK Biobank has decided to introduce restrictions on downloading data for very large datasets: these very large datasets will only be available through the RAP. For example, researchers must only access and use the Whole

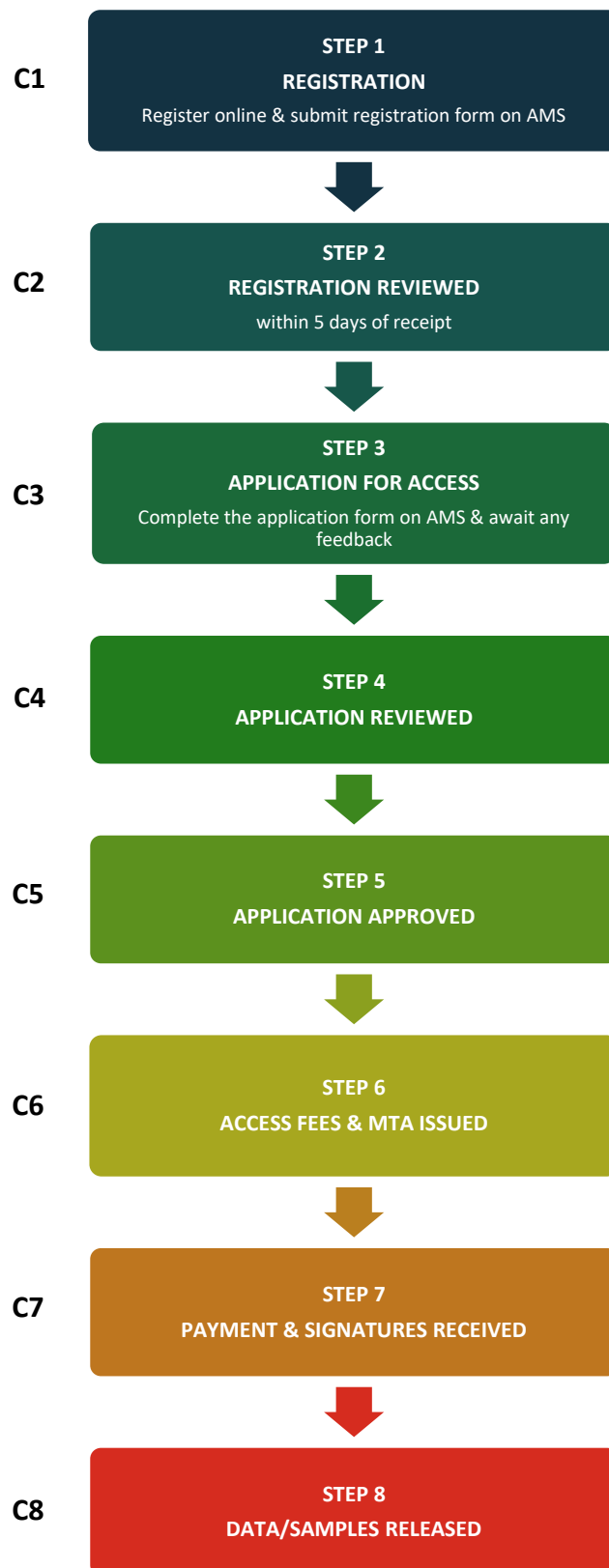
Genome Sequence data and (from now on) the Whole Exome Sequence data on the RAP. It will still be possible for the other UK Biobank data to be downloaded by a researcher from the RAP or existing UK Biobank provided download services, as before in a de-identified form.

- B17.7 Researchers must not subvert (or attempt to subvert) the principle of accessing the Whole Genome Sequence data or Whole Exome Sequence data via the RAP only. For example, it would not be appropriate for a researcher to make a minor modification of a sequence (such as adding a '0' to the data content) for it to be treated as derived data and therefore downloadable from the RAP.
- B17.8 All data is available within the RAP, but access to data (and the ability to download data) depends on the Tier Access Fee paid. There are also certain restrictions on downloading from the RAP. Please refer to UK Biobank's [website](#) for further information.
- B17.9 There is no limit on the size of data (save that the cost of data storage to the researcher will increase according to the amount of data stored in the RAP) or the type of data that can be imported into the RAP. Data must be used in line with the UK Biobank's MTA and the RAP terms and conditions.
- B17.10 It should be noted that the main UK Biobank dataset accessible through the RAP is stored in the AWS cloud on the London node (EU-West-2).

## **B18 Low-Middle Income Countries and student researchers**

- B18.1 Applications from Low and Low-Middle Income Countries ("LMIC") will be considered for the reduced Access Fee where they meet the criteria defined by the [World Bank guidelines](#). UK Biobank will monitor LMIC applications to ensure the benefit of a reduced fee for a LMIC Applicant is not being used by other institute to avoid paying the full Access Fees.
- B18.2 Applications from bona fide postgraduate students will be considered for the reduced Access Fee where the following criteria are met:
- i) The application is submitted by a student or their supervisor for the sole purpose of performing a postgraduate student project (e.g. MSc, PhD or equivalent). Authorship of the resulting paper must be led by the student;
  - ii) The application cannot be used to conduct research for any other purpose, nor can it be used for multiple student (or other) projects; and
  - iii) Any Collaborators must have a clearly articulated and relevant role in of the student's research project (and will be permitted only at UK Biobank's discretion).
- B18.3 For eligible LMIC and student applications, a reduced Access Fee is payable and provides access to all datasets via the RAP only (full Access Fees apply to downloaded data).
- B18.4 A grant application process will be available in early 2022 to provide postgraduate student researchers, early career researchers and researchers from LMIC with researcher credits to be used in the RAP which will enable free compute on the RAP. This is provided in conjunction with Amazon Web Services (AWS).

## C THE APPLICATION PROCESS



**Please note** – any queries regarding registration, application or the MTA should be addressed to the Access Team via AMS or email ([access@ukbiobank.ac.uk](mailto:access@ukbiobank.ac.uk)) in the first instance.

## **C1 Registration**

C1.1 All researchers who wish to access UK Biobank data are required to register with UK Biobank via the [Access Management System \(AMS\)](#). This registration process, overseen by the UK Biobank Access Team, is set out [here](#). All researchers must submit a registration form so that UK Biobank can determine:

- i) that the researcher is who they say they are and is appropriately employed (or engaged) by the Applicant Institution; and
- ii) that the researcher is a bona fide researcher.

C1.2 In order to determine (i) and (ii) above, the Access Team will review each registration and consider the following information (amongst other factors) within the researchers registration form:

- i) their name, address, and email (appending an electronic version of their curriculum vitae or similar document);
- ii) a list of their peer-reviewed publications (with hyperlinks to the papers whenever possible); and
- iii) the research department, and website for their Institution.

## **C2 Registration reviewed**

C2.1 The Access Team aims to review registrations within 5 days of receipt. The review will result in a registration being approved or declined.

C2.2 When a registration has been approved (involving the Access Team satisfactorily confirming the identity and the bona fides of the researcher), the researcher will be assigned a unique identifying number (indicating to UK Biobank that they are an approved researcher).

C2.3 Summary details of researchers are published on the UK Biobank website along with summary details of their (when approved) research application.

## **C3 Application for access**

C3.1 Once registered, in order to access the Resource, an Applicant PI must complete and submit an application form (available within AMS) to UK Biobank. An Applicant PI must also select the data they require. This application needs to be completed, to the satisfaction of both:

- i) the UK Biobank Access Team, who ensure the information is accurate and complete; and
- ii) the UK Biobank Scientific Team, who assess the information provided in order to make a judgement as to whether the application meets the required criteria for access.

C3.2 The application process is set out on the UK Biobank website [here](#). This application process includes the provision of the following by the Applicant PI to UK Biobank:

- i) a short lay summary of the application;
- ii) names of all researchers working on the application (including any Affiliate Institution(s), Collaborator Institution(s), any Applicant Researcher(s), Collaborator Researcher(s) and/or any researcher from an Affiliate); and

- iii) summary scientific rationale of project (research question and aims; background and any pilot data; a brief overview of the planned methodology; expected value and public health impact of results).

C3.3 The Applicant PI also needs to ensure that each Applicant Researcher, Collaborator Researcher and any researcher from an Affiliate associated with the Approved Research Project has registered (following section C1 above) with UK Biobank.

C3.4 The Applicant PI must add contact information for a signatory who is authorised to sign the MTA on behalf of each Institute.

C3.5 UK Biobank's orientation is to facilitate research and thus the emphasis is on whether:

- i) the research project is compatible with UK Biobank's access criteria; and
- ii) is generally viable/feasible given the nature of the UK Biobank Resource.

C3.6 UK Biobank does not consider that its remit is to second guess the science behind the application (except in situations where the application is potentially untenable, absurd or unethical).

#### **C4 Application reviewed**

##### *Data applications*

C4.1 All data applications are reviewed by:

- i) the UK Biobank Access Team, who ensure the information is accurate and complete; and
- ii) the UK Biobank Scientific Team, who assess the information provided in order to make a judgement as to whether the application meets the required criteria for access. Please see section C10 below for more information about the roles of these parties in the application review process.

C4.2 There are four possible outcomes to this review:

- i) the application is approved by the UK Biobank Scientific Team and is listed for information only to the Access Sub-Committee. The Access Sub-Committee can raise any queries in relation to the application if they wish to do so;
- ii) the application is referred back to the Applicant PI for amendment;
- iii) the UK Biobank Scientific Team escalate the application to the Access Sub-Committee with a recommendation for it to be declined. The Access Sub-Committee will review and discuss the application and may approve or decline the application. Where an application is declined, reasons will be provided and where relevant, suggestions whereby a successful application may be made; or
- iv) the UK Biobank Scientific Team escalate the application, where unusual, contentious, ethico-legal or novel issues arise, to the Access Sub-Committee for specific consideration and approval.

C4.3 If an Applicant PI is advised that UK Biobank is minded to decline an application then they may request that the application be reconsidered by UK Biobank.

C4.4 The process for having an application reconsidered is as follows:

- i) Within 3 months of the relevant decision, the Applicant PI should submit a written request, giving their reasons why they consider that the decision should be revised;
- ii) Within 3 months (although likely to be sooner) of receipt of such a request, the Access Sub-Committee or the Board (as appropriate) will aim to consider it along with the original application (and any other information that it considers pertinent) and UK Biobank will then respond to the Applicant PI;
- iii) If considered necessary, the Access Sub-Committee or the Board may seek additional advice (e.g. from scientific or other experts, or the EAC), in which case the Applicant PI will be advised by UK Biobank of any revision to the timetable for review.

C4.5 If, following reconsideration, the application is declined then the Applicant will not be able to submit the same proposal again within a 12-month period (unless the Access Sub-Committee has indicated specifically that it may be submitted subject to specific changes being made).

*Sample and re-contact applications*

C4.6 All sample and re-contact applications are considered in the first instance by the UK Biobank Access Team/Scientific Team/Laboratory Team. In turn these applications are **all** referred to the Access Sub-Committee to review and consider:

- i) sample applications according to the sample release policy (available here);
- ii) (third party) re-contact according to the re-contact procedures (available here).

**C5 Application approved**

C5.1 Once all parties in the application review process are satisfied that the application is accurate and meets the required criteria for access, UK Biobank will approve the application. This approval is valid for 90 days during which time the Applicant must pay the Access Fees and sign the MTA. Please see section C6 below for more information.

C5.2 It will generally take a matter of weeks from application submission for an application to be approved, but may take longer for complex applications to be approved. For the current application processing times, please check UK Biobank's website [here](#).

**C6 Access Fees and MTA issued**

C6.1 UK Biobank charges researchers Access Fees to access the Resource on a cost-recovery basis. Please see section A5 above for more information.

C6.2 Once the Access Fees have been calculated by UK Biobank, they will be raised and available to view in the payment section of the application on AMS. This allows the Applicant to generate an invoice on which VAT will be included (if appropriate, and as such VAT will not be included if the Applicant is based outside of the UK).

C6.3 Payment to UK Biobank must be made in full and in British pounds sterling (GBP). When paying the Access Fees, the Applicant shall quote the invoice number and/or application reference number as the payment reference, and also send a remittance note to [creditcontrol@ukbiobank.ac.uk](mailto:creditcontrol@ukbiobank.ac.uk).

C6.4 All Applicants and Collaborators are obliged to enter into the MTA with UK Biobank. It is not negotiable. This is for the simple reasons of transparency / fairness in that UK Biobank's remit is to treat all Applicants in an equivalent manner and not offer preferential or differential arrangements.

C6.5 The MTA is available on UK Biobank's website [here](#), however an MTA will be sent via email to the relevant parties for signature. All MTAs are now executed electronically. No hard copies are executed or provided.

C6.6 The Applicant should facilitate prompt payment of the Access Fee request and return the signed MTA as soon as possible.

## **C7 Payment and signatures received**

C7.1 Once payment of the Access Fees has been made and the MTA has been signed by all parties, the Access Team will inform the Applicant and access to the UK Biobank Resource will be granted and the Approved Research Project will begin.

## **C8 Data/Samples released**

C8.1 Once the MTA has been signed and the Access Fees have been paid:

- i) UK Biobank data will be available in the RAP, or via download for certain datasets, to approved researchers working on the Approved Research Project; and/or
- ii) UK Biobank samples will be released to approved researchers working on the Approved Research Project in the manner agreed between UK Biobank and the Applicant in the MTA.

## **C9 Accessing the RAP**

C9.1 Any researcher approved by UK Biobank can create an account in the RAP at any time during the application process.

C9.2 Once payment of the Access Fees has been made and the MTA has been signed by all parties in accordance with sections C6/C7 above, the researcher can dispense a project in the RAP under their Application ID number as follows:

- i) if the researcher has a tiered application (i.e. access to specific tiers of data under the new Access Fee regime since 1 April 2021), the relevant tiers of data will be available in the RAP to dispense at this point;
- ii) if the researcher has a non-tiered application, the data will be available in the RAP to dispense when the researcher receives the notification from the UK Biobank that is available to download.

## **C10 Roles of the parties in the application review process**

C10.1 [UK Biobank Board](#) has overall responsibility for the Access Procedures. It delegates oversight of the review process, the conduct of the access process and all access decisions to its Access Sub-Committee. The Access Sub-Committee is obliged to report to the UK Biobank Board on a quarterly basis and highlights any particular issues or considerations.

C10.2 [The Access Sub-Committee](#) has overall control and responsibility for the Access Procedures:

- i) it has a minimum of two Board members (and is chaired by a Board member) and can contain external members;
- ii) meetings of the Access Sub-Committee are attended by the members of the Access Sub-Committee, the UK Biobank PI, the UK Biobank Scientific Team, the UK Biobank Access

Team, senior members of the UK Biobank Executive (including the deputy CEO and the General Counsel), a member of Ethox (See C10.7) and a representative from the EAC;

- iii) it meets quarterly immediately before UK Biobank Board meetings;
- iv) relevant experts can be invited to attend specific meetings of the Access Sub-Committee to give advice on particular applications;
- v) it considers the reports provided to it by the UK Biobank Access Team on the status of each application (which will highlight any material issues) at its quarterly meetings;
- vi) it can review the detail of any individual application;
- vii) it is able to feedback comments at any time to UK Biobank Access Team about any applications that it wishes to review in more detail before any data and/or samples are released; and
- viii) refers all applications on which it does not reach a unanimous decision to the UK Biobank Board, along with any others on which it requires further guidance.

C10.3 *The UK Biobank Principal Investigator (“UKBPI”)* is responsible for providing scientific leadership to UK Biobank and ensuring that the Resource is used to optimum effect by setting clear criteria and priorities for its use. The UKBPI is advised by a [Strategic Oversight Committee](#) which contains individuals with appropriate scientific expertise. In particular, the UKBPI (or their designate):

- i) is responsible for developing and managing the access process, and for proposing modifications to the access process to the UK Biobank Board as experience with access to the Resource increases; and
- ii) seeks advice on applications from the Strategic Oversight Committee and, as required, from other relevant experts.

C10.4 *The UK Biobank Access Team* undertakes the administrative work related to access applications and conducts checks against the established criteria. In particular, the Access Team:

- i) establishes the identity of potential researchers;
- ii) reviews each application form ; and
- iii) provides a report on the status of each application for information or review by the Access Sub-Committee.

C10.5 *The UK Biobank Scientific Team* provide scientific review and guidance on each application.

C10.6 *The UK Biobank Laboratory Team* review and provide guidance on sample applications.

C10.7 *Ethox* is a multidisciplinary bioethics research centre based in the University of Oxford’s Department of Public Health. It has an arrangement with UK Biobank to provide ethics advice on request, and by regular discussion of applications under review, related to:

- i) specific issues raised by particular applications;
- ii) general considerations involved in certain types of research; and
- iii) more general ethics advice related to the work of UK Biobank.

C10.8 The [Ethics Advisory Committee](#) (EAC) superseded the original Ethics and Governance Council and is a sub-committee of the UK Biobank Board with remit to provide advice to the UK Biobank Board on ethical issues that arise during the maintenance, development and use of UK Biobank.