

Researcher Responsibilities Guidance:

Publication and acknowledgement, completion of the annual reports and return of results to UK Biobank

UK Biobank was set up to enable researchers to readily access the detailed and extensive data resource. In return, UK Biobank has a certain set of requirements (which are contained in the Material Transfer Agreement), which it applies to all researchers.

These requirements oblige researchers to publish their findings and return information and materials to UK Biobank in a timely manner. UK Biobank will endeavour to remind researchers about these obligations but equally UK Biobank would re-iterate to researchers that it considers that these obligations are fundamentally their responsibility (and are not contingent on whether a reminder is issued).

Publication and acknowledgement

- 1. All researchers (with approved research projects) must use all reasonable endeavours to publish their findings (this obligation is set out in the Material Transfer Agreement (MTA) which is available here). The publication of findings should be within six (6) months of the completion date of the approved research project:
 - in an academic journal; or
 - on an open-source publication site.
- 2. If the publication is available as pre-print (such as in BioRxiv) then both the pre-print and the subsequent publication itself shall be made available to UK Biobank. In terms of the six (6) month time frame, UK Biobank will take this from the date of first publication (i.e., from the date on which the findings are first made public, whether in a presentation, pre-print, publication or similar).
- 3. UK Biobank requires that the relevant first publication shall be sent to UK Biobank *at least two (2) weeks* before the expected date of first presentation/publication in whatever format (e.g., paper journal, on-line report, meeting abstract). The researcher shall upload such documents to <u>AMS</u> in the first instance. If this is not possible, the researcher shall email such documents to access@ukbiobank.ac.uk.
- 4. All publications must include the following credit information within the acknowledgements section of their manuscripts, 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 information should be linked, wherever possible, to reference search tools (such as PubMed and MEDLINE).

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- 5. UK Biobank recognises that there may be factors which impact on the publication of findings such as awaiting peer review, a journal's own timetable, protecting Intellectual Property Rights and as such the relevant dates are not necessarily so definitive. In such cases, the researcher shall contact UK Biobank with appropriate information explaining any such delay. In the event of non-compliance with this requirement, UK Biobank will follow a comparable protocol as set out in relation to (non-compliance with the) return of results below.
- 6. A researcher is permitted to incorporate UK Biobank's participant scans or images within a publication of findings bearing in mind the following criteria:
 - reconstructions of the head and skull resulting in potentially identifiable images are not permitted;
 - images which could reveal very individuated external pathology (which are potentially identifying, for example an unusual amputation) should not be used;
 - participant level data (such as gender, age etc.) should not be used in conjunction with a particular image;
 - UK Biobank's licence to a researcher to use a UK Biobank image is limited solely for the necessary purposes of the publication of the findings;
 - A credit © UK Biobank is also required;
 - If there is any reasonable doubt relating to the publication of a particular image the researcher should contact UK Biobank at access@ukbiobank.ac.uk.

Completion of annual reports and return of results

These obligations include the following requirements for researchers:

- To submit an annual report (which is on the anniversary of the effective date of the MTA)
 which confirms that the details of the researchers are accurate and that the research project
 remains compliant with the approved application and UK Biobank's security requirements
 regarding its data;
- To return the results data to UK Biobank the data which underpins the findings within 6 months of publication of the findings. This includes findings published on preprint servers, unless the same research has been submitted for peer review to an alternate journal within this 6-month timeframe.

The purpose of this section of the note is not only to remind researchers of these obligations but also to set out the triage of actions which UK Biobank may elect to take in the event of non-compliance.

- 1. Where possible automatic reminders will be issued by UK Biobank in advance of the relevant deadline for compliance. For example:
 - Annual report: various reminders will be sent in advance of the anniversary for submitting the annual report (which date is set by the effective date i.e., if the MTA is executed on 1 January 2022, then the first annual report is due on 1 January 2023);
- 2. The reminder will highlight the relevant due date and requirement and provide details of the location of the necessary documentation (such as the annual report) which is required.
- 3. If the annual report is outstanding after the due date, the status of the research project will also automatically move to "lapsed" which means the project will be inactivated temporarily within

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AMS (which de-activation steps may include de-activating the researcher(s) themselves). This will result in the researchers working on the research project being unable to refresh their datasets or submit change. Further, the research project's access to the RAP will be inactivated. This inactivation will be lifted on prompt compliance with the requirement.

- 4. In the event that the relevant requirement remains outstanding 3 months after the relevant deadline, then UK Biobank has a number of options (which are not mutually exclusive) which it will consider and implement:
 - Terminate the MTA and require the immediate deletion of all UK Biobank data;
 - Contact the researcher's institution and prevent any further researchers from that institute from gaining access to UK Biobank;
 - (And in instances of repeated, overt or wilful non-compliance) UK Biobank will contact the funders of the research and publicise the non-compliance.
- 5. If the approved project has approved Collaborators, then the following will also apply:
 - If the non-compliance is related to the Applicant, then the steps in 3 and 4 will apply to both the Applicant and **all** those listed as Collaborators (as UK Biobank considers that the Applicant has *primary* responsibility to UK Biobank and so Applicant non-compliance should impact on all researchers working on the approved project);
 - If the non-compliance is related to a single Collaborator, then the steps in 3 and 4 will apply solely to the Collaborator;
 - If non-compliance is related to a number of Collaborators, then UK Biobank may elect to take the same steps as apply to non-compliance from the Applicant.

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