

# UK ME/CFS Biobank Application (Outline)

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## Background Information

Academic, non-commercial, and commercial researchers will be eligible to apply to use samples and/or data from the UK ME/CFS Biobank if they present a sound scientific rationale for the proposed study and have a good research track record. Eligible researchers must be supported by their institution.

All research proposals intending to use samples from the UK ME/CFS Biobank must be developed in line with the Biobank's mission. Proposals intending to develop the following types of studies will be prioritized:

- testing or generating new hypotheses on the mechanisms (pathophysiology) of ME/CFS,
- improving diagnosis (biomarkers) and phenotyping, and/or,
- basic science, e.g. pharmacological *in vitro* studies potentially leading to clinical trials on therapeutic approaches.

The UK ME/CFS Biobank holds aliquots of the following blood derivatives:

serum (0.2ml), plasma NaHep (0.25ml), plasma EDTA (1ml), whole blood (0.5ml), peripheral blood mononuclear cells (PBMC – 1ml with  $5 \times 10^6$  cell), granulocytes pellet (2ml), and PAXgene blood RNA tubes.

Availability of aliquots will be subject to previous usage by researchers.

## Summary Information Sheet

### Procedure for obtaining the UK ME/CFS Biobank's samples and/or data

#### ***Who can get access to the samples and/or data?***

Academic and commercial researchers will be eligible to apply to use samples and/or data from the UK ME/CFS Biobank if they present a sound scientific rationale for the proposed study and have a good research track record. Eligible researchers must be supported by their institution.

All research proposals intending to use samples from the UK ME/CFS Biobank should be developed in line with the Biobank's mission; proposals intending to develop the following types of studies will be prioritized:

- testing or generating new hypotheses on the mechanisms (pathophysiology) of ME/CFS,
- improving diagnosis (biomarkers) and phenotyping, and/or,
- basic science, e.g. pharmacological *in vitro* studies potentially leading to clinical trials on therapeutic approaches.

### Steps to apply for access to samples and/or data

#### • **Step 1 – Submission of an Outline Research Proposal**

Researchers must submit an outline research proposal to the UK ME/CFS Biobank Guardian Board<sup>1</sup> using the outline application form (below).

Forms should be submitted electronically to: [mecfsbiobank@lshtm.ac.uk](mailto:mecfsbiobank@lshtm.ac.uk). The Guardian Board will review the application and aim to notify the applicant of their decision within two weeks. If the outline proposal is approved by the Guardian Board, the applicant will be invited to submit a full proposal (Stage 2). If your application is taken through to a Full Research Proposal, you will be sent a full application form.

#### • **Step 2 – Submission of a Full Research Proposal**

Submissions must:

- have a sound background,
- have a robust methodology which can be safely, ethically and effectively carried out in the institutions/ laboratories applying for samples,
- match hypotheses, objectives, and methods with available blood samples,
- statistically justify sample size, and
- if requesting additional data or blood test results, explicitly state what is needed and why.

At this stage, applicants should submit their projects to a Local Ethics Committee if they do not yet have local ethics approval (see workflow at page 5).

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<sup>1</sup> The Guardian Board has three members and includes a person with ME/CFS, a representative from an ME charity, and a member of the CureME research group at LSHTM.

The Full Research Proposal will be reviewed by the UK ME/CFS Biobank Guardian Board. The input of peer reviewers will be sought as needed for studies outside Guardian Board expertise. The researchers should expect a response from the Guardian Board within four weeks. Once the Guardian Board has agreed that the research proposal can proceed, approval from your local ethics committee will be required. If there is a delay and the applicants do not have local ethics committee approval by the end of the time interval for this step, a conditional approval can be issued. However, final approval for release of samples and/or data will be conditional on the presentation of applicable ethics approvals.

- **Step 3 – Application to the UCL-RFH BioBank Ethical Review Committee (B-ERC)**

The LSHTM Biobank Coordinator will submit an application to the UCL-RFH BioBank B-ERC following approval of your full application. The B-ERC will take six to eight weeks to consider the application.

- **Step 4 – Signature of the Material or Data Transfer Agreements (MTA and/or DTA) by all parties**

If approval is granted, the applicants should receive the Material Transfer Agreement (MTA) for signature. The MTA is a legal document that establishes that the 'Recipient' of the samples provided by the UK ME/CFS Biobank will use them appropriately and will dispose of remaining samples in accordance with the required procedures. Additionally, the MTA covers reporting, publication acknowledgments, and Intellectual Property (IP) issues. The MTA will be signed by London School of Hygiene & Tropical Medicine ('LSHTM') and The University College London – Royal Free Hospital BioBank ('UCL-RFH'), where the UK ME/CFS Biobank samples are hosted, and the Principal Investigator or the Institution's representative on behalf of the 'Recipient'. You should expect this process to take up to four weeks.

- **Step 5 – Shipment of samples and/or transference of data to the 'Recipients'**

Once the MTA is signed by the parties, the teams at the UCL-RFH BioBank and the LSHTM as applicable will prepare the required samples and/or data to be shipped and/or transferred.

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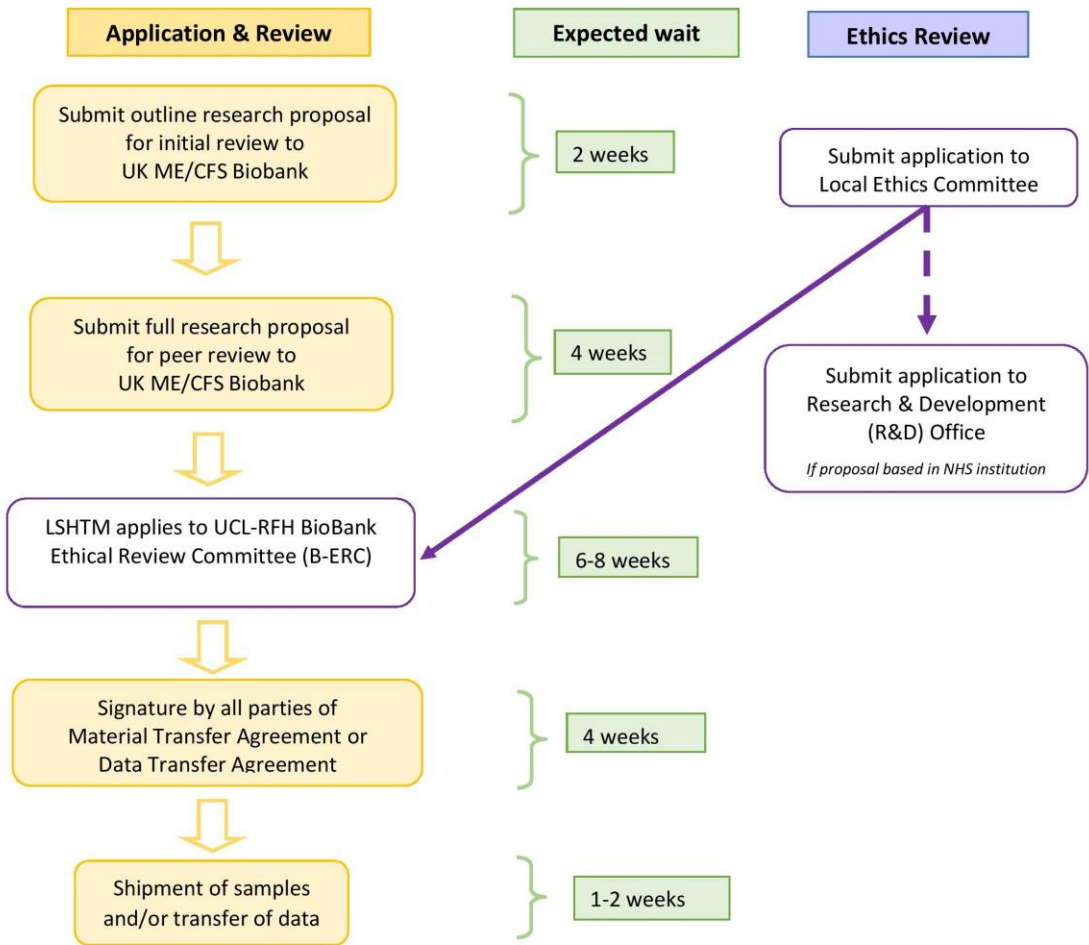
**Fees:**

UK ME/CFS Biobank services are provided on a cost recovery basis. Applicants can obtain quotes for batches of blood derivative samples and/or dataset from the Biobank team ([mecfsbiobank@lshtm.ac.uk](mailto:mecfsbiobank@lshtm.ac.uk)).

**Table 1 – Timeframe for applications to access samples and/or data**

<b>STEPS</b>	<b>Timing</b>
1. Submission of an Outline of Research Proposal to the UK ME/CFS Guardian Board	2 weeks
2. Submission of a Full Research Proposal to the Guardian Board	4 weeks
4 Submission of the application to the <u>UCL-RFH BioBank Ethical Review Committee (B-ERC)</u>	6 – 8 weeks
5 Signature of Material Transfer Agreement or Data Transfer Agreement by all parties	4 weeks
6 Shipment of samples and/or transfer of data to the applicants	1 – 2 weeks

## Workflow for accessing samples and/or data



# APPLICATION FORM 1 – Research Proposal Outline

Applicants should return the completed form to: [mecfsbiobank@lshtm.ac.uk](mailto:mecfsbiobank@lshtm.ac.uk)

Date of Application DD/MM/YY	/ /
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## Applicant

Name of Principal Applicant	
Title & Position of Principal Applicant	
Name & Position of Co-Investigator(s)	

## Institution

Institution where research will be conducted	
Address	
Telephone N°, including country code	
E-mail	

## Project title


## Commercial/non-commercial intent

Does this research include any commercial interests?	(Yes/No)
If yes, please explain nature of commercial interests:	



## Outline of proposal

*This must not exceed 1 single-spaced page (written in a minimum size 11 font (in Arial or Times New Roman). The proposal should be clear and concise and use the following sub headings: (i) **title**; (ii) **brief background**; (iii) **objectives**; (iv) **methods** - including materials, particularly samples and/or data required from the UK ME/CFS Biobank; and (v) **expected outcomes**.*

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