# UNDERSTANDING ME/CFS

Myalgic Encephalomyelitis / Chronic Fatigue Syndrome Call 2024







## Understanding ME/CFS

Supported by



Myalgic Encephalomyelitis / Chronic Fatigue Syndrome ME/CFS Call 2024

This is a call for small exploratory research projects that address fundamental research questions to advance understanding of post-acute infectious diseases such as ME/CFS. The aim of this call is to generate preliminary data.

#### Scope of the Call

This call is open to research teams that aim to advance our understanding of etiopathogenesis, diagnostics and/or therapy of post-acute infectious diseases, namely ME/CFS. Projects addressing novel research directions and questions are strongly encouraged. This call seeks to support projects that generate preliminary data. Projects should bring together experimental and clinical approaches in a meaningful way. Interdisciplinary collaborations across biomedical, computer and clinical sciences are highly welcome. ME/CFS is part of a complex disease cluster called post-acute infectious diseases. Projects investigating other post-acute infectious diseases that show post-exertional malaise are also eligible for funding.

#### Who can apply?

- Core research team up to three researchers
- Principal Investigators (PI) from all disciplines
- The coordinating PI must be based at a university or non-university research institution in Vienna
- Co-PIs may be based outside of Vienna (funding limited to 30% of the overall budget)
- Co-PIs from Lower Austria may apply for up to 49% of the overall funding (Joint Projects)

#### **Project Duration**

12 – 15 months

#### Funding

- Call volume: € 600,000
- Project budget: up to € 100,000
- Personnel and non-personnel
- costs can be claimed
- Max. 40% non-personnel costs
- No overhead costs

#### Timeline

- Proposal deadline:
- June 18th, 2024, 2pm CET
- $-\,$  Expected funding decision: October, 2024
- Project start: latest January, 2025

#### Process

- Selection by international Jury
- Application via WWTF Funding Portal
- Selected projects may receive the opportunity to apply for additional funding at a later stage



WWTF

## **Call Specifications**

## **Understanding ME/CFS**

Myalgic Encephalomyelitis / Chronic Fatigue Syndrome (ME/CFS) Call 2024

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## About this document

This document specifies the process, criteria, and instrument of this call. It is aimed at applicants wishing to submit a proposal in the ME/CFS Call 2024. For further information regarding the funding and submission guidelines, as well as references to WWTF policies, please consider the following documents:

Submission Guideline	Guide to creating, editing and submitting a proposal
WWTF Funding Guideline	General Guideline for WWTF funding activities
Guideline for Good Scientific Practice	Guidelines by the Austrian Agency for Research Integrity
Open Science Policy	Open Science Policy of WWTF
Gender Equality Strategy & Plan	Gender Equality Strategy & Plan of WWTF
Reporting and Accounting Guideline	Specifies reporting and accounting for funded projects

## 1. Scope of the call

This special call is issued within the WWTF instrument "supplementing measures" ("Ergänzende Instrumente") specified in the <u>WWTF Funding Guideline</u>.

This call invites researchers from the biomedical, computer and clinical sciences to submit small interdisciplinary research proposals that advance knowledge of the etiopathogenesis, diagnostics and/or therapy of post-acute infectious diseases like ME/CFS. Projects investigating overlapping features from other diseases showing clinical post-exertional malaise are also eligible. <u>This is a special call for explora-</u> tory projects that seek to generate preliminary data.

#### 1.1. Why ME/CFS?

Myalgic Encephalomyelitis / Chronic Fatigue Syndrome (ME/CFS) is a complex and poorly understood chronic disease. As part of the family of post-acute infectious diseases, it is characterised by a wide range of complex and serious debilitating conditions with a variety of symptoms. This includes the cardinal symptom post-exertional malaise. Other symptoms like sleep dysfunction, pain, neurological/cognitive manifestations, as well as autonomic, immunological, and neuro-endocrinological symptoms are part of ME/CFS. Individuals with ME/CFS often do not return to pre-disease levels of activity.<sup>1,2</sup> The cause of ME/CFS is currently unknown. ME/CFS affects individuals of all ages, ethnicities, and socioeconomic groups. It is estimated that in Austria up to 80.000 patients suffer from ME/CFS<sup>3</sup>, with women being more likely to be diagnosed than men<sup>4</sup>.

<sup>&</sup>lt;sup>1</sup> Bateman et al. Mayo Clinic Proceedings. 2021

<sup>&</sup>lt;sup>2</sup> https://25megroup.org/me/

<sup>&</sup>lt;sup>3</sup> http://tinyurl.com/muw-MECFS

<sup>&</sup>lt;sup>4</sup> Bakken et al. BMC Med. 2014

<u>The goal of this call is to support small exploratory research projects</u> that address fundamental research questions to advance understanding of post-acute infectious diseases such as ME/CFS and to generate preliminary data. Highly welcome are:

- Projects that push the state of the art
- Projects that bring together experimental & clinical approaches (Translational)
- Projects that bring together approaches from different scientific disciplines (Interdisciplinary)

The focus is on advancing the understanding of post-acute infectious diseases such as ME/CFS. However, projects investigating other post-acute infectious diseases that show substantial post-exertional malaise in their phenotype are also eligible for funding. <u>Please note that solely observational projects in clinical settings and health service research do not fit the scope of this call.</u>

#### 1.2. Phenotypic Characteristics

**ME/CFS:** The definition of ME/CFS must be based on either of these international consensus criteria:

- Canadian Consensus Criteria (CCC) or the revised CCC
- International Consensus Criteria
- <u>NICE Guidelines</u> for ME/CFS
- IOM 2015 Diagnostic Criteria

**Post-acute infectious diseases:** Other post-acute infectious diseases can also be investigated as part of the proposed research project. Research has shown significant overlap in the biological mechanisms between a wide range of post-acute infectious diseases<sup>5</sup>. Projects investigating other post-acute infectious diseases are therefore also invited (e.g., Long COVID). To be included in the scope of this call, the disease to be studied must meet the phenotypic criteria of post-exertional malaise as defined by one of the above-mentioned international consensus criteria.

#### 1.3. Interdisciplinary Collaboration

In this call we encourage the collaboration between biomedical, computer and clinical sciences and other disciplines. The interdisciplinary expertise required for the proposed research project may be based within the same research group or traverse research groups and institutions. Plans for collaboration between expertise groups must be demonstrated throughout all critical stages of the project, from formulation of the research question, experimental design to data analyses.

#### 1.4. Research Data and Data Management

"Research data" in the context of WWTF funded projects include, but are not limited to study protocols, observations and measurements, results of experiments, metadata, software codes, hyperparameters, images. All research data produced in the context of WWTF-funded projects (i.e., owned by the involved researcher) should be made accessible according to the FAIR principles<sup>6</sup> via a repository to facilitate the

<sup>&</sup>lt;sup>5</sup> Choutka et al. Nat Med. 2022

<sup>&</sup>lt;sup>6</sup> https://www.go-fair.org/fair-principles/

reproduction of results. WWTF requires applicants to reflect on data management in the application process.

## 2. Financing of this call

This call is co-financed by the <u>WE&ME Foundation</u> and WWTF in equal shares. The WE&ME Foundation was established in 2020 by the Ströck family and is situated in Vienna, Austria. The Ströck family and the dedicated WE&ME team are committed to funding groundbreaking research that unveils the complexities of ME/CFS, moving closer to effective treatments and a cure.

## 3. Submission

For the submission of the proposal written in English language, please go to the <u>WWTF Funding Portal</u>.

#### Important Information for your Submission

- Proposal deadline: June 18th, 2024, 2 pm CET
- All core team members i.e., coordinating PI (PI&C) and co-PIs, may access and edit the proposal. **Only the PI&C can submit the proposal.**
- **Signatures of the authorized signatory at each partner institution** ("authorization") are required in the application process.

## 4. Eligibility of applicants and roles in the project

The general eligibility of applicants is specified in the <u>WWTF Funding Guideline</u>. A project's **core team** may include **up to three Principal Investigators (PIs).** This includes a PI&C and up to two co-PIs.

- Core team members may share equal management and scientific roles in the project.
- WWTF especially encourages young and female scientists to apply as PI.
- Each core team member must submit a CV, which will form part of the evaluation.
- A researcher may appear as a core team member (i.e., PI&C, co-PI) in a maximum of two proposals in this call.

One PI must be designated as **PI&C**.

- For legal and administrative reasons (contact person, funding contract, reporting), WWTF requires a PI&C to be named.
- The PI&C must have an affiliation at a Viennese research institution, which will serve as a legal contract partner.

Up to two **co-PIs** may also be named in the core team.

• Co-PIs may be based in Vienna, Lower Austria or elsewhere (in Austria or internationally) in fulfilment of the requirements of regular WWTF projects or Joint Projects (see below).

Additional project partners and collaborators are permitted in the research team.

- Industry partners are not eligible for funding.
- Non-academic collaboration partners (e.g., NGOs) may be part of the research team.

#### **Research partners outside Vienna:**

- For regular WWTF projects, project partners outside of Vienna may receive up to 30% of the total requested funding.
- This call operates under the "Joint Projects" agreement with the Province of Lower Austria. For the criteria and conditions that exist for partners from Lower Austria, see Section below.

## 5. Specifics of Joint Projects with partners in Lower Austria

WWTF welcomes **joint project (JP) applications** between Viennese and Lower Austrian universities and research institutions in this call. The Lower Austrian share is financed by the Province of Lower Austria.

- The total maximum funding amount for a JP consortium is also € 100,000.
- The PI&C must be affiliated to a Vienna research institution.
- At least one core team member must be affiliated to a research institution in Lower Austria.
- The share of the overall funding allocated to an institution in Lower Austria must be between 30% and 49%. In case that the share is <30%, the project is considered as a regular WWTF project.

## 6. Content and structure of the proposal

Proposal (For more details, please see <u>Submission Guideline</u>)

Lay Summary and Scientific abstract

Work programme (max. 8 pages): outline of the main scientific idea and approach

Project core team (with CVs and publications lists) (upload of PDF, template with structure is provided)

Budget overview

Signatures: required from the institutions of the core team members and partner institutions

## 7. Funding and evaluation criteria

The following criteria are used in the evaluation.

• Scope: Is the project within the scope of the call as described in the Call Specifications?

The key criteria in the evaluation of proposals are **scientific quality**, **novelty to generate preliminary data**<sup>7</sup> **and interdisciplinarity**:

- Scientific excellence and academic potential of the applicant(s): Accomplishments and potential of the applicants to conduct the proposed research (measured by academic age).
- **Innovative character of the proposed research project:** Does the proposed research work meet the highest relevant international quality standards? Does the project show scientific originality and innovative aspects? Are the methods and research approaches appropriate and complementary? Does the project have the potential to explore novel research avenues and approaches and thereby generate promising preliminary data?
- **Team composition and interdisciplinary collaboration:** Teams should include an appropriate mix of expertise, bringing together researchers from complementary scientific disciplines. A clear description of the roles, responsibilities, and competencies of all core team members is mandatory.

Further criteria include relevance and academic & clinical impact, feasibility of the proposed project plan, Data management and Gender aspects. Please note that **career breaks** such as for parental leave, care duty and prolonged illness will be taken into account in the evaluation of the proposals. In order for these to be considered, please provide the relevant time periods.

## 8. Eligible costs

All costs that are directly attributable to the project. Please also consider your organization's internal guidelines for eligible expenses/costs.

#### 8.1. Personnel costs

- Eligible forms of employment contracts are full-time and part-time contracts as well as marginal employments ("Arbeitsvertrag"). Contracts for services ("Werkvertrag") are only permitted if the nature of the work means that it cannot be performed through employment contracts.
- All persons employed through a WWTF-funded project should receive a fair employment contract with at least a minimum wage according to the "Kollektivvertrag" (collective agreement) of the Austrian Universities / non-university research institutions. For staff employed at institutions without a collective agreement, the minimum wage should adhere to the standards of the Austrian Science Fund (FWF salary scheme available online).
- Applications for personnel costs must be in one of the following categories:
  - Senior Personnel: highly qualified scientists, usually permanently employed
  - **Post Doc:** or equivalent qualification, including Senior Postdocs

<sup>&</sup>lt;sup>7</sup> Preliminary data as a basis for a potential second round of funding, see chapter 14 below

- PhD Student: or equivalent qualification level
- Diploma Student: Bachelor or Master students
- Office/Technician: administrative or technicians (proportional funding only)
- Personnel costs cannot be claimed for permanent senior staff who are already fully financed by the institution. Exceptions apply in cases where senior staff must acquire third party funding for co-financing their own position (e.g., non-university research institutions and Universities of Applied Sciences). In these cases, permanently employed senior staff may claim up to 20% of their annual salary from WWTF.

#### 8.2. Non-personnel costs

- Running costs for basic infrastructure (telephone costs, rents) as well as costs for the acquisition of infrastructure and basic equipment are not eligible for funding, as these should be covered by the category "overhead costs".
- Non-personnel should not exceed 40% of the overall budget.
- Eligible non-personnel costs are: Equipment (Smaller equipment up to € 1,500), consumables, travel costs for e.g., scientific meetings and conferences, publication costs, workshop/conferences (e.g., organizing costs) and Other costs (e.g., third-party costs; costs for childcare and/or career coaching for female WWTF-funded personnel).

#### 8.3. Indirect costs (overheads)

In this call, at this stage, WWTF **does not pay overheads** due to the small amount of total funding per project.

## 9. Gender aspects in the application phase

WWTF's <u>Gender Strategy and Gender Equality Plan</u> must be considered throughout the application. Please note, that WWTF requests jury members to take into account both gender and specific roles in research team composition, as well as gender in research content during evaluation processes. Besides taking the academic age and atypical career paths into consideration, WWTF has established a preferential rule for projects led by early-stage career researchers and female PIs, i.e., in case of equal quality, these should be given priority for funding.

## 10. Guidelines for good scientific practice and ethics

Compliance with the **rules for good scientific practice,** including the observance of ethical aspects in research, is mandatory. This pertains to the application process and, in case of funding, the actual research work. WWTF is member of the OeAWI and processes apply accordingly.

Project proposals may include **ethical aspects** that require the approval from an ethics committee/institutional review board.

- If the approval from the ethics committee/institutional review board is required for the planned project this must be clearly stated.
  - An acknowledgement of receipt from the ethics committee/institutional review board must be submitted with the proposal.
  - The final approval ("Votum") must be submitted to WWTF the latest before project start.
- Should it not be possible to obtain a final ethical approval before the jury meeting due to reasons which are beyond the control of the applicant, the applicant must explain the reasons in the application and send the preliminary approval to the responsible call manager once received.
- The approval by the ethics committee should be specific for the planned WWTF project.
- Non-compliance will result in the rejection of the proposal on formal grounds.

## 11. Open Science

WWTF requires compliance with its <u>Open Science Policy</u>. This document outlines the rights, roles and responsibilities of WWTF, researchers, and research organizations.

## 12. Selection and decision process

The core element of WWTF's decision making processes is an **international jury** mandated to make a funding recommendation to the WWTF boards.

- The jury is comprised of 4-6 outstanding international experts selected by WWTF that have no current affiliation to an Austrian institution (names of jury members will be published after the WWTF Board of Directors finalize the formal funding decision)
- Please note that the proposals are intended for a jury panel with expertise covering a range of proposals.
- Please note that there is no opportunity for rebuttals to either recommendations by the jury panel or decisions by the WWTF Board of Directors.

#### 12.1. Formal eligibility check by WWTF

WWTF office conducts a formal eligibility check of the proposal based on the criteria outlined in the <u>WWTF Funding Guideline</u>. Substantial deficiencies and missing sections in the application will lead to the exclusion of the application from further evaluation and rejection on formal grounds. The strict timeline of the call does not allow for proposals to be sent back to the applicants for amendments.

#### 12.2. Evaluation of proposals

- Each proposal is independently assessed by at least two jury members based on the evaluation criteria.
- The jury decides in a meeting (on-site or online) if a proposal should be recommended for funding. The result is a recommendation for each project: "to be funded" or "not to be funded".

#### 12.3. Formal funding decision

The jury recommendation will be **formally confirmed** first by the WWTF Advisory Board and then approved by the WWTF Board of Directors.

- The decision may include budget cuts as well as additional conditions and recommendations.
- Unsuccessful applicants will also receive a short statement by the jury explaining the main reasons why the project was not selected for funding.

## 13. Funding contract

In case of funding, WWTF office will contact the PI&C to draw up the funding contract.

- Projects may start immediately and should start no later than 2 months after the formal funding decision by the WWTF Board of Directors.
- Projects must conclude the latest by June 2026 (no extensions will be granted)
- The formal funding contract will be signed between WWTF and the host institution of the PI&C.
- In Joint Projects, the host institution of the co-PI in Lower Austria is an additional contract partner.
- For universities, this is a project according to §27 of the Universities Act 2002. The institution then authorizes the respective PI to sign for the full scientific and financial responsibility of the project.

## 14. Potential additional funding: ME/CFS consolidator call

In case of funding and successful implementation of the WWTF project, the PI&Cs and the core team of the funded projects might be invited to apply for further funding in a possible second consolidation call. This consolidation call would aim to select the most promising follow-up projects for additional funding.

Please note that this will only be possible if sufficient funding is made available by the funders for this second call.

## 15. Public relations

Funded projects will be showcased via WWTF and WE&ME public relations activities. This includes displaying the projects via respective websites and contributing to other multimedia activities relevant for making the outcomes of this call visible.

## 16. Monitoring and reporting

Funded teams are committed to delivering one final report and participating in evaluation and monitoring. WWTF offers the possibility to adapt the work plan according to project needs. Projects must conclude the latest by June 2026 (no extensions will be granted). For details see the <u>Reporting and Accounting Guideline</u>.