London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT

FUNDING OPPORTUNITY – AWARD TO ENABLE THE STUDY OF HUMAN TISSUE SAMPLES / CLINICAL DATA FOR BIOMEDICAL RESEARCH INTO ME/CFS

In November 2017 – January 2018, the UK ME/CFS Biobank (UKMEB) raised around £17,000 from a crowdfunding campaign, to fund a release of samples at no cost to researchers. The campaign was conducted with the assistance of partner organisations and charities.

These funds will cover the costs of releasing samples and data to researchers, who can apply for their use to conduct high-quality studies. This open call is in line with the Biobank's core mission of enabling translational, biomedical research into ME/CFS, and is now open as of 17 May 2018.

The funds available will cover:

- the review of applications
- the preparation of data and material transfer agreements
- the selection and release of samples;
- the selection of and access to relevant data;
- the shipping of samples to any intended destination globally;

It is **not** envisioned that the funds available would cover laboratory consumables, personnel costs, machine costs, publication costs, overheads or any other cost beyond those stated above, apart from in exceptional circumstances as adjudged by the UKMEB Steering Committee. Nonetheless, it is hoped that this call will provide the necessary spark to initiate, enable or enhance a research project of priority to the UKMEB.

The funds available could be disbursed as a single award or up to three separate awards, depending on the value of samples applied for and other funding available.

Approval in principle under the terms of this call **need not** be contingent on full funding already being in place, and a successful application could be used to support grant applications in-progress or already-planned. Applicants should however have clear plans for how the remainder of the costs associated with their project will be funded, with an expectation that such work be conducted within a reasonable timeframe.

Pilot proposals, including hypothesis generation and the testing of new hypotheses and confirmatory studies, will be equally considered. There will be no geographical restriction on applications.

In an effort to broaden the field as a whole, we would particularly encourage:

- early-career researchers;
- researchers entering the field of ME/CFS research;

- researchers in institutions or localities where ME/CFS research and awareness is under-developed.

Applicants will also be expected to share results of their work and all data/results generated, in periodic reports and a final report to the UKMEB. This is to enhance the value of the collection and provide accountability to crowdfunding donors. Publication & usage rights will remain with the awarded organisation, per the standard terms of a UKMEB Material/Data Transfer Agreement.

About the UKMEB

The Biobank functions as an open resource for clinical and biomedical research into ME/CFS, and in particular for research into biomarkers of the disease. It empowers research into the diagnosis, prognosis, and stratification (sub-grouping) of ME/CFS, enabling a wide range of research studies in an extremely cost-effective manner.

The UKMEB is the first ME/CFS-specific biobank in Europe and one of the first in the world. The biobank's rigorous, disease-specific protocols enable strong conclusions to be drawn from its samples, and have served as a model for other biobanks across the globe. We currently store samples from over 500 donors representing those with ME/CFS, MS and healthy controls. Over 30,000 aliquots of blood (collected over two time-points) have been processed and are currently held at the UCL/RFH Biobank in London.

The UKMEB is managed from the London School of Hygiene & Tropical Medicine, and is a notable part of LSHTM's diverse research agenda. The UKMEB is also part of EUROMENE, the European Network on ME/CFS, and has distributed samples to researchers in the UK, Europe and America.

All research proposals intending to use samples from the UK ME/CFS Biobank must be developed in line with the Biobank's mission, which includes supporting studies involving the following:

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

Of the over 500 participants in the Biobank, all those with ME/CFS have been diagnosed by physicians and are compliant with the Canadian Consensus Criteria (CCC) and/or the CDC '94 (Fukuda); case definition compliance is available for four other commonly-used criteria. Samples are available from four groups of participants:

- Mild and moderate ME/CFS;
- Severe (home/bed-bound) ME/CFS
- Multiple sclerosis
- Healthy controls

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Samples available as of April 2018

Sample type	Stored aliquot/ tube volume	Collection tube (BD)	Number of aliquots
Whole blood	0.5ml	EDTA	3,021
Serum	200 µl	Red serum	6,770
Plasma	1 ml	EDTA	2,029
Plasma	250 µl	Na Hep	5,382
Red Blood Cells (RBCs)	2 ml	Na Hep	773
Peripheral Blood Mononuclear Cells (PBMCs)	$5x10^6$ cells in 1ml	Na Hep	9,106
Peripheral Blood Mononuclear Cells (PBMCs)	$5x10^6$ cells in 1ml	EDTA	2,198
Blood for RNA	2.5 ml	PAXgene	584
Total			**29,863**

Data

A variety of clinical assessment data and blood test results are available at 2 time-points:

Questionnaires

- Symptoms experienced
- Sociodemographic variables
- Family and individual health histories
- Potential risk factors (exposures)
- Medical Outcomes Survey Short Form (SF-36v2)
- General Health Questionnaire (GHQ-28)
- Epworth sleepiness score
- Fatigue scales assessing severity and disability
- Pain and fatigue analogue scale

Clinical assessments

- Urinalysis by dipstick (glucose, protein, blood, and specific gravity)
- Pulse oximetry
- Blood pressure (seated and standing)
- Standing height
- Weight and bioimpedance
- Waist circumference
- Hand grip strength test
- Spirometry

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Blood tests

- Full blood count
- Blood chemistry and creatinine
- Liver function
- Thyroid function
- CRP
- ESR
- Rheumatoid factor*
- Tissue transglutaminase antibodies*
- Serum vitamin B12*
- Folate*

**for baseline only*

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Application

Applicants should complete a UKMEB outline application, a simple two-page form. In addition, for the award of a subsidised sample release, applicants should also complete a **cover letter**, outlining responses to the questions below, in no more than four sides of A4 including figures where appropriate.

1) how the proposal addresses the aims of the UKMEB and of research into ME/CFS and the needs of people with ME/CFS more generally;
2) the potential for translation of the results into patient benefits;
3) the number and type of samples needed (with justification);
4) details of who is going to conduct the research and where;
5) existing resources for conducting the research (if funded, from whom, and if funding has been applied for, from whom);
6) whether the research aims to test new hypotheses or validate previous results.

Timescales

Application deadline: 16 July 2018

Selection: 20 August 2018, including review from the UKMEB Guardian Board and invited external reviewers where appropriate.

Full application: immediately following selection.

The above-intended timescales are subject to change, at the discretion of the UKMEB.

Criteria for Selection

- Quality of the application;
- Potential for translation into patient benefits;
- Consistency with the aims of the UKMEB;
- Capacity to conduct the proposed research (including available funding, personnel time and requisite experience);
- Approximate time to complete the project;
- Unavailability of funding from other sources for the specific research proposed, and in particular from major funding agencies;
- No conflict/duplication with existing work involving the UK ME/CFS Biobank.

Release of samples will be subject to the completion of a full UKMEB application and ethical clearance, at site, the UCL-RFH Biobank, and the LSHTM.

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Applications, including an **outline application** and **cover letter** should be emailed to mecfsbiobank@lshtm.ac.uk before **16 July 2018**.

Further information about the applications process and the UKMEB in general is available via our website http://cureme.lshtm.ac.uk/ and the outline application form included above.

The UKMEB is happy to respond to enquiries about this call and to discuss proposals in advance of submissions. Please contact mecfsbiobank@lshtm.ac.uk.