Guidance for researchers applying to access samples

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Prepared For UK Biobank applicants

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1 Introduction

The UK Biobank Access Procedures provides guidance on the process for applying to use the UK Biobank resource. Applications involving the use of depletable samples are subject to a review of a) the science behind the application, b) the justification for the use of samples, c) the methodology of the proposed assays, d) the quantity/volume requested and e) may be prioritised against other applications. This process is outlined in this document.

An overview of the process is outlined in Figure 1 and further detail of each stage is described below.

2 What information should you provide during the application process?

Following submission of a preliminary application that requests samples, you will be asked to provide additional information on:

- **Sample requirements**: This includes sample type, number of samples requested (including duplicates), empty wells, sample volume (and if applicable, DNA concentration) and shipment requirements.
- **Assay details:** This includes assay methodology to be used, validation data (from the laboratory performing the assay), performance characteristics (e.g., intra- and inter-batch CVs) and proposed QC plan.

The UK Biobank laboratory and scientific teams will discuss these criteria with you to agree the methods, QC plan and inclusion criteria. Once this has been finalised we can provide you with a final costing (which is valid for 90 days) and these criteria will be included in the MTA.

We will also assign a Project Manager who will liaise with you throughout the duration of the project.

3 Pilot study

For most projects, we will ask that you demonstrate the quality of the assay data using the most appropriate means. The applicable means will depend on the nature of the assay. It may be the case that the assay is very well known and reliable: alternatively it may be a new untested assay. These factors will determine the how the assay is tested, the nature of the pilot samples used (UK Biobank's or possibly third party samples) and the quality metrics to be generated and benchmarked. If pilot samples are required, these will be supplied by UK Biobank. Blind Spike Duplicate and negative control samples will ordinarily be included in both the pilot and main study.

The pilot data (and any other relevant meta-data) must be returned to UK Biobank for review against the QC metrics as outlined in the MTA. We may involve external experts as necessary. If the pilot data meets the agreed criteria, then the requested samples can be processed.

4 Release of samples for the main study

Once the pilot has been completed satisfactorily, sample processing for the project will begin at UK Biobank. Samples will be selected based on the criteria included in the application. Timelines for the project will be supplied by the Project Manager who will regularly update the Principal Investigator on progress and scheduled shipment dates.

Samples will be shipped to the requested location and a sample manifest provided including a sample name, plate name and well position, and any other necessary fields, as outlined in the MTA.

We may require periodic updates on the sample processing and this will be included in the MTA. For example, this might include the return of data at agreed intervals (e.g. after 5,000 samples) or a verbal update on the data quality.

Once all of the assay results have been returned to UK Biobank, we will make available the phenotypic dataset for your research project. We will not make these assay data available to other researchers until the stated completion date of your project (as per our Access Procedures).

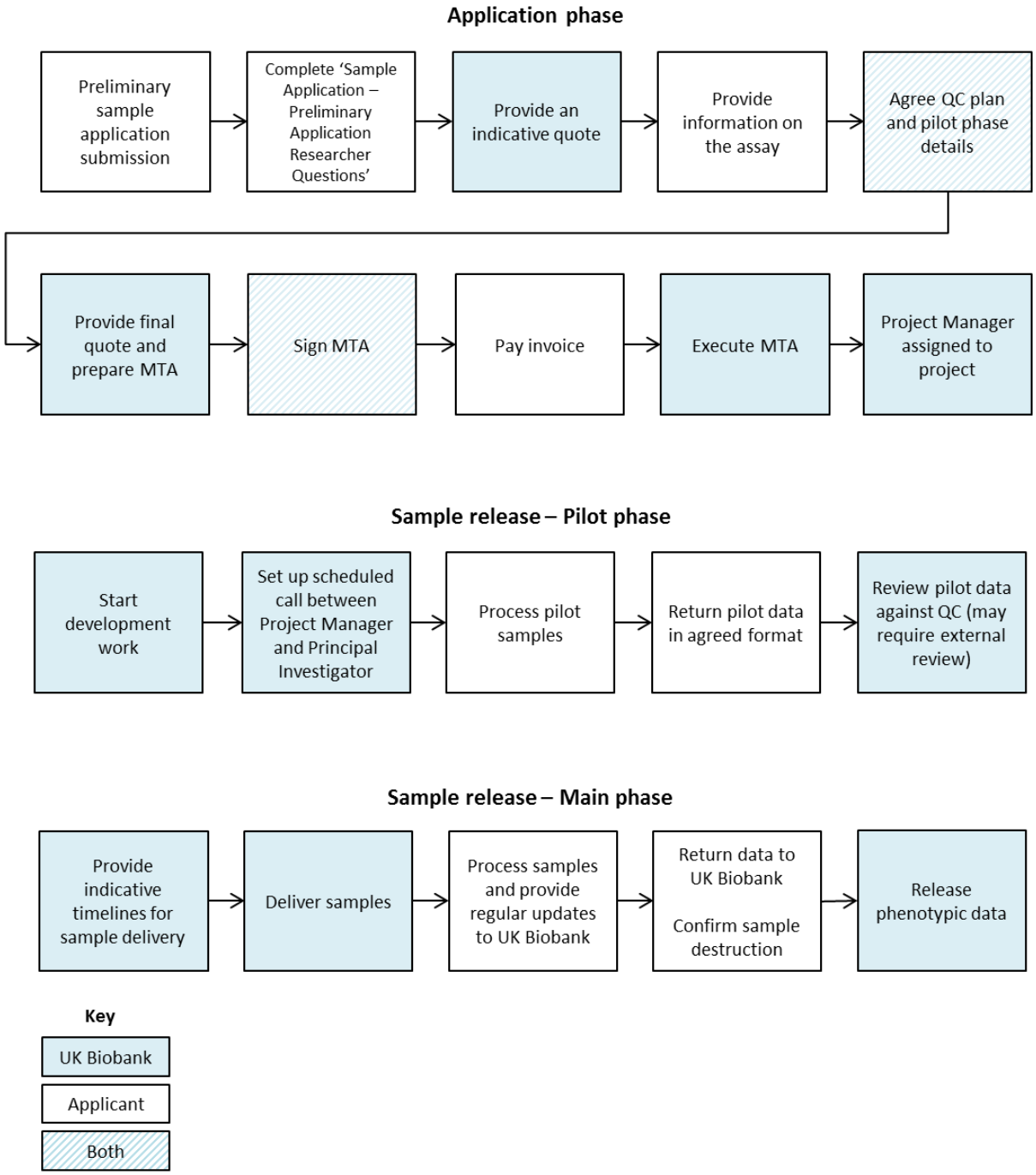

Figure 1: Overview of the application and review process for applications involving samples (in addition to the standard process outlined in UK Biobank Access Procedures)