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**Coordination of research on priority medicines for children**

**Guidelines for submission of transnational  
proposals  
within the ERA-NET PRIOMEDCHILD  
Joint Call for Proposals**



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## Content

1. Introduction .....	3
2. Project Scope and Funding .....	3
2.1 Recommendations for project budget and project duration:.....	3
3. ERA-NET PRIOMEDCHILD requirements.....	4
3.1 Composition of Consortia.....	4
3.2 Responsibility of the Project Coordinator .....	4
4. Application Procedure .....	5
4.1 Application scheme .....	5
4.2 Information, communication & further assistance for applicants .....	6
4.3 Pre-proposal .....	6
Filling the Pre-proposal form .....	7
Eligibility check and evaluation.....	7
4.4 Full Proposal .....	8
Filling the Full Proposal form .....	8
Full proposals evaluation .....	8
4.5 Rebuttal process.....	8
Rules and regulations for the rebuttal.....	9
5. Delivery (Electronic submission system).....	9
6. Confidentiality .....	10
7. Conflict of interest .....	10
8. Project start and monitoring research project performance .....	10
Appendix I National Contact Persons .....	12



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## 1. Introduction

The Guide for applicants on submission of Pre-proposal and Full Proposal (hereinafter referred to as 'the Guide') is intended as a source of practical knowledge for all interested in participating in the ERA-NET PRIOMEDCHILD Call. General information on the Call and its procedures is included in the Call Text „*ERA-NET PRIOMEDCHILD Call Text*”

The Call Text with National eligibility criteria, Application forms and other call documents are published on the PRIOMEDCHILD website ([www.PRIOMEDCHILD.eu](http://www.PRIOMEDCHILD.eu)). A list of National Contact Persons with relevant information is included in the Appendix I to the Guide.

## 2. Project Scope and Funding

The objective of the PRIOMEDCHILD Call is to enable scientists and researchers in different countries to build an effective collaboration on a joint research project aiming at better medicinal treatments for children. Funding is intended for international projects in the area described in the Call Text, paragraph 2.1 “*Call topics for research proposals*”.

### ***2.1 Recommendations for project budget and project duration:***

The budget for the project must convincingly allow the achievement of the project goals and should not exceed national funding organisation funding limits for each partner (for details see the Annex “Information on National eligibility criteria” of the Call Text).

Partners (public, private, or from non-PRIOMEDCHILD countries) that cannot be funded may participate in a consortium at their own cost.

Budget & Funding Modalities:

- Funding for research projects will be for 36 months.
- Funding of research partners is provided by the national funding organisations according to *National eligibility criteria* (Annex to the Call Text).
- A Consortium Agreement has to be in place within three months of the project start. The first instalments can be transferred only after a Consortium Agreement has been signed by all parties (for further information please see the document *Consortium agreement guidelines* at the PRIOMEDCHILD website).



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### **3. ERA-NET PRIOMEDCHILD requirements**

PRIOMEDCHILD has developed formal criteria that are applied in the eligibility check and evaluation process to select the best projects as outlined in the goal of PRIOMEDCHILD. These criteria have been agreed by all participating national funding organisations and are described in the call text, but please note that this does not exclude more specific criteria set up by the national research funding organizations.

The eligibility criteria are given in the Call Text document: "*ERA-NET PRIOMEDCHILD Call Text*".

#### ***3.1 Composition of Consortia***

It is the aim of the PRIOMEDCHILD Call to facilitate funding support from the member countries and to allow for flexibility with regard to the composition of the consortia.

Successful consortia eligible for funding will display the following characteristics:

The consortium must consist of at least three partners (academic research groups or other public research organisations as well as enterprises, e.g. SME's) from at least three different countries of which a minimum of two research partners should be from PRIOMEDCHILD funding partner countries. The maximum number of project partners in a consortium should not exceed 8.

- The consortia should show a clear added value of the planned cooperation. Also the workload must be balanced between countries and between consortium partners.
- Each applicant can only apply for funding once in the PRIOMEDCHILD call
- Parties from countries that do not take part in the PRIOMEDCHILD call may be part of a consortium at their own cost if their contribution is mandatory to achieve the project goals. Please state clearly in the proposal if the availability of funds for these partners is already secured or if not, how they plan to obtain funding in advance to the start of the project.
- Industrial partners that cannot be funded by their national funding organisation may participate in a consortium at their own cost.

#### ***3.2 Responsibility of the Project Coordinator***

- The consortium must be coordinated by a project coordinator from a PRIOMEDCHILD member country contributing to the call.



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- The project coordinator will lead the consortium through the application procedure and is fully responsible for the overall project coordination.
- The project coordinator has to make sure the project complies with PRIOMEDCHILD requirements and thus is eligible for the PRIOMEDCHILD joint call. While all partners should resolve possible queries with their respective national organisations, the project coordinator has a responsibility to co-ordinate these activities in close contact with the PRIOMEDCHILD call secretariat and the PRIOMEDCHILD contact persons of his/her national funding organisation.
- All communication with the PRIOMEDCHILD Call Committee concerning the project will be through the project coordinator. Accordingly, the project coordinator has to disseminate information provided by the PRIOMEDCHILD Call Committee to all consortium partners.
- When building the consortium, the project coordinator has to confirm with the consortium partners that they are eligible for support from their respective national funding organisations. In the case of contribution from non-PRIOMEDCHILD member states, the project coordinator should ensure that he is satisfied as to the availability of funds to support the contribution of that/those of the partner/s.

## **4. Application Procedure**

### ***4.1 Application scheme***

The application process is divided in **two steps (Pre-proposals and Full Proposals)**.

In the first evaluation round, the Pre-proposals are checked for formal eligibility and they are subject to a first evaluation according to the criteria given in the Call Text. Coordinators of positively evaluated Pre-proposals are invited to submit a Full Proposal to the PRIOMEDCHILD Call Secretariat via the website.

In the second round, Full Proposals are subject to a thorough quality assessment with respect to:

Scientific quality:

- novel, innovative research within the scientific scope of the call and innovative potential of the expected results for industrial application where appropriate;
- scientific impact
- feasibility of project;
- Quality of the consortium, scientific track record of applicants;



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Relevance of project:

- transnational added value and complementarity of expertise;
- evidence of true cooperation within the research consortium and with groups and organizations outside the research consortium;
- addressing ethical issues
- economic and societal impact including plan for use and dissemination of knowledge
- adequateness and scientific justification of requested resources and financial requirements

Positively evaluated projects will be recommended for funding. These results are due to be available in the end of September 2010. After a formal decision at the national level, projects will be funded through the national research funding organisations. The PRIOMEDCHILD Call Secretariat will inform the project coordinator about the status of this decision.

#### ***4.2 Information, communication & further assistance for applicants***

- Each funding organisation has nominated PRIOMEDCHILD National Contact Persons who can be contacted for information about the specific national regulations and requirements (see Appendix I). It is recommended to contact this PRIOMEDCHILD National Contact Person prior to the Pre-proposal and Full Proposal submission process.
- The only official communication line for the PRIOMEDCHILD call is between the PRIOMEDCHILD Call Secretariat and the project coordinator. The project coordinator is the only contact person informed by PRIOMEDCHILD Call Secretariat in all relevant questions during the application procedure, so she/he must provide this information to the research partners.
- For further assistance and to download the application forms please see the PRIOMEDCHILD website.
- For additional information and support the nominated PRIOMEDCHILD Call Contact Persons can be contacted.

#### ***4.3 Pre-proposal***

In this step the Pre-proposals are judged regarding the eligibility and according to the evaluation criteria given in the Call Text. The Pre-proposal has to be submitted by 7<sup>th</sup>



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**January 2010** to the PRIOMEDCHILD Call Secretariat by the project coordinator using the electronic submission system described in *Chapter 5*. The Pre-proposal application form and financial form are available to download on the PRIOMEDCHILD website.

### Filling the Pre-proposal form

- The Pre-proposal 'Summary of the Project' should provide the objectives, the rationale, the methodology highlighting the novelty, originality and feasibility as well as the added value of the collaboration, the division of the collaborative project into subprojects, a preliminary descriptive work plan and the resources.
- Please follow the template of the form. The project should be in line with the PRIOMEDCHILD requirements cited in the Call Text.
- For the financial information please fill in the pre-proposal budget excel sheet.
- The Pre-proposal form is a single document and the space available for your information has been limited on purpose. No additional documents will be considered.

### Eligibility check and evaluation

Eligibility will be checked by the PRIOMEDCHILD Call Committee through the participating national funding organisations with regard to the following criteria:

- 1) PRIOMEDCHILD requirements that are applied to all member countries,
- 2) national criteria that exclusively apply to the applicants from these countries (see *National eligibility criteria* (Annex to the Call Text)).

The scientific assessment of the pre-proposals will be carried out by the Scientific Advisory Board (a committee of experts) according to the evaluation criteria which are listed in the Call Text.

The results of the Scientific Advisory Board assessment are communicated to the project coordinator no later than **1<sup>th</sup> of March 2010** through the PRIOMEDCHILD Call Secretariat by e-mail. Only eligible and positively evaluated proposals will be considered for further project evaluation. The project coordinator will be informed about the results.

The information given in the Pre-proposal is binding and changes (composition of the consortia, fundamental changes in the projects) between the Pre-proposal and the Full Proposal will be allowed only after agreement with the PRIOMEDCHILD Call Secretariat.



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#### **4.4 Full Proposal**

Coordinators of successful Pre-proposals are invited to submit a Full Proposal to the PRIOMEDCHILD Call Secretariat. The applicants have to return the Full Proposal application form and the full proposal budget sheet by **10<sup>th</sup> May 2010** using the electronic submission system (see also paragraph 5).

##### **Filling the Full Proposal form**

- Please check the information previously given in the Pre-proposal and make sure that the full proposal contains the same fundamental information.
- If you feel any change is necessary, please indicate it clearly and contact the PRIOMEDCHILD Call Secretariat in order to justify it.
- Please follow the template and be aware that the project description should allow evaluators to address properly all the evaluation criteria as given in the call text.
- For the financial information please fill in the full-proposal budget excel sheet.
- The Full Proposal form is a single document and the space available for your information has been limited intentionally. No additional documents will be considered.

##### **Full proposals evaluation**

The evaluation of the Full proposals is conducted by the Scientific Advisory Board with relevant expertise in the project field. Written reviews from external referees will be collected. Based on the written reviews and their own opinion, the Scientific Advisory Board will establish a ranking of the proposals. Based on the ranking and the available funding, the PRIOMEDCHILD Call Committee will suggest which projects to fund. Call Partners will decide at the level of the national research funding organisations on the final funding of the project.

The evaluation process provides applicants with the opportunity to reply to issues raised by the expert referees consulted. The guidelines for this process are described in item 4.5. The rules and regulations are binding for all applicants.

#### **4.5 Rebuttal process**

- Reviews from external referees are obtained on each proposal. All reviews received on each application are then fed back to the corresponding project coordinator as representative of the consortium, without revealing the identity of the peer reviewer.





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- The project coordinator will send a response to the comments back to the PRIOMEDCHILD Call Secretariat. The project coordinator may consult with other research partners in the consortium, but only one response from the project coordinator must be sent.
- Please note that this response is optional. No response does not exclude the proposal from the next stage of the review procedure.
- The project coordinator has to respond to the statements according to the rules and regulations listed below. The reviewers will not see the response.
- Following submission of the response to the PRIOMEDCHILD Call Secretariat there will be no further discussion between the applicants and the PRIOMEDCHILD Call Secretariat or the Scientific Advisory Board.
- The written reviews and the optional rebuttal are then given to the Scientific Advisory Board. The SAB members will evaluate the proposal with reference to the reviewers' comments and applicants' responses.

### **Rules and regulations for the rebuttal**

- Please send your response as pdf-file by email to the PRIOMEDCHILD Call Secretariat.
- The response is strictly limited to a **maximum of 2 pages** of A4 written in Times New Roman size 11 with 1.5 line spacing. Attachments or appendices are not permitted. All exceeding pages will be deleted regardless of the content.
- The purpose of the response is to enable the applicants to address technical queries and points of fact, and the response must be confined to these issues. In particular, the response must not discuss the competence, expertise or suitability of the referee.
- The response can only provide feedback on comments specifically raised by the referees and should not be used to otherwise introduce entirely new information or to change the proposal e.g. by presenting new work, additional publications or new financial calculations.

## **5. Delivery (Electronic submission system)**

All proposal forms are sent to the PRIOMEDCHILD Call Secretariat via a secured electronic submission system of the Netherlands Organisation for Health Research and Development (ZonMw). Please submit your proposal with the online submission tool via the ZonMw website: <http://www.zonmw.nl/subsidie/subsidiekalender>. Log in and from the two options, select 'submit application'. Submit your proposal by providing the information that is requested in each field: project title, duration of project (max 36



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months) and planned start, short summary of the project (max 5000 characters), and keywords and uploaded Pre- or full proposal form and budget excel sheet in pdf format. Prior to submitting your proposal form you have the opportunity to create a pdf file to view your proposal. After completion of all sections enter a PIN code.

Please submit your project in time. PRIOMEDCHILD Call Secretariat strongly recommends submitting Pre-proposals and Full Proposals well before the given deadlines.

## 6. Confidentiality

PRIOMEDCHILD ensures complete confidentiality to applicants, i.e. the proposal will only be read by the national funding organisations involved and by the international experts, and be handled by the PRIOMEDCHILD call secretariat. All of these persons will have signed a confidentiality agreement.

## 7. Conflict of interest

In order to exclude individual conflicts of interest the applicants are encouraged at the Full Proposal phase to provide the names of companies / research groups / individual evaluators (e.g. direct competitors, names of individuals) that/who should be excluded from the PRIOMEDCHILD Scientific Advisory Board and peer reviews. Please send your request, stating the reason for excluding the referees to the PRIOMEDCHILD call secretariat. Your request must reach the secretariat by 10<sup>th</sup> of May 2010 at the latest. Your request will be treated confidentially.

## 8. Project start and monitoring research project performance

Within three months of the project start, a Consortium Agreement addressing the points given in the **Consortium agreement guidelines** must be signed by all consortium members and made available on request to the national funding organisation, together with any other information required by national regulations.

The monitoring of the projects performance is conducted by each of the national funding organisations of the research partners according to the national regulations and the individual contracts between applicants and national research funding organisations.

The project coordinator is required to provide an annual project progress report and a final report to the PRIOMEDCHILD Call Secretariat, using the project-progress-report -form which will be available on the PRIOMEDCHILD-website.



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The coordinators might be asked to present the results of their projects at status seminars organized by the PRIOMEDCHILD secretariat.



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## Appendix I National Contact Persons

Country	Partner	Website	National Contact Person
The Netherlands	The Netherlands Organisation for Health R&D	www.zonmw.nl	Deborah Alfarez <a href="mailto:alfarez@zonmw.nl">alfarez@zonmw.nl</a> +31 70 3495140
Estonia	The Estonian Science Foundation	www.etf.ee	Iige Maalman <a href="mailto:iige@etf.ee">iige@etf.ee</a> +372 6996213
Finland	The Academy of Finland	www.aka.fi	Maiju Gyran <a href="mailto:maiju.gyran@aka.fi">maiju.gyran@aka.fi</a> +358 9 7748 8291
France	Agence Nationale de la Recherche	<a href="http://www.agence-nationale-recherche.fr/">http://www.agence-nationale-recherche.fr/</a>	Jenifer Clark <a href="mailto:jenifer.clark@agencerecherche.fr">jenifer.clark@agencerecherche.fr</a> +33 1 78 09 80 78
Great Britain	The Medical Research Council	www.mrc.uk	Carolina Mailhos +44 20 76705296 scientific queries: <a href="mailto:carolina.mailhos@headoffice.mrc.ac.uk">carolina.mailhos@headoffice.mrc.ac.uk</a> eligibility queries: <a href="mailto:admin.eaa@headoffice.mrc.ac.uk">admin.eaa@headoffice.mrc.ac.uk</a>
Italy	The Italian National Institute of Health	www.iss.it	Pietro Panei <a href="mailto:panei@iss.it">panei@iss.it</a> + 39 06 499020 83
Latvia	The Latvian Academy of Sciences	www.lza.lv	Ieva Cipruse <a href="mailto:ieva.cipruse@lza.lv">ieva.cipruse@lza.lv</a> +371 67227790
Poland	The National Centre for Research and Development	www.ncbir.gov.pl	Bogdan Podwysocki <a href="mailto:b.podwysocki@ncbir.gov.pl">b.podwysocki@ncbir.gov.pl</a> +48 22 583 05 01