

Imagine for Margo & Fondatioun Kriibskrank Kanner & Kick Cancer & CRIS & KIKA



Fight Kids Cancer 2023-2024 Competitive Call

Paediatric brain tumours exclusive call

Deadlines:

Expression of Interest (EoI) submission 17th October 2023 Invited Full Proposal submission 15th February 2024

Information about your application, including the personal information provided on the forms, will be processed and stored electronically by the European Science Foundation (ESF) Secretariat. In accordance with the call process, the Information contained in your application may be passed on to the funders and external reviewers in confidence.

Your application and personal information will be stored by the ESF electronic system for programme management purposes but will not be shared with other organisations outside the FKC partnership. We will use details provided in the application for correspondence about the call and may also use this information for future analyses of the performance of the programme.

By submitting your application to the FKC Programme you have indicated your acceptance of these data protection terms and conditions.

The FKC Programme is operated by the European Science Foundation



Contents

1.	Background	. 3
2.	Objectives	. 4
3.	Types of Projects	. 4
4.	Funding & Project Duration	. 5
5.	FKC call boundary conditions	. 6
С	all process and timeline	. 6
Ε	igibility of projects and partners	. 7
6.	Expressions of Interest' and Full proposals' Structure	. 8
E	xpression of Interest Format (EOI)	. 8
F	ull proposal Format	. 8
7.	Project evaluation and selection process	. 9
E	valuation process	. 9
S	election process	10
8.	Evaluation Criteria	11
С	riterion 1: Scientific excellence	11
С	riterion 2: Quality and efficiency of the implementation and the management	11
С	riterion 3: Impact	11
9.	Programme structure and project reporting	12
Ann	ex A: List of countries and entities eligible for funding	13
Ann	ex B: Project Finances Information and Guidelines	14
ANN	IEX C: Template for the Fights Kids Cancer Competitive Call expression of interest	19
ANN	IEX D: Template for the Fights Kids Cancer Competitive Call Full Proposal	21
Ann	ex E: Ethics self-assessment to the Fight Kids Cancer Competitive Call	27

1. Background

Despite the advances made, cancer remains a leading cause of death by disease in children and adolescents, and acute and long-term effects of treatment are unacceptable. In recent years, there have been revolutionary advances in research for certain adult cancers, which are not mirrored in children.

Paediatric cancers and their treatments differ from adult cancers. Hence, **there is an urgent need for research projects developed specifically for children with cancer**. In the field of oncology, childhood cancer research has been lagging behind, with stagnating cure rates over the last 15 years. Some types of paediatric malignancies still have a low cure rate, or no cure and yet affected children hardly benefit from innovative therapeutic approaches. Research on those malignancies remain largely insufficient.

The range of oncology treatments and targeted therapies have been rapidly expanding over the last years. Children should not be left behind innovative and more efficient treatments.

To address these issues, three European philanthropic organisations that actively support research on paediatric cancers have decided to join forces and establish the FIGHT KIDS CANCER (FKC) research programme. These organisations are:

- <u>KickCancer</u> (Belgium)
- Imagine for Margo (France)
- Fondatioun Kriibskrank Kanner (Luxemburg)

In 2022 and 2023, <u>CRIS</u> (Spain) and <u>KIKA</u> (the Netherlands) joined the Programme and co-finance the projects selected through the FIGHT KIDS CANCER Programme.

The FKC programme secretariat is managed by the European Science Foundation (ESF).

FKC aims to address the lack of research dedicated to paediatric cancers by sustainably providing support to the best European research through annual competitive calls for projects. The funds will support the best early phase clinical trial projects and translational research projects aimed at accelerating therapeutic innovation for children and adolescents with cancer.

This 2023-2024 Call will exclusively be dedicated to research on paediatric brain tumours.

Brain tumours are the second most common cause of death of cancer in children, however there has been no new approved new drugs to treat these tumours for the last 23 years. Therefor to meet the urgent needs of the young patients with a brain tumour, the FIGHT KIDS CANCER Programme Committee decided to dedicate the **2023-2024 Call exclusively to brain tumours**. The **2024-2025 Call** will be a **general call again, open to all paediatric cancer types**.

The core drivers underpinning the FKC programme are the following:

- The FKC call originates from parents' and patients' non-government organisations (NGOs) that are keen to steer research towards areas that will effectively benefit young patients by focusing on:
 - improving their survival rate
 - improving their quality of life during and after the treatment
 - improving our knowledge on cancer causes and resistance to treatment
- In this context, each project supported by the programme **is expected to show a strong potential of having impact** on the lives of childhood cancer patients.

- The FKC programme and call aim at promoting trans-European collaborations. FKC provides an efficient 'one stop shop' for funding that allows to:
 - <u>Accelerate</u>: research teams can start working faster without waiting for the fragmented funding approval from several national funding organisations;
 - <u>Streamline</u>: the administrative workload for research teams will be simplified due to a single application and follow-up process;
- The stability of the FKC programme over the years and the recurring nature of its annual calls will nurture greater productivity in the paediatric oncology scientific community.

2. Objectives

The FIGHT KIDS CANCER programme aims to deliver innovative and impactful research relevant to paediatric cancer, as well as to strengthen the development of pan-European research initiatives. In this, the programme ambitions to foster closer working ties between basic translational and clinical researchers. Specifically, this should encourage collaboration among the leading academic laboratories and practitioners, and lead to novel innovative projects.

FKC has four main objectives:

- 1. To realise real impact on young patients: Improve their survival rate and reduce toxicity to restore young patients to full health after treatment.
- 2. To advance cutting-edge science to further the knowledge of paediatric malignancies.
- 3. To support improved interdisciplinary research, methods, and collaborations for tackling the issues of today.
- 4. To strengthen collaboration and the development of scientific capacity across Europe.

The FKC call for projects aims towards overcoming the structural lack of research dedicated to paediatric cancers by ensuring a recurring endowment that will be granted to the best European research projects every year. An additional ambition is to foster closer working ties between clinicians and translational researchers.

Philanthropy integration

FKC aims at being a strongly integrated programme with positive and constructive relations between the research community and the funders. Funded projects teams are expected to collaborate and interact with the funding organisations. This includes participating in selected organisation's activities, supporting their communication's endeavours towards donors, sharing their expertise in research for example through conferences.

3. Types of Projects

Projects are expected to propose research on either Early Phase Clinical Trials or Translational Research Projects. The focus of this call is exclusively on paediatric brain tumours. Applicants to both categories are encouraged to address innovative interventions or approaches towards novel treatment (such as innovative therapies including immune-oncology, platform trials, artificial intelligence, imaging, radiotherapy, surgical approaches).

The two types of projects are:

- 1. **Early Phase Clinical Trials** to evaluate innovative therapies for children and adolescents with cancer. The key elements of the proposals are:
 - (Demonstrated) availability of investigational drug(s)
 - Designs of early phase clinical trials that rapidly and efficiently assess the innovative agents
 - $\circ~$ Enrolment of patients must commence not later than 12 months from the start of funding
 - \circ $\;$ Trial to be conducted and financed in at least 2 European countries
 - Study of the impact on the quality of life of the studied treatment regimen is strongly encouraged
 - o Immune oncology approaches are welcome
 - Platform trials are welcome
 - Co-funding of early phase clinical trial projects is possible, however precise details, justification and timelines must be provided
- 2. **Translational research** projects addressing childhood and adolescent cancers. Proposals are encouraged on:
 - Projects identifying novel targets or mechanisms of action
 - Projects that may result in innovative new therapies or better models of disease
 - Projects that are ancillary to ongoing/completed clinical trial
 - o Projects that leverage and advance paediatric tumour models
 - o Multi-disciplinary or multi-institution collaborations are strongly encouraged
 - A clear pathway to a clinical trial should be included

High-risk / high return proposals will be considered. The Funders will favour projects that give access to the paediatric population to novel technologies.

It is anticipated that submitted proposal should address more than one of the above criteria.

4. Funding & Project Duration

For this call, the following limits on funding and project duration apply:

- Up to 5 million euros for early phase clinical trials projects (up to 5 years)
- Up to 2 million euros for translational research projects (up to 4 years)

The level of the call envelope may be revised at the discretion of the Programme Committee.

All applicants should refer to the project finances information and guidelines (see Annex B) for the presentation and justification of the budget requested.

FKC funding is provided exclusively to cover the costs directly incurred by the projects funded, all budget elements associated with FKC funding must be itemised and fully justified. No indirect cost can be funded by FKC. Selected projects will be asked to provide adequate evidence for their whole cost basis.

If the project will benefit from complementary funding, this should be properly described and demonstrated.

Requested funding will be considered during the evaluation and selection processes, budgets may be reduced if considered excessive.

It is expected that projects will start at the earliest in January 2025.

As flexibility is the key motivation for the modification of the grants' duration and amount, the FKC Funders want to emphasize the fact that applicants **should apply for what they need** and not refrain from applying for smaller amounts or shorter projects such as primer or preliminary studies.

Each project will be evaluated on its merit alone. Shorter, high-risk high-gain projects are as welcome as are biology companion projects. Translational projects applying for longer duration or higher amounts will be expected to facilitate collaboration across institutions and borders within Europe to meet the FKC selection criteria.

5. FKC call boundary conditions

Call process and timeline

The FKC call follows a two-stage process involving i) the submission and shortlisting of Expressions of Interest (EoIs) and, ii) submission and selection of Full Proposals.

The call, evaluation and selection process follows the structure and the provisional timeline below:

<u>1st September 2023</u>	Launch of the call, opening of the Expression of Interest (EoI) phase				
17th October 2023 16:00 (4pm) (CEST, UTC+1)	Deadline for Eols submission				
October-November 2023	Independent assessment of Eols				
December 2023	Programme Committee EoIs shortlisting meeting <u> — Invitation to submit Full Proposal</u>				
15 th February 2024 16:00 (4pm) (CET, UTC+1)	Deadline submission Full Proposal				
February-March 2024	Assessment of Full Proposals by the review panel				
22 nd April 2024- 29 th April 2024	Rebuttal period				
<u>22nd-24th May 2024</u>	Review panel meeting and recommendation to the Programme Committee Programme Committee selection meeting				
<u>June 2024</u>	Information to applicants				
January 2025	Earliest possible start of funded projects				

Both the Expressions of Interest (EoIs) and Full Proposals must be submitted electronically using the ESF on-line submission system. Closure of the online platform is time sensitive; it will not be possible to submit EoIs/Full Proposals after the call deadline times.

Strict confidentiality will be ensured during the entire process regarding to the identities of applicants and the content of the proposals.

Eligibility of projects and partners

The **lead institution** must be an eligible research organisation located in an eligible country (see Annex A for details).

Other project partners can be from related fields of expertise, providing they operate as not-for-profit.

Partners from countries not listed as eligible may participate to projects, provided they are not delivering a core component of the project upon which major activities are dependent. Such partners should commit to cover the costs associated to their participation in the project.

Funding is aimed at supporting new research projects.

An individual cannot be named as the lead investigator on more than one competing proposal (whether early phase clinical trial or translational research); however, it is allowed for an individual to lead one proposal and be named as a partner on a separate proposal.

For translational research projects, although this is not a formal requirement, multi-disciplinary or multiinstitutions collaborations are strongly encouraged.

<u>Eligibility Criteria</u> (for both Early phase clinical trials and Translational research):

- Proposal is submitted through the dedicated on-line submission system before the deadline (17th October 2023 for EOI & 15th February 2024 for Full Proposal – both at 16:00 Brussels time);
- Proposal is written in English;
- Proposal is written in **single-spaced typescript** in **Arial 11**, on A4 sized paper with margins of at least 15mm. References, Gantt chart and tables should be no less than **Arial 9**;
- Proposal is submitted by an eligible participant (or a consortium of eligible participants). Eligible participants are listed in Annex A. If one participant requesting FKC funding is not eligible, the whole proposal will be rejected;
- Proposal is complete and follows the template i.e. all elements forming the application (on-line form and proposal) have been provided; <u>Page limits are absolute</u>. **Any pages exceeding the limits will be removed from the application submitted to reviewers;**
- The content of the proposal relates to the call objectives and expected types of projects (see sections 2 and 3 above);
- Requested contribution is within the funding limits specified in section 4;
- Commitment from the applicant (if selected) that they will collaborate with the funding organisations to assist in the dissemination of the project's ambition, paediatric cancers awareness raising and fundraising activities of the funders (for example provision of written quotes, videos explaining project goals, and when possible attendance of the annual fundraising Race events held during the last week-end of September).

Specific eligibility criteria for early phase clinical trials

- Documentation for provision of investigational drug(s) must be provided (can be named in the Expression of Interest, but a support letter is required for the Full Proposal);
- Demonstration that the trial is conducted in at least two European countries that will benefit from FKC funding (as listed in Annex A);
- The investigating organisations are clearly identified.

6. Expressions of Interest' and Full proposals' Structure

The evaluators and the Programme Committee members will base their assessments and decisions <u>exclusively</u> on the information provided in the EoIs and Full Proposals.

Therefore, it is of utmost importance that these documents:

- i) clearly indicate how the proposed research will contribute to the FKC programme objectives and,
- ii) properly and efficiently address the evaluation criteria detailed in section 8.

Expression of Interest Format (EOI)

The EoI has two parts:

- The first part gathers basic proposal information (project name, contact details). This part is to be filled online using a dedicated form.
- The second part provides the core of the EoI, it summarises the project proposed and gives details on the team involved. This part will be uploaded as a single pdf file.

Annex C provides the template to be used and uploaded on the application platform.

Full proposal Format

This is only relevant for applicants who have been invited to submit a Full Proposal.

As for EoIs, basic information will be provided using an online form and the core of the Full Proposal will be uploaded as a single pdf document.

At this stage, **filling a mandatory ethics questionnaire will also be required**, it is strongly advised to review this questionnaire (see Annex E) in advance.

To complete submission, applicants will also be asked to confirm they will be willing to support the dissemination activities of FKC funders in order to promote the programme and demonstrate its impact.

Full Proposal layout

Below is a summary of the elements to be included in a Full Proposal. Annex D provides Full Proposal template and guidelines.

Part A:

Section	Pages limit	Content
A1. Scientific excellence and implementation	7 pages maximum	 Quality and reliability of the research project Quality of the team/institution Implementation

(evaluated according to Criteria 1&2)		
A2. Impact (evaluated according to Criteria 3)	1 page maximum	 Pathways to impact for children and adolescents with cancer Quality of the proposed measures to exploit and disseminate the project results to targeted peers (e.g. scientific, industry) Quality of the proposed measures to communicate the project activities and results to the public

Part B:

Section	Pages limit	Content
B1. Budget & justification	2	Budget TableText justifying the cost items
(essential but non- scored element)		
B2. Annexes		 Gantt chart (1-page maximum) Risk management (1-2 page max) Lay language summary of the project (1/2 page) CV (maximum 2 pages per person, list of up to 10 most relevant publications) References (maximum 2 pages) Letters of support (no limitation)

7. Project evaluation and selection process

Evaluation process

Early phase clinical trial proposals and translational research proposals will be evaluated separately, and two different review panels will be set-up to assess Full Proposals.

EoIs and Full proposal will be assessed against three evaluation criteria (detailed in section 8):

- Scientific excellence
- Quality and efficiency of the implementation and the management
- Potential Impact

All experts involved in the assessments (external referees and review panel members) will be identified and appointed based on their expertise of the topics covered by the applications. Special attention will be given to conflicts of interest in their identification and appointment.

The following evaluation process will be implemented:

1) <u>Stage 1a:</u> Evaluation of the Eol

After eligibility check, all eligible EoIs will be assessed by at least two independent experts. Experts will provide their comments to the FKC Programme Committee.

2) Stage 1b: Shortlisting of Eols

The FKC Programme Committee will review the EoIs together with the experts' assessments. Based on these, it will shortlist the most promising EoIs that will be invited to submit a Full Proposal.

Applicants not shortlisted will also be informed of the outcome of the shortlisting phase.

3) <u>Stage 2: Evaluation of Full proposals</u>

The ESF will perform the eligibility check of full application submitted, any application that is not compliant will be rejected and informed shortly after the closing of the call.

The evaluation of eligible Full Proposals will involve review panel assessment.

The evaluation of Full Proposals will be implemented as follows:

- Evaluation by review panels member
- Rebuttal phase: applicants will have the opportunity to comment on review panel member's assessment
- Review panel meeting. Their recommendations are provided to the Programme Committee

Selection process

Review panel reports will be used by the FKC Programme Committee in their decisions regarding projects to be selected for funding. It has to be noted that the Programme Committee may diverge slightly from the review panels recommendations for programme portfolio management reasons.

Some projects may be put on a reserve list and be funded in case a selected project does not complete grant agreement and/or additional funding is made available.

Following the Programme Committee decisions, all applicants will receive their assessment report. The selected successful applicant(s) will be invited to accede to the project's grant agreement preparation.

FKC funders are actively involved in raising awareness and disseminating information on paediatric cancers and funded activities. Therefore – and to support this effort- when requested to do so, investigators of funded project will be expected to provide project information (e.g. progress, key achievement; interesting news) in a timely manner.

8. Evaluation Criteria

Proposals submitted will be assessed against three evaluation criteria. The content of the application documents (for EoIs and Full Proposal) should properly address these criteria.

Criterion 1: Scientific excellence

- Scientific and intellectual merit of the research objectives and hypothesis
- Thoroughness: definition of the problem(s) and proposed solution (inc. availability and quality of background information)
- Level of novelty and originality in the research proposed

Criterion 2: Quality and efficiency of the implementation and the management

- Overall feasibility of the project with regards to its objectives (e.g. timeline, expertise and capacity mobilised, availability of technologies, access to infrastructure)
- Appropriateness of the research methodology, inc. use of infrastructures and equipment
- Level of novelty and originality in the research methodology (e.g. use of novel technologies/methodologies; innovative application of existing methodologies/technologies).
- Quality and relevance of the of the team management structure, project management plan (inc. resources) and associated deliverables
- Quality and relevance of the research team and the research environment
- Quality and relevance of collaborations and partnerships (inc. co-funding)
- Robustness of the risk mitigation plan
- Training and career development opportunities
- Quality and relevance of the Data Management Plan

Criterion 3: Impact

- Relevance to the FKC programme aims and objectives:
 - To realise real impact on young patients: Improve their survival rate and reduce toxicity to restore young patients to full health after treatment
 - To advance cutting-edge science to further the knowledge of paediatric malignancies.
 - To support improved interdisciplinary research, methods and collaborations for tackling the issues of today.
 - \circ To strengthen collaboration and the development of scientific capacity across Europe.
- Potential to deliver strong potential impact.
- Potential contribution to the advancement of the state of the art
- Adequacy of the level of risk against potential gain (FKC is willing to support high risk/high gain projects)
- Quality of the exploitation and dissemination plan:
 - Quality of the proposed measures to exploit and disseminate the project results to targeted peers and key stakeholders (e.g. scientific community, industry)
 - Quality of the proposed measures to communicate the project activities and results to the public
 - If relevant, adequacy of the intellectual property rights management

9. Programme structure and project reporting

Programme Secretariat

The FKC programme partners have entrusted the European Science Foundation (ESF – www.esf.org) to implement the FKC programme. Acting as programme secretariat, ESF interacts with applicants and reviewers on behalf of – and under mandate from – the FKC programme partners.

In this framework, the ESF is:

- Operating the competitive call
- Implementing the scientific assessment
- Facilitating the work of the FKC Programme Committee
- Centralising the joint programme funding
- Representing the FKC partners when signing the Grant Agreement with the teams selected
- Representing the FKC partners when transferring funds to the research team
- Representing the FKC partners when collecting deliverables and monitoring project progresses.
- Representing the FKC partners on all other FKC-related activities and requests.

Therefore, Grant Agreements will be signed by ESF on behalf of the FKC programme partners.

The FKC Programme Committee is composed by FKC partners representatives and scientific experts in the fields of paediatric cancer. While ESF facilitates the FKC Programme Committee work and regularly interacts with its members, it is set-up and supervised by the FKC partners independently from ESF.

For questions regarding any element of the proposal preparation and submission, please contact the Fight Kids Cancer Secretariat¹: <u>fightkidscancer@esf.org</u>

Project reporting

Funded projects will be required to submit an annual report that will support project monitoring. These reports will detail: the progress of the work plan, use of resources and identify any challenges, they will be externally reviewed. In addition, and in accordance with each project's workplan, deliverables and milestones are to be submitted upon completion to the ESF acting as the Programme Secretariat for FKC. These reports will be shared with the FKC funders.

¹ The European Science Foundation is the Secretariat Office for the Fight Kids Cancer programme

Annex A: List of countries and entities eligible for funding

Countries:

Legal entities established in the following countries will be eligible to receive funding through the FKC call:

Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom.

Legal entities:

For the purposes of this call a legal entity must be established in a country named as eligible in the list above. A legal entity will be eligible to receive funding if they are defined as a non-profit company or organisation that has legal rights and obligations. This includes institutions of higher learning, research centres, and non- profit organisations. It is anticipated that any legal entity taking part is under the direct or indirect control of a participant or under the same direct or indirect control of the participant.

Though described as a legal entity, an exclusion is extended to private for-profit organisations seeking to benefit financially from this funding source. Such organisations are not eligible to receive funding, however participation is not precluded if contributions are provided in kind.

'non-profit legal entity' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual member.

Annex B: Project Finances Information and Guidelines

FKC financial support is targeted **<u>exclusively</u>** towards costs identified in project proposals submitted to the annual call and selected by the Programme Committee. FKC financial support may not be used to meet costs on any other project or activity.

The FKC Funders want to emphasize the fact that applicants should budget for what they need and not refrain from applying for smaller amounts or shorter projects such as primer or preliminary studies.

Any financial commitment or expenditure incurred before a research grant starting date or any commitment in excess of the amount awarded is not eligible for FKC funding. **The maximum grant amount set out in the agreed final budget can NOT be exceeded**.

ESF, on behalf of the funders, reserves the right to examine, in detail, all items of expenditure that will be charged to an grant. Additionally, the funders and other representatives from the FKC Programme Committee may request justification on the use of resources from the project team.

The 'maximum grant amount' of the project is calculated on the basis of the estimated eligible costs submitted by the applicants in their proposal.

Budget requested should be set at be at 2023 price levels and cannot be adjusted to inflation after the selection decision.

Only duly justified eligible costs may be taken into account to determine the final grant. Payment will be limited to the actual costs within the fixed amount of the grant. All costs associated with the research project must be itemised and fully justified in Section 3: Budget & Justification.

The main categories of costs which can be funded from a research grant are indicated in the section below.

In line with policies on open access publication, each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications produced with FKC support. It is expected that publication of the results of a trial are made regardless of their outcome (i.e. negative or positive result). Any delay to open access publication, requires the early agreement of the FKC Programme Committee.

Costs associated with open access will be considered a legitimate research expense and included in the overall research budget as long as:

- The costs are proportionate, reasonable and represent value for money.
- Existing arrangements and resources at the host institution are used first when available and appropriate. Where open access is sought for publications from multiple organisations, it is the responsibility of the corresponding author to lead on any costs.

Funded costs categories

1) Directly Incurred Costs

Directly Incurred Costs are costs that are explicitly identifiable as arising from the execution of a project, are charged as the cash value actually paid and are supported by the normal accounting practices of the organisation. The grant can only reimburse eligible costs (i.e. costs that comply with the general and specific conditions set out in this Annex). In order to be eligible, actual costs must be:

- Actually incurred and paid by the beneficiary:
 - Only actual expenses paid excluding any estimated, budgeted or imputed cost
 - Fully dedicated to the project
 - Definitively and genuinely borne by the beneficiary (not by any other entity)
- Documented and genuinely recorded in the participant's records according to participant's usual accounting practices
- incurred during the project's dates

The 'project duration' is the period running from the project starting date to the end date of the project. If costs are invoiced or paid later than the end date, they are eligible only if the debt existed already during the project duration (supported by documentary evidence) and the final cost has been actually paid before the submission of the financial report.

Directly Incurred Costs can include:

Direct Personnel costs

Payroll costs for staff, full or part-time, who will work on the project and whose time can be supported by a full audit trail during the life of the project e.g. research assistants or dedicated technicians. In particular this includes:

- costs for employees (or equivalent)
- costs for individuals working under a direct contract
- costs for beneficiaries that are individuals without salary

Personnel costs are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action. Their cost is limited to the share of their time spent on the project, reported on timesheets.

Exceptional payroll items such bonus, gift vouchers etc. are not eligible.

Travel and subsistence

Funds for travel and subsistence can be use by staff where travel is required by the nature of the work and dedicated to the project.

Funding will be provided for journeys, visits and trials where these costs are approved at the outset of the grant. Each journey must be itemised, justified and fully costed in the application. Travel should be in economy class or equivalent. Where an overnight stay is required, then the accommodation cost for one night before the meeting and one night after the meeting is possible if the travel/agenda does not allow travel on the first or last day of the meeting.

FKC will consider funding the cost of low-carbon approaches to collaboration (including, where appropriate, the costs of technology or of less economic, but more environmentally friendly means of transport). However, FKC will not pay for the cost of proposed carbon offsetting arising from travel associated with research grants.

Requests for funding to attend conferences will be expected. These must be named, justified and costed in the application. The justification should show how the conference will either directly benefit the research or facilitate future impacts of research. There will also be engagement opportunities (e.g. Cancer races) organised by the funding organisations which the successful applicants are encouraged to participate in, and **it is anticipated that budget should be set aside for travel to (up to 2) such events over the course of the project duration**.

Equipment

The priority for FKC grants is on research. Equipment procurements are eligible under certain circumstances where a clear benefit for the delivery of the project is demonstrated. For all items of equipment costing over €10,000 (including VAT), applicants will need to:

- confirm that the piece of equipment is not readily available for use within the host institution, or any other accessible location (for instance by making reference to any asset registers consulted)
- provide evidence that all other reasonable options have been considered
- if the equipment requested will replace existing equipment, explain what will happen to the existing equipment and why the existing equipment needs to be changed.
- state the contribution that the applicant's organisation will make towards the cost of the equipment
- explain the dependence of the project on this capital as well as any contingency plans that would be invoked should it not be possible to fund the capital elements of the proposal

In any case, **the eligible cost is limited to the share of the usage related to the project**. This must be apportioned with the global length of depreciation and the projects usage rate.

Example:

• An equipment is bought for 25.000 € and will be used & depreciated for 5 years (depreciation cost is then 5,000€/years),

- The project funded by FKC will use it for 2 years
- The project funded by FKC will use at 50% of its usage time

The eligible cost to be integrated to the budget will then be $5,000 \in :5,000 \in (annual depreciation) \cos X 2 (number of years for the project) X 50% (project's usage) = <math>5.000 \in$

Purchase of IT equipment such as computer, laptop, printer is not deemed eligible cost.

Directly Incurred Costs must be identifiable and Verifiable

The applicant must be able to show (with records and supporting documents) the actual costs of the work, i.e., what was actually paid for the work. Costs must be calculated according to the applicable accounting rules of the country in which the applicant is established and according to the beneficiary's usual cost accounting practices.

In addition, for personnel costs (declared as actual costs), the beneficiaries must keep time records for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the FKC Programme Committee may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

Moreover, a beneficiary can NOT transfer budget between cost items listed and justified in the budget table (i.e. personnel cost cannot be used to cover travels).

When the actual grant amount is calculated, the eligible costs cannot include costs under budget categories that did not appear in the proposal, unless the initial estimated budget was amended or if these additional costs were approved in writing.

2) Indirect Costs

Indirect costs are not allowable costs in the FKC programme.

Indirect costs are described as non-specific costs such as overheads. They include the costs of the Research Organisation's administration such as personnel, finance, banking fees, library and some departmental services.

3) Other costs

In-kind contributions free of charge and costs of linked third parties — For in-kind contributions provided by third parties free of charge and costs of linked third parties, the eligibility rules apply *mutatis mutandis*.

Direct costs of subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are deemed to be eligible.

Costs related to preparing, submitting and negotiating the proposals — Cannot be declared as eligible for the action (they are incurred before the action starts).

Costs related to drafting the consortium agreement — Are not eligible because the consortium agreement should be signed before the project starts. However, costs related to updating the consortium agreement are eligible if incurred during the action duration.

Travel costs for the kick-off meeting — Even if the first leg of the journey takes place before the action starting date (e.g. the day before the kick-off meeting), the costs may be eligible, if the meeting is held during the action duration.

If you are in any doubt about whether a specific cost should, or should not, be covered within direct costs, please contact the FKC Secretariat at <u>fightkidscancer@esf.org</u>_____

ANNEX C: Template for the Fights Kids Cancer Competitive Call expression of interest FIGHT KIDS CANCER

FKC 2023-2024 Project Proposals

Expression of Interest

Deadline for submission: 17th October 2023 16:00 (4pm) (CEST, UTC+1)

Part 1: Proposal Summary						
Information	Detail					
Proposed Project Title	Please fill in					
Proposed Project length (months)	To be completed online only					

Part 2: Lead PI details and collaborators						
PI Information	PI Details					
Last (family) name	Please fill in					
First (given) name	Please fill in					
Title (Ms, Mr, Dr, etc.)	Please fill in					
Institution name	To be completed online only					
Department	To be completed online only					
Country	To be completed online only					
Email address	To be completed online only					
Phone number	To be completed online only					
Details of each Co-Investi	gator collaborating on the project					
Name (s), Institution(s) and country	Please list ALL Co-I including their full name & email, institution					
	To be completed online only					

Part 3: Project summary					
Information	Detail				
Budgetary information	Total project's budget: To be completed online only Maximum grant amount claimed from FKC: To be completed online only				
Briefly describe your proposed research using	To be completed online only				

clear & concise language (max 250 words)	
Keywords (max 5)	To be completed online only

Part 3: Case for Support

This should describe the proposed research (including 1 research objectives, 2 implementation of the science and 3.the way that the research will deliver impact). **Maximum 1200 words.**

Please fill in

Part 4: Expertise of the Consortium						
Biosketch [*] of the lead PI						
This section should summari	ise the expertise of the PI. and include the top 3-5 publications to					
demonstrate track record in	both academic excellence and delivering impact.					
Max 200 words						
(publications not included	Please fill in					
in this limit)						
Biosketch [*] of each Co-I co	llaborating partner					
This section should summari	ise expertise of each of the Co-Is and include the top 3-5 publications to					
demonstrate track record in	both academic excellence and delivering impact.					
Max 200 words per person						
(publications not included						
in this limit)						
	Please fill in					

* A biosketch is a streamlined version of your CV

This form should be return through the submission platform no later than 16:00 local time (CET/GMT+1/UTC +1) on 17th October 2023.

ANNEX D: Template for the Fights Kids Cancer Competitive Call Full Proposal



Deadline for submission: 15th February 2024 16:00 (4pm) (CET, UTC+1)

This box is only for information and should not appear in the proposal

Proposals must respect the following standards:

- A minimum font size of 11 points, except for references, the Gantt chart, and tables where the minimum font size is 9 points
- Arial font
- Single line spacing
- A4 page size
- All margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers).
- Must be completed in English

If tables are used, they should illustrate the core text of the proposal and should not contain the core text itself. The text should not contain any hyperlinks in the core text. Each page should contain a header with the proposal acronym. All pages should be numbered in a single series on the footer of the page using the following numbering format "Page X of Y".

The description of the proposed research project should be is completed off-line (consisting of Part A and Part B) and then uploaded as a pdf and. It is the responsibility of the applicant to verify that the submitted PDF documents are readable. Page limits are absolute, and any applications which exceed the limits will be rejected.

Part A:

The maximum total length for this part is **8 pages**. Excess pages (per section and overall) will not be considered. It is the responsibility of the applicant to verify that the submitted PDF documents are readable and are within the page limit. It should be composed as follows:

- Section 1: Scientific excellence & implementation (7 pages maximum)
- Section 2: Impact (1-page maximum)

The elements to be included in Part A are described are summarised below:

Part A: Section 1: Scientific excellence & implementation – 7 pages maximum

• Quality and reliability of the research project;

In this part, you should provide an introduction, a state-of-the-art, specific hypotheses and objectives plus a general overview of the project. The research methodology and the approach should be also described. The originality and the innovative aspects of the research project should be highlighted and explained, especially regarding how the project is expected to make advancements in the field of paediatric oncology. Any novel concepts, approaches and methods that will be implemented should be described.

• Quality of the team/institution;

You should describe the qualifications and experience of the principal investigator(s), as well as the team in general. You must provide information regarding the level of experience on the research topic proposed and a narrative track record of work (main international collaborations, level of experience in supervision of PhD and postdoctoral researchers, publications, past and on-going projects, and any other relevant results). Finally, the research project should also show that it will be well-integrated within the team/institution. Short and concise CVs will have to be joined in the Annexe (see below Part B section 4 for details).

• Implementation;

In this part, you should describe the work planning (Work Breakdown Structure, including deliverables and milestones) and provide an outline of the project management structure and approach.

The proposed schedule (in months) must be detailed from the start of the project. The associated Gantt chart, which include Work Packages titles, indication of major deliverables and milestones, should be joined as an Annexe (see below Part B section 4 for details).

Resources (technical, expertise and skills) required to support the methodology and to reach the project objectives should be described. You should also indicate the planned number of personmonths and how they are to be used in the different tasks (note that detailed cost justification should be provided in section 3).

A risk analysis and associated risk management plan should be provided as an annex (see below Part B section 4 for details).

Part A: Section 2: Potential Impact – 1 page maximum

o Pathways to impact for children and adolescents with cancer

This should summarise how the research activities during and after the project will contribute to the FKC programme objectives:

• To realise real impact on young patients: Improve their survival rate and reduce toxicity to restore young patients to full health after treatment

- To advance cutting-edge science to further the knowledge of paediatric malignancies.
- To support improved interdisciplinary research, methods, and collaborations for tackling the issues of today.
- To strengthen collaboration and the development of scientific capacity across Europe.

• Quality of the proposed measures to exploit and disseminate the project results to targeted peers (e.g. scientific, industry)

In this part, you should describe the dissemination and exploitation of the knowledge that will be generated by the project. Potential impact should also be described. The planning of the dissemination and exploitation activities should appear in the Gantt chart (see Part B section 4).

Quality of the proposed measures to communicate the project activities and results to the public

In this part, you should demonstrate how the public engagement activities will contribute to create awareness around the research and the results, especially in a way that can be understood by the public. The planned activities should also be included in the Gantt chart.

Part B:

- Section 3: Budget & justification
- Section 4: Annexes (Gantt chart, Risk management, CV, References)

Part B: Section 3: Budget and Justification

The Justification of Resources should not exceed **2 pages.** This should state the full cost of the project and explain why the requested resources are needed, including identifying how the proposal presents good value for money.

All costs associated with the project must be itemised (using the table templated below) and fully justified (text to be provided in addition to the table). Cost items that are not properly justified may be removed from the proposed grant.

If contingency costs cannot be clearly identified, itemised and justified, they cannot be included in the project budget.

Complementary funding and in-kind support should be mentioned here and supported by letters of support, to be provided in annex 6.

Budget table (excel spreadsheet below, to adapt according to the number of partner and number of year)

Costs Partner 1 Partner 2 Partner 3 Partner 4	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0
Partner 2 Partner 3				3		
Partner 3						€ 0.0
						€ 0.0
Partner 4						€ 0.0
						€ 0.0
Partner 5						€ 0.0
ence	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0
Partner 1						€ 0.0
Partner 2						€ 0.0
Partner 3						€ 0.0
Partner 4						€ 0.0
Partner 5						€ 0.0
erials	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0
Partner 1						€ 0.0
Partner 2						€ 0.0
Partner 3						€ 0.0
Partner 4						€ 0.0
Partner 5						€ 0.0
cify if in-kind or subc	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0
Partner 1						€ 0.0
Partner 2						€ 0.0
Partner 3						€ 0.0
Partner 4						€ 0.0
Partner 5						€ 0.0
d budget	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0
Total per partner						
Partner 1	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0
Partner 2	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0
Partner 3	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0
Partner 4	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0
Partner 5	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€0.0
	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE
	ence Partner 1 Partner 2 Partner 3 Partner 3 Partner 4 Partner 5 erials Partner 1 Partner 2 Partner 3 Partner 4 Partner 5 cify if in-kind or subc Partner 1 Partner 2 Partner 3 Partner 3 Partner 3 Partner 5 cid budget Total per partner Partner 1 Partner 1 Partner 2 Partner 3 Partner 3 Partner 3 Partner 3 Partner 3 Partner 3 Partner 1 Partner 3 Partner 4	ence $€ 0.0$ Partner 1Image: Sector of the sector	ence $€ 0.0$ $€ 0.0$ Partner 1IIPartner 2IIPartner 3IIPartner 5IIPartner 5 $€ 0.0$ $€ 0.0$ Partner 1IIPartner 2IIPartner 3IIPartner 5IICify if in-kind or subc $€ 0.0$ $€ 0.0$ Partner 1IIPartner 2IIPartner 3IIPartner 4IIPartner 5IICify if in-kind or subc $€ 0.0$ $€ 0.0$ Partner 1IIIPartner 5IIPartner 6IIPartner 7IIPartner 8IIPartner 9IIPartner 9IIPartner 1 $€ 0.0$ $€ 0.0$ Partner 1 $€ 0.0$ $€ 0.0$ Partner 3 $€ 0.0$ $€ 0.0$ Partner 4 $€ 0.0$ $€ 0.0$ Partner 5IIPartner 1 $€ 0.0$ $€ 0.0$ Partner 3 $€ 0.0$ $€ 0.0$ Partner 4 $€ 0.0$ $€ 0.0$ Partner 5IIPartner 3 $€ 0.0$ $€ 0.0$ Partner 4 $€ 0.0$ $€ 0.0$ Partner 5IIPartner 6IIPartner 7IIPartner 9IIPartner	ence $€ 0.0$ $€ 0.0$ $€ 0.0$ $€ 0.0$ Partner 1IIIPartner 2IIIPartner 3IIIPartner 5IIIerials $€ 0.0$ $€ 0.0$ $€ 0.0$ Partner 1IIIPartner 2IIIPartner 3IIIPartner 5IIICify if in-kind or subc $€ 0.0$ $€ 0.0$ $€ 0.0$ Partner 1IIIPartner 2IIIPartner 3IIIPartner 4IIIPartner 5IIIPartner 6IIIPartner 7IIIPartner 8IIIPartner 9IIIPartner 9IIIPartner 9IIIPartner 1 $€ 0.0$ $€ 0.0$ $€ 0.0$ Partner 1 $€ 0.0$ $€ 0.0$ $€ 0.0$ Partner 1 $€ 0.0$ $€ 0.0$ $€ 0.0$ Partner 3 $€ 0.0$ $€ 0.0$ $€ 0.0$ Partner 4 $€ 0.0$ $€ 0.0$ $€ 0.0$ Partner 1 $€ 0.0$ $€ 0.0$ $€ 0.0$ Partner 1 $€ 0.0$ $€ 0.0$ $€ 0.0$ Partner 3 $€ 0.0$ $€ 0.0$ $€ 0.0$ Partner 4 $€ 0.0$ $€ 0.0$ $€ 0.0$ Partner 5I	ence $€ 0.0$ $€ 0.0$ $€ 0.0$ $€ 0.0$ $€ 0.0$ Partner 1 </td <td>ence$€ 0.0$$€ 0.0$$€ 0.0$$€ 0.0$$€ 0.0$$€ 0.0$Partner 1II<!--</td--></td>	ence $€ 0.0$ $€ 0.0$ $€ 0.0$ $€ 0.0$ $€ 0.0$ $€ 0.0$ Partner 1II </td

Part B: Section 4: Supporting Annexes

The following Annexes must be provided with the proposal:

1) Annex 1: Gantt chart (1 page max)

The Gantt chart should illustrate the work schedule of the project, it should include:

- <u>Deliverable</u>: Distinct output of the research project, important for the research project's overall objectives. It may consist of a report, a document, a publication, etc. The numbering of deliverables should be ordered according to delivery dates. Please use the following numbering convention: "WP *number*. *Number* of the deliverable within that WP". For example, deliverable 1.2 is the second deliverable of the work package 1.
- <u>Milestones:</u> Defined control points in the research project that help to structure the progress of the project. They may correspond to the completion of key deliverables, necessary for the next step of the project, or intermediary results or achievements that may operate as a checkpoint to apply corrective measures if necessary.

2) Annex 2: Risk management (2 pages max)

This part should present and discuss relevant research/administrative risks that might occur and impact on the project implementation. Associated risk management and mitigation measures should be described.

3) Annex 3: Lay language summary of the project (1/2 page max)

This is a description of the project in lay terms and will be a key communication and dissemination tool. Therefore, it must be understandable by the general public and include the following information:

- Indication targeted by the project and general information on the indication:
 - # patients per year in Europe generally
 - # patients in relapse/high risk per year in Europe if relevant
 - Overall chances of survival of target group of patients and / or information about toxicity and long-term side effects
- Purpose of the project's intervention
- Nature of the project's intervention
- Next steps for patients after the conclusion of your project (clinical trial, phase II or III trial, amendment of standard of care...)

4) Annex 4: Project team CVs

CVs of the principal investigator(s) and co-investigator(s) should be attached in annexes, with a maximum of 2 pages per CV. CVs should include current and previous positions, a maximum

of 10 most relevant publications and obtained research funding. It is recommended that CVs use a consistent template within projects.

5) Annex 5: References (2 pages max)

In general, the citations and the bibliography should follow <u>The Lancet citation style</u>. References need to be cited in the text sequentially in the Vancouver numbering style, as a superscripted number (Arabic numerals: 1, 2, 3, 4...) after any punctuation mark. Two references are cited separated by a coma without space, three or more consecutive references are given as a range using an en rule (i.e. 1–4). References should be listed on a new page, titled 'References', in the Annexes. It needs to include all the references you have cited in the text. The journal titles should be abbreviate using the style from the <u>NLM</u>.

6) Annex 6: Letters of Support

Letters of support should be included to provide evidence of existing engagement with relevant users, partners, researchers, drug availability etc. For example, the types of letters an applicant should include are:

- a. Letter of support that drugs are identified and will be provided for the opening of the trial
- b. Letter of support from complementing project/funding
- c. Letter of support from the applicant's organisation

Letters of support are required from any named Project contribution – up to 2 pages each:

- For research involving investigational drug(s), applicants should include a letter of support that the drug will be provided (for both pre-clinical and clinical research)
- The letter of support should confirm the organisation's commitment to the proposed project, identify the value, relevance, and possible benefits of the proposed work to the partner, the period of support, the full nature of the collaboration and how the partner will be involved in the project and provide added value
- Applicants should include any in kind and or leveraged support that has been secured for the proposal through the attachment of a letter from the Project Partner or Collaborating Project.

Any letter of support should be written when the proposal is being prepared and targeted specifically to the project.

It is reminded that a letter, guaranteeing that investigational drugs will be available for early phase clinical trial projects, is an eligibility criterion.

Annex E: Ethics self-assessment to the Fight Kids Cancer Competitive Call



FIGHT KIDS CANCER SUPPORTING A PROGRAMME FOR INNOVATIVE RESEARCH

Ethics self-assessment to the Fight Kids Cancer Competitive Call

Fight Kids Cancer Competitive Call

Information about your application, including the personal information provided on the forms, will be processed and stored electronically by the European Science Foundation (ESF) Secretariat and representatives of the Call's Funders. In accordance with the selection process, the Information contained in your application may be passed on to external reviewers in confidence. Reviewers will be asked to destroy information after the review and selection process is completed.

Your application and personal information will be stored by the ESF electronic system for programme management purposes but will not be shared with other organisations outside the FKC partnership. We will use details provided in the application for correspondence about the call and may also use this information for future analyses of the performance of the programme.

By submitting your application to the FKC Programme you have indicated your acceptance of these data protection terms and conditions.

Completion of the tables below constitutes part of the proposal submission for the FKC call and must be uploaded at the time of submission.

For details about ethics requirement and information/documents to provide later, please refer to the ethics guideline.

	1: Human Embryonic Stem Cells (hESCs)	YES	NO	Page (in the proposal)		
Does y	our research involve Human Embryonic Stem Cells (hESCs)?					
lf	Will they be directly derived from embryos within this project?					
YES:	Are they derived from established cells line?					
Section	2: Humans					
Does y	pu research involve human participants?					
If YES:	Are they persons unable to give informed consent (including					
	children/minors)?					
	Are they patients?					
Does ye particip	our research involve physical interventions on the study pants?					
If YES:	Does it involve invasive techniques (e.g., collection of human					
	cells or tissues, surgical or medical interventions, invasive					
	studies on the brain, etc.)?					
	Does it involve collection of biological samples?					
Section	3: Human Cells/Tissues					
-	ou research involve human cells & tissues (other than hESCs,					
see sec	tion 1)?					
If YES:	Are they available commercially?					
	Are they obtained within this project?					
	Are they obtained from another project or institution?					
	Are they obtained from a biobank?					
Section	4: Protection of personal data					
Does y	pur research involve processing of personal data?					
If YES:	Does It involve the processing of special categories of					
	personal data (e.g. genetic, health, sexual, lifestyle,					
	ethnicity)?					
	Does it involve processing of genetic, biometric or health data?					
Does yo	our research involve further processing of previously collected					
person	al data (including use of pre-existing data sets or sources,					
mergin	g existing data sets)?					
Does yo	our research involve publicly available data?					
lt is pla EU?	nned to export personal data from non-EU countries into the					
lt is pla	nned to import personal data from non-EU countries into the					
EU?						
Section	5: Animals					
Does y	our research involve animals?					
If YES:	Are they vertebrates?					
	Are they genetically modified?					

Section 6: Third countries		
In case that participants from countries that are not designated in		
Annex A are involved, do the research related activities undertaken in		
these countries raise potential ethics issues?		
Specify the countries involved:		
Section 7: Health and safety		
Does your research involve the use of elements (chemicals,		
radioactive material) that may cause harm to humans, including		
research staff?		
For research involving human participants, see section 2.		
Section 8: Misuse of research results		
Does your research have a potential for misuse of research results?		
Section 9: Other ethics issues		
Are there any other ethics issues that should be taken into		
consideration?		
Please specify:		