UKRI-NSCF Joint Call - Inclusive Ageing in the UK and China: Understanding New Health and Social Risks

Ethics Addendum

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

Note: “Chinese agency” refers to the National Natural Sciences Foundation China (NSFC). The two UK councils participating in this call are the Economic and Social Research Council (ESRC) and the Medical Research Council (MRC), both constituent bodies of UK Research and Innovation (UKRI).

Full Application Stage – Ethics Documents Required (if applicable)

A. Letters of support
These documents must all be dated, signed by BOTH the Principal Investigators (PIs) in China and the UK and attached via Je-S before the call deadline, they include:

- **Human participation/human tissue letter**
  (2 sides of A4 max, attachment type ‘letter of support’)
  This should be signed by the UK PI and the Chinese PI when human/human tissue research is proposed and/or when the Chinese partner or another third party (ANY organisation other than the host UK research organisation) is responsible for recruitment of people as research participants and/or providing human tissue.  
  *See section 2 below for further details.

- **Use of Animals letter**
  (2 sides of A4 max, attachment type ‘letter of support’)
  This should be signed by both PIs based in China and the UK.  
  *See section 3 below for further information.

- **Use of Stem cells letter**
  (2 sides of A4 max, attachment type ‘letter of support’)
  This should be signed by both the PIs based in China and the UK.  
  *See section 4 below for further details.

B. ‘Use of animals overseas’ form(s)
(attachment type ‘letter of support’)
If the animal research takes places outside the UK (in China 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.
Ethics Addendum Documents Details

1. Ethics

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

It is the responsibility of the PIs based in China 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:

- NSFC 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 in 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; and
- China applicants should refer to NSFC ethics guidance.

Approval(s) for the research detailed in the UK-China 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 the NSFC 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 NSFC and UKRI 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.

2. Use of humans / human tissue

2.1 UKRI (including ESRC and MRC) guidance

A signed and dated letter of support must be attached to the proposals when human/human tissue research is proposed (in either country). The letter should be titled ‘Human participation/human tissue letter’ and must be signed by both the PIs, based in China and the UK. It must be clear from the letter which human/human tissue research is being proposed in which country.
The letter should state that all applicants will comply with the NSFC and UKRI policies including the guidance in the standard MRC Guidance for Applicants and in this call-specific Ethics Addendum. The letter should also acknowledge that the PIs based in China and the UK understand that MRC’s current policy for research involving humans to take place overseas, is that **for research to be undertaken internationally, both local and UK ethical approval is required.** The letter should also state that the PIs based in China and the UK understand that for human studies (including clinical studies) involving human participants and/or patients in the UK or overseas, appropriate consent must be obtained.

In addition, where the Chinese research organisations or another third party (any organisation other than the UK research organisation) are responsible for recruitment of people as research participants and/or providing human tissue, details should be included in the ‘Human participation/human tissue letter’ must include confirmation of the following:

- which international (non-UK) partner is involved and that the partner has agreed to recruit the participants/provide tissue;
- that what is being supplied is suitable for the research being undertaken; and
- that the quantity of tissue (where relevant) being supplied is suitable, but not excessive for achieving meaningful results.

The letter of support must be an integral part of the application (as an attachment) and must focus on the proposal it accompanies.

**Note:** For clinical studies involving human participants and/or patients, appropriate consent must be obtained.

### 3. Use of animals

#### 3.1 UKRI (including ESRC and MRC) guidance

In addition to UKRI guidance, the proposed research, both in the UK and in China, 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.”

3
Investigators proposing the use of animals (in either country) should read the guidance and provide:

- a signed and dated letter with the heading ‘Use of Animals letter’ (uploaded as a ‘Letter of Support’ on the Je-S application) which must be signed by both the PIs located in China and the UK stating that:
  - all animal research (undertaken in either country) will adhere to all relevant national and local regulatory systems in both the UK and China
  - they will follow the guidelines laid out in the responsible in the use of animals in bioscience research, document and ensure that work is carried out to UK and Chinese 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, China or elsewhere) and through which funder the resources are being sought. Applicants should include confirmation that animal welfare standards at these institutions meet the requirements outlined above.

- if applicable, the MRC ‘Use of Animals Overseas’ form(s)’ (uploaded as a ‘Letter of Support’ on the Je-S application) - please 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 which forms required for which species.

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.

4. Use of stem cells

4.1 UKRI (including ESRC and MRC) guidance

Please see section 5 of the standard MRC Guidance for Applicants for further information.

If applicable, a signed and dated letter with the heading ‘Use of Stem Cells letter’ (uploaded as a Letter of Support to the Je-S application) should be submitted and MUST be signed by both the PIs based in China and the UK.
Contacts

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

Josie McGregor or Evie Bate
Email: HealthyAgeingChina@esrc.ukri.org
Telephone: +44 1793 41 3094 or +44 1793 41 3175

China applicants should contact NSFC with any questions.