# Outline Experimental Medicine Applications: Frequently Asked Questions

### General

1. Can I submit research which has previously been submitted to an MRC Research Board, Fellowship or DPFS and was not funded?

Applications previously declined by the MRC or another Research Council will not be considered by the MRC within 12 months (from the date of submission to the original Research Council, as either an outline, Expression of Interest or full application) unless substantially revised.

#### 2. How much funding is available?

Up to £10M (80% FEC) is available each year, split over two Panel meetings. The Experimental Medicine scheme will support a range of award scales (cost and duration), from smaller, focused, more exploratory and highly innovative projects (based e.g. on an intellectually sound hypothesis but perhaps lacking extensive pilot data), to larger awards based on a more substantial platform of evidence.

#### 3. What is the expected duration of the grants?

There is no formal expectation of the duration of the Experimental Medicine grants. Project duration should be dictated by the timelines required to complete the proposed work, although this will usually be between 12-60 months.

#### 4. Will the application attract full economic costs (FEC)?

The proposals should be costed on the basis of the full economic costs (FEC) necessary to deliver the research. If a grant is awarded, the MRC will typically fund 80% of the FEC and the RO(s) must agree to find the balance of FEC from other resources.

Costs for subcontracts with contract ROs for the synthesis/manufacture of an entity or matched placebo carried out under Good Manufacturing Practice will be paid at 100% FEC. Please speak to the Programme Manager regarding any Exceptions Costs queries.

#### 5. When will I be informed if my application was successful?

Full applications are expected to be considered by the Panel at meetings held twice a year, and feedback will be given shortly after. The Principal Investigator will be notified of the decision by email communication.

#### 6. How do I apply?

Outline and full applications must be submitted using the Joint electronic Submission (Je-S) System. Applicants should refer to the general guidance for applicants (on Je-S Help) and MRC standard terms and conditions. Please note the full applications are by invitation only, following the assessment of outline applications.

#### 7. Is there an Expression of Interest or Outline stage?

All applicants must submit an outline application via the Joint electronic Submission (Je-S) System. Please refer to the "Guidance for Applicants" for further information on submission of an outline application

8. Can I create my own case for support document as I would for a normal research grant?

No, only applications that use the outline application case for support form will be accepted.

#### 9. Can I include annexes in my application?

Applicants may only include the specific attachments, as separate documents, listed below:

- Case for support form
- CV
- Publication list
- Gantt chart
- Supporting figures and data tables
- Justification of resources
- MICA form
- Letter of support
- Covering letter

Further information on mandatory and recommended attachments for outline and full applications can be found in the Guidance for Applicants.

#### 10. How are proposals assessed?

Outline applications will be assessed by the Experimental Medicine panel, based on:

- Fit to the call remit
- Rationale & potential impact
- Research strategy
- Quality and skills of the research team
- Research environment & infrastructure
- Experimental design & statistical considerations
- Risk mitigation & management
- Value for money

If successful at outline stage, applicants will be invited to submit full proposal which will be sent out for external peer review and assessed by the Experimental Medicine panel convened by MRC. This panel will make the final funding decisions. Full proposals will be assessed on the standard criteria for an MRC research grant, plus the additional Experimental Medicine-specific criteria detailed in the call specification.

#### 11. Will I need to complete the MRC Industry Collaboration Framework (ICF) form?

If the application involves an industrial partner, an ICF form should be submitted for both outline and full applications. A Letter of Support from the Project Partner is also mandatory. Please refer to the <u>MRC Industry Collaboration Framework (ICF) – UKRI</u> for further guidance

#### 12. Does my proposal need to have milestones?

Yes. All Experimental Medicine applications will have milestones which will be postaward monitored by the MRC. Milestones are a standard feature of MRC Translationfocussed grants and allow the MRC to mitigate risk and support potentially high-risk projects. Milestone success criteria, including specific Go/ No-Go criteria, should be detailed in the Deliverability section of the Case for Support form.

Projects will typically have two Milestones with success criteria that reflect major progress points and allow mechanistic hypotheses to be laid out and tested. They are valuable for providing an indication of timelines for key steps, such as regulatory steps, study team recruitment, participant recruitment, study completion and data analysis.

#### 13. Will I need to have regulatory/ethical approval?

The MRC does not require ethics permissions and regulatory approvals to be in place when you submit an application (outline or full). However, given that research involving human subjects or requiring the use of human tissue/organs may raise various ethical and regulatory issues, applicants will be required to demonstrate that they have adequately considered these matters. Early discussions with regulatory/approval bodies are advised to ensure that all requirements can be met in a timely manner.

Once an application is successful, it is the responsibility of the host institution to ensure that the appropriate ethics and regulatory approval has been obtained and that no research requiring such approval is initiated before it has been granted. Please read the MRC terms and conditions for further details.

#### 14. Are early career investigators able to apply?

Yes, investigators in receipt of Fellowships (MRC, NIHR, Charity, Learned Societies) and NIHR lectureships are eligible if their fellowship T&C's allow. For full applications only, a letter of support from the investigator's RO will be required.

#### 15. Will you publish a list of the awards that are made?

Following the funding decisions, a list of awards will be made available on Gateway to Research.

# 16. If my query is not answered by the FAQs, or I have a scientific query regarding my application, who do I contact?

For scientific queries please email the Programme Manager for Experimental Medicine: Alexandra.Phillips@mrc.ukri.org

For other queries please contact: Experimental.Medicine@mrc.ukri.org

## **Experimental Medicine Remit**

#### 1. Are there any areas that are outside the remit of this scheme?

The Experimental Medicine Panel welcomes applications covering all human disease areas. However, the following types of projects are out of remit:

- Observational studies involving no experimental challenge;
- Full translational projects developing or evaluating new therapeutics or devices (please refer to the MRC DPFS scheme);
- Clinical efficacy trials (please refer to the EME funding scheme);
- Experimental intervention/challenge in animals, using clinical assets to explore disease mechanisms and pathways (supported by the <u>Research Boards</u>);
- Use of samples from clinical studies to improve the deep characterisation/ phenotyping of subjects, in order to better understand disease aetiology (supported by the <u>Research Boards</u>);
- Proposals which are predominantly descriptive are unlikely to be shortlisted;
- High-throughput screening approaches to target validation.

#### 2. Will proposals involving preclinical animal work be considered?

The focus should be on understanding human disease through experimental investigation in humans. While projects may include a limited, well-justified element of non-human work (if informing the proposed work in humans), the main focus of the project should be on human participants.

#### 3. Do proposals need to focus on a therapeutic intervention?

The experiment does not need to test a therapeutic intervention. While all proposals need to involve an experimental challenge (for example, pharmacological, immunological, behavioural, physiological, psychological or infectious), proposals investigating disease pathways and mechanisms, validating targets or providing proof of concept mechanistic data for novel readouts and technologies are also within the remint.

Studies should aim to provide new mechanistic insights that could lead to future clinical impacts. This could be through enabling new therapeutic or diagnostic approaches or by generating opportunities for "reverse translation" to discovery science.

#### 4. If my application doesn't fit the call remit, what options do I have?

If your application does not fit the remit of this call, but is within the broader sphere of MRC interest, then you may apply via other normal funding mechanisms. Please see Funding opportunities for more information.

5. If my query is not answered by the FAQs, or I have a scientific query regarding my application, who do I contact?

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