Annex IV. Guidelines for Canadian Applicants

1. Scope

This annex applies to Canadian applicants requesting funding from the Canadian Institutes of Health Research (CIHR) within the ERDERA Clinical Trial Call. It specifies unique eligibility criteria and other requirements applicable to Canadian applicants.

For the purposes of this annex, the term "Canadian partner(s)" refers to Canadian applicant(s) to this funding opportunity.

2. Eligibility Criteria for Canadian Partners

For a Canadian partner to be eligible, all the requirements stated below must be met:

A. The Nominated Principal Applicant (NPA) leading the Canadian component must be an independent researcher affiliated with a Canadian post-secondary institution and/or its affiliated institutions (including hospitals, research institutes, non-profit organisations with a mandate of health research and/or knowledge translation).
B. The NPA must have their substantive role in Canada for the duration of the requested grant term.
C. The Institution Paid must be authorized to administer CIHR funds by the application deadline.

Eligible Roles

A. Canadian partners may participate as **consortium partners.**
B. Canadian partners may also act as **coordinating investigator.**
C. Canadian patient advocacy organisations (PAOs) or patient partners are eligible to participate in the role of co-applicant or collaborator.

Restrictions

Canadian Small and medium-sized enterprises (SMEs) are **not eligible for CIHR funding**.

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General CIHR Policies

Before submitting an application to this funding opportunity, Canadian partners should review the relevant policies and guidelines on the CIHR Funding Policies page, including the CIHR Application Administration Guide – Part 2 General Requirements for Grants and Awards Applications, to ensure understanding of their roles and responsibilities.

Allowable Costs

Canadian partners are advised to consult the Use of Grant Funds section of the Tri-Agency (CIHR, NSERC and SSHRC) Guide on Financial Administration (TAGFA) to determine if an expenditure is an appropriate use of grant funds.

3. Sponsor Requirements

3.1 Legal Sponsor (mandatory requirement)

A. All consortia, including those with a Canadian coordinating investigator, are required to include a Legal Sponsor that is established in an EU Member State or Norway.
B. Canadian institutions **cannot be the legal Sponsor**, regardless of their scientific role.
C. The Legal Sponsor of the consortium:
    - Signs the Award Agreement with Fondazione Telethon
    - Receives ERDERA funding managed by Fondazione Telethon
    - Is responsible for fund distribution to consortium partners, except for Canadian partners if they are funded by CIHR (see Section 4.1).

3.2 Canadian Sub-Sponsor / National Structure

For consortia involving Canada partners:

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A. **A Canadian sub-sponsor or equivalent institutional structure** must be identified for the Canadian component of the trial. This entity will provide a coordination function for the Canadian component, including support for obtaining regulatory and ethics approvals, as needed and as appropriate. Note that this could be the institution paid for the Canadian NPA.
B. In addition, a **Canadian Clinical Trial Management Organisation (CTMO)** must be identified, or access to such an organisation must be demonstrated, in line with the overall consortium requirements for multinational trial management. More information is available in the Eligibility Criteria section of the ERDERA call text.
C. For successful consortia with a Canadian component, agreements must be established between:
    - The EU legal Sponsor and
    - The Canadian sub-sponsor/institution and Canadian CTMO and participating institutions
D. These agreements will define:
    - Roles and responsibilities
    - Coordination of trial implementation, including regulatory and operational interfaces between EU and Canadian components

3.3 Financial responsibility of the Legal Sponsor

The legal Sponsor for each consortium must have the capacity to receive and redistribute ERDERA funds to all partners of the consortium.

Critical requirement: If Canadian partners are funded through the ERDERA central fund (see Sections 4.1 and 4.2), the legal Sponsor of the consortium must be able to **transfer funds to Canadian institutions.**

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4. Funds Management and Distribution for Canadian Partners

When required, Canadian partners must prepare budgets compliant with CIHR rules, without needing to indicate whether funds will come from CIHR or ERDERA, provided that budgets remain compatible with both systems (See section 5 for details on the application process).

4.1 CIHR Funding (primary source)

A. CIHR funds will be awarded to the top ranked consortia that include a Canadian component, until the available CIHR funds have been exhausted. The institution paid must be in Canada and must be authorized to administer CIHR funds by the application deadline (see list of CIHR eligible institutions).
B. CIHR funds will be administered in accordance with CIHR Application Administration Guide and the Tri-agency Guide on Financial Administration.
C. For CIHR-funded Canadian partners, funds will be transferred directly to the NPA's institution and managed within Canada.

4.2 ERDERA Central Fund (secondary funding)

A. Once CIHR funding has been exhausted, additional eligible Canadian partners may be funded through the ERDERA Central Fund. In such cases, ERDERA, through Fondazione Telethon, becomes the funding source and Fondazione Telethon's financial rules and requirements will apply (see the ERDERA Call text for details).
B. For **Canadian partners funded through FTELE**, funds are transferred to the consortium's EU legal Sponsor, which is responsible for redistributing funding to all consortium partners, including Canadian institutions, and for ensuring that funding to Canadian partners is transferred in accordance with the applicable funding arrangements.

5. Application Process Specific to Canadian Partners

- Stages 0–2: **Submission only through the Fondazione Telethon platform** for all the Canadian partners, along with the other partners of the consortium.
- Stage 3 (Full Proposal), Canadian partners must:
    - Submit a full proposal through the Fondazione Telethon platform, along with the other partners of the consortium **AND**

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- Submit a short proposal and budget (in Canadian dollars) to CIHR (via ResearchNet). More information will be published on the CIHR website in early 2027.

6. Partner Linkage Tool

In support of the formation of multinational consortia and to facilitate networking between partners in Canada and other ERDERA-eligible countries, CIHR has created a partner linkage tool. More information is available at https://cihr-irsc.gc.ca/e/54771.html.

7. Contacts

For all enquiries relating to requirements for Canadian partners, please contact the Canadian Institutes of Health Research at: PDD-IGStrategic-CEP-IGStrategique@cihr-irsc.gc.ca

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