Peacebuilding and Resilience in an era of global health challenges: a bilateral research call to enhance understanding and support for mental health challenges in Colombia

Ethics Addendum

This addendum provides supplementary information for ethics issues related to health and medical research for UK and Colombian applicants to this joint call. It should be read in addition to the main call documents, including the Ethics Template, Call Specification, and Je-S Guidance.

The funders participating in this call are the Economic and Social Research Council (ESRC) the Medical Research Council (MRC) and Arts and Humanities Research Council (AHRC), all constituent bodies of UK Research and Innovation (UKRI). Minciencias are the Central Ministry for Technology and Innovation in Colombia.

1. Ethics Details

Any research involving humans/human tissue and/or animals (whether undertaken in the UK or Colombia) must comply with legislation in both the UK and Colombia. It must also comply with the relevant policies and guidance of Minciencias, and UKRI (including ESRC and MRC policies and guidance).

It is the responsibility of the PIs based in Colombia and the UK and their research organisations to ensure that appropriate ethical approval is granted and adhered to, and that no research requiring ethical approval is initiated until it has been granted.

Applicants must be clear in their applications in which country the proposed research involving humans and/or animals will take place and must fully complete the ethical information section for research taking place in either country.

1.1 Ethics guidance

All projects funded under this initiative must comply with:

- Minciencias and UKRI (including ESRC and MRC) guidance and policies on ethics, including requirements in this call-specific Ethics Addendum;
- MRC’s relevant policies and guidance regarding the use of humans/human tissue and/or animals in research, including those explained the standard MRC Guidance for Applicants in
section 4 on proposals involving animal use and section 5 on ethics and approvals section 5 on ethics and approvals;

- MRC Industry Collaboration Agreement must be in place if collaborative research is taking place between academic and industry researchers.
- Colombian applicants should refer to Minciencias ethics guidance.

Approval(s) for the research detailed in the UK-Colombia project must be granted by the appropriate bodies before any work can commence. Institutions, applicants and grant holders have the responsibility to ensure that all approvals are granted for the research considered for this initiative.

The Principal Investigator/Research Organisation must be prepared to furnish Minciencias and UKRI with a copy of the ethical approval, and any correspondence with the committees, if requested by the funders. The Principal Investigator must notify the funders if a regulator or a research ethics committee requires amendments that substantially affect the research question, methodology or costs to the extent that the project is no longer the same as that approved for funding by the partners.

Je-S Application Stage – Ethics Documents Required

- Human Participation letter of support (2 sides of A4 max, attachment type ‘Other’) for all applications

This document must be dated, signed by BOTH the Principal Investigators (PIs) in Colombia and the UK and attached via Je-S before the call deadline. Please see MRC Ethics Template and Human Participants Letter document for further details on what is needed to be included.

- Use of animals letter (2 sides of A4 max, attachment type ‘Other’) only required if animals are being used

The letter must be dated, signed by BOTH the Principal Investigators (PIs) in Colombia and the UK and attached via Je-S before the call deadline and include details confirming that:

- All animal research (undertaken in either country) will adhere to all relevant national and local regulatory systems in both the UK and Colombia
- They will follow the guidelines laid out in the responsibility in the use of animals in bioscience research document and ensure that work is carried out to UK and Colombian standards. If primates are used they should also confirm that they will follow the NC3Rs Guidelines: Primate Accommodation, Care and Use
- Before initiation of the proposed research work, appropriate approvals from institutional and/or central animal ethics committees will be obtained for experimental protocols to be adopted in their projects. Successful proposals may be expected to provide copies of these permissions before funding is released.
- Details on which animal research will take place in which country (UK, Colombia or elsewhere) and through which funders the resources are being sought. Applicants should include confirmation that animal welfare standards at these institutions meet the requirements outlined above.
• ‘Use of animals overseas’ form(s) (attachment type ‘other’) only if the animal research takes places outside the UK (in Colombia or other countries)

Please complete the appropriate ‘use of animals overseas’ form(s). *See section 4.4.6 of the standard MRC Guidance for Applicants as well as the use of animals overseas section of the National Centre for the Replacement, Refinement & Reduction of Animals in Research (NC3Rs) which contains information about the forms required for which species. See also section 3 below for further information.

In addition to UKRI guidance, the proposed research, both in the UK and in Colombia, must comply with the principles of the MRC common guidance on responsibility in the use of animals in bioscience research and NC3Rs Guidelines: Primate Accommodation, Care and Use.

In particular, UK institutions should be aware of the following aspect of the guidance relating to research or collaboration outside the UK:

“When collaborating with other laboratories, or where animal facilities are provided by third parties, researchers and the local ethics committee in the UK should satisfy themselves that welfare standards consistent with the principles of UK legislation (e.g. the Animals (Scientific Procedures) Act 1986), and set out in this guidance, are applied and maintained.

Where there are significant deviations, prior approval from the funding body should be sought and agreed. International research should also be compliant with all relevant national and local regulatory systems in the host country where the research is to be conducted.”

All applicants are required to comply with Section 4: ‘Proposals involving animal use’ of the standard MRC Guidance for Applicants. Applicants should detail in the letter any additional information which was not included in the proposal document but which is pertinent to the animal research proposed and which the funders should be aware of.

In addition, researchers should be reminded that sufficient information and justification regarding any animal research proposed, regardless of country, must be provided in the proposal order to allow full peer review to take place.

• MRC Industry Collaboration Agreement (attachment type ‘other’) only if you think you qualify

Any research proposal involving a collaboration with one or more industrial partners (contributing either in cash or in kind) is handled by MRC as a MICA. MICA is not a scheme in itself, but a mechanism to support the establishment of an agreement between academic and industry research partners, which can be applied to the majority of our funding schemes and calls.

Please read the guidance and complete the MICA form if you think you qualify.

Contacts

For further information, applicants based in the UK should contact:

• Case officer: Alexa Mills
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