Canada-UK Artificial Intelligence Initiative: building competitive and resilient economies and societies through responsible AI

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Ethics Addendum

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

Note: "Tri-Agency", "Tri-Council" and "Canadian agencies" refers to the three federal research funding agencies — Canadian Institutes of Health Research (CIHR); the Natural Sciences and Engineering Research Council (NSERC); and, the Social Sciences and Humanities Research Council (SSHRC). The four UK councils participating in this call are the Arts and Humanities Research Council (AHRC), the Economic and Social Research Council (ESRC), the Engineering and Physical Sciences Research Council (EPSRC), and the Medical Research Council (MRC).

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 Canada 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 Canadian PI when human/human tissue research is proposed and/or when the Canadian 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 Canada 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 Canada and the UK.
  *See section 4 below for further details.

B. 'Use of animals overseas' form(s)
(2 sides of A4 max, attachment type 'letter of support')

If the animal research takes places outside the UK (in Canada or other countries), please complete the '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 Canada) must comply with legislation in **both** the UK and Canada. It must also comply with the relevant policies and guidance of the Canadian funding agencies, and UKRI (including MRC and ESRC policies and guidance).

It is the responsibility of the PIs based in Canada 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.

Note: All PIs based in Canada must select the relevant tick boxes (yes or no) for proposal involving human beings as research subjects; involving human pluripotent stem cells; involving the use of animals; and/or, involving hazardous substances when completing the Terms and Conditions for Applying for Canadian Tri-Agency Funds.

1.1 Ethics guidance

All projects funded under this initiative must comply with:

- Tri-Agency and UKRI (including MRC and ESRC) 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; and

- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2018 and amended) and the Tri-Agency Framework: Responsible Conduct of Research (2016). Of note, applicants should also consult the TCPS 2 Tutorial Course on Research Ethics (CORE).

Approval(s) for the research detailed in the UK-Canada 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 Canadian funding agencies, MRC/ESRC/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 Canadian funding agencies, MRC and ESRC/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 MRC/ESRC/UKRI 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 Canada 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 relevant Canadian funding agencies, ESRC, MRC 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 Canada 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 Canada 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 Canadian research organisations or another third party (any organisation other than the UK research organisation) is 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.

2.2 Tri-Agency guidance

Researchers must adhere to Tri-Agency, MRC, ESRC and UKRI guidance and policies on use of human/human tissue, including requirements in this call-specific Ethics Addendum. Applicants must consult the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2018 and as amended) and submit the proposal to their organisation's Research Ethics Board. Applicants must also submit appropriate documentation as highlighted in point 2.1 above.

3. Use of animals

3.1 MRC/ESRC/UKRI guidance

The proposed research, both in the UK and in Canada, 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."

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 Canada 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 Canada

- 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 Canadian 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, Canada 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.

3.2 Tri-Agency guidance

Researchers must adhere to the Tri-Agency, MRC, ESRC and UKRI guidance and policies on use of animals, including requirements in this call-specific Ethics Addendum and on the Canadian Council of Animal Care (CCAC) standards and procedures. Applicants must submit appropriate documentation as requested within the MRC 'Use of animals' section 4 noted above, and once the project is funded must submit relevant permits for research conducted in Canada. Canadian researchers must submit the proposed animal research to their institutional animal care committee for review and approval prior to commencing animal-based work.

4. Use of stem cells

4.1 MRC/ESRC/UKRI 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 Canada and the UK.

4.2 Tri-Agency guidance

Researchers must adhere to the Tri-Agency and MRC/ESRC/UKRI guidance and policies on use of stem cells, including requirements in this call-specific Ethics Addendum document. All applications involving stem cells must ensure compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2018 and as amended) (See Chapter 12, section F).

Note: If through peer review the application is found to fall into this category and is recommended for funding, it will be forwarded, with your consent, to CIHR's Stem Cell Oversight Committee (SCOC) to ensure compliance with Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2018 and as amended) (See Chapter 12, section F). The SCOC review is in addition to the normal review by local Research Ethics Boards (REBs). Funding will not be released until approval has been obtained from the SCOC.

Contacts

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