

UK Biobank Ltd Withdrawal Protocol

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2 Amendment History

Version	Date Issued	Brief Summary of Change	Owner's Name/Signature
0.1	14.12.2011	Original draft	Lorraine Gillions
0.2	26.03.2012	Final draft for consultation	Jonathan Sellors
1.0	03.04.2012	Final agreed version	Lorraine Gillions

3 Approvals

3.1 Content

Version	Name	Organisation	Signature	Date
0.1	Lorraine Gillions	UK Biobank	Lorraine Gillions	14 th December 2011
0.1	Erin Scobie	UK Biobank	Erin Scobie	15 th December 2011
0.2	Jonathan Sellors	UK Biobank	Jonathan Sellors	26 th March 2012
0.2	Rory Collins	UK Biobank	Rory Collins	30 th March 2012

3.2 Quality Review

Version	Due Date	Name	Organisation	Signature	Date

4 Distribution

Version	Name	Organisation
1.0	Andrew Trehearne	UK Biobank

- 4.1 This is a UK Biobank controlled document. The policies described in this document form part of the UK Biobank Access Procedures. Amendments are only permitted via the document change procedure defined in **GEN02**. On receipt of a new version, please destroy all previous versions (unless a specified earlier version is in use throughout the project).

5 Introduction

- 5.1 This document has been written to support the Access Procedures and expand upon the Participant Withdrawal process as described in the UK Biobank Protocol, [[url to Ethics and Governance Framework](#)] and [[url to Participant Information Leaflet](#)].

6 Purpose and Objectives

- 6.1 This protocol defines the impact of Participant Withdrawal on applications to access the UK Biobank Resource. The objective of this protocol is to ensure that the Access Team and all researchers are aware of their roles and responsibilities'.

7 Participants Withdrawal Rights

- 7.1 Participants were advised at enrolment that they had the right to withdraw from UK Biobank at any time without having to explain why and without penalty. This was essential to preserve and demonstrate the voluntary nature of participation.
- 7.2 Despite UK Biobank's efforts to stay in touch with participants, it may well lose contact with some as they relocate, emigrate, or do not respond to communications. Where a participant has not actively withdrawn, UK Biobank will continue to use the samples and data and maintain linkages, although it will not be able to update some data (e.g. those collected by repeat questionnaire).
- 7.3 During enrolment, UK Biobank provided information to participants about the options for withdrawal in a Participant Information Leaflet. The 3 options are:
- a. No further contact
 - b. No further access
 - c. No further use

8 Impact on Access to the Resource – samples not released

- 8.1 The consequences if a participant withdraws with "no further contact" are as follows:
- 8.1.1 Data: (a) UK Biobank can continue to use all the participant's phenotypical data and to link to their health records and (b) from that date, UK Biobank cannot recontact this participant; and
 - 8.1.2 Samples: UK Biobank can continue to supply these samples to researchers.
- 8.2 The consequences if a participant withdraws with "no further access" are as follows:
- 8.2.1 Data: (a) UK Biobank can continue to use all the participant's phenotypical data and all linkage data supplied to that date and (b) from that date, UK Biobank cannot incorporate any further linkage data relating to that participant and UK Biobank cannot recontact this participant; and
 - 8.2.2 Samples: UK Biobank can continue to supply these samples to researchers.

8.3 The consequences if a participant withdraws with "no further use" are as follows:

8.3.1 Data: (a) UK Biobank can continue to hold the participant's phenotypical and linkage data for audit purposes and (b) from that date, UK Biobank cannot incorporate any further linkage data relating to the participant and (c) from that date, UK Biobank cannot continue to supply these data to researchers; and

8.3.2 Samples: (a) UK Biobank cannot continue to supply these samples to researchers and (b) UK Biobank will destroy these samples.

9 Impact on Access to the Resource – samples released

9.1 From UK Biobank's standpoint the above protocol still applies but the following additional steps are needed (only relevant in relation to the "no further use" option).

9.2 The consequences if a participant withdraws with "no further contact" are as follows:

9.2.1 Data: this would have no impact on the researcher; and

9.2.2 Samples: this would have no impact on the researcher.

9.3 The consequences if a participant withdraws with "no further access" are as follows:

9.3.1 Data: this would have no impact on the researcher; and

9.3.2 Samples: this would have no impact on the researcher.

9.4 The consequences if a participant withdraws with "no further use" are as follows:

9.4.1 Data: UK Biobank contacts the researcher to request that (a) the data (of any type) from that participant are no longer used in further research and effectively deleted (rendered unusable) but that (b) it can still be included in analyses that have already been done; and

9.4.2 Samples: UK Biobank contacts the researcher to request that (a) the samples from that participant are destroyed forthwith and (b) *to the extent possible* sample remnants should also be destroyed forthwith.