# **Request for Proposals**

Foundation for Cancer Research Support (RakFond)
Competition of Clinical Research Projects in Oncology

**RFP Code:** 2019-01

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Please visit <a href="https://www.rakfond.org/rfp-2019-01-en/">www.rakfond.org/rfp-2019-01-en/</a> for the most up-to-date version of this RFP.



Foundation for Cancer Research Support (RakFond)

Rochdelskaya str. 15, bld. 17-18, room III Moscow, 123022 Russia www.rakfond.org/en/

# Part I. Overview Information

Funding Opportunity Title	RakFond's Competition of Clinical Research Projects in Oncology			
Funding Opportunity Aim	The aim of this Funding Program is to provide funding and other support to investigators based in Russia to promote and advance world-class clinical research in oncology.  Proposal submissions for clinical studies in oncology and related areas are encouraged.			
Eligibility	Scientist and / or investigator affiliated only with eligible organizations based in Russia.			
RFP Code	2019-01			
Key Dates				
Posted Date: Open Date: Registration Due Date: Application Due Date: Formal Compliance Review: Scientific Review: Notice of Award: Final Report:	April 25, 2019 April 25, 2019 June 20, 2019 July 1, 2019 July 15, 2019 August 30, 2019 by September 20, 2019 2 months after project conclusion date			
Award Description	Award Amount: up to 500 000 (five hundred thousand) RUR (inclusively) for clinical research expenses (salaries excluded).  Access to the online service for clinical trials management Enrollme.ru.  Expert assistance in the clinical trial statistical design and data analysis.  Award Term: up to 18 months; not renewable; no-cost extension of up to 6 months can be provided in exceptional cases.			
Applicant Registration	Registration before June 20, 2019 is required, early registration is highly recommended  Register at: <a href="https://www.rakfond.org/rfp-2019-01-registration/">www.rakfond.org/rfp-2019-01-registration/</a>			
Technical Point of Contact	grant@rakfond.org			
Submission	Application and scans of supporting documents by email by Application Due Date.  Winners must send originals of all application documents to RakFond no later than 7 days after the results are announced.			
RFP Email	grant@rakfond.org			

RFP Mailing Address	Foundation for Cancer Research Support (RakFond) Rochdelskaya str. 15, bld. 17-18, 3rd floor, room III, Moscow, 123022, Russia
Solicitation Website	www.rakfond.org/rfp-2019-01-en/

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# Part II. Full Text of Announcement

# Section I. Funding Opportunity Description

# 1. Background

The Foundation for Cancer Research Support (RakFond) is a non-profit organization whose main tasks include: financing research and development activities, development of new methods and tools for the prevention, diagnostics and treatment of cancer, promoting the development and improvement of research and scientific activities of research institutions, scientific centers, oncological hospitals, and individual specialists in the field of oncology. RakFond was founded in 2017 and operates on the territory of the Russian Federation. For more information, visit <a href="www.rakfond.org/en/">www.rakfond.org/en/</a>.

# 2. Objectives

The overall objectives of this funding opportunity are:

- To promote clinical research in oncology and related areas;
- To provide effective additional support of clinical research projects, including expert assistance and access to the online service for clinical trials organization and management;
- To assist scientists and investigators in achieving publishable results and advancing their research projects.

# 3. Scope

Proposals for randomized clinical trials in oncology and related areas, including cancer prevention, diagnostics, monitoring and treatment, rehabilitation and quality of life of cancer patients, are welcome.

# Section II. Award Information

# 1. Summary

Instruments of Support	Winners receive funding to carry out approved research projects, as well as access to online service for clinical trials management <a href="Enrollme.ru">Enrollme.ru</a> and expert assistance in the clinical trial statistical design and data analysis.
Funds Available and Anticipated Number of Awards	The number of awards are contingent on a sufficient number of meritorious proposals and availability of funds.  Access to online service <a href="Enrollme.ru">Enrollme.ru</a> and expert assistance may be provided to non-winning applicants at the discretion of RakFond.
Award Budget	Up to 500 000 (five hundred thousand) RUR (inclusively). Proposal budget must reflect the actual needs of the proposed project. Salary and travel expenses are not allowed. The final award budget may be subject to negotiation with RakFond.
Award Project Period	The scope of the proposed project should determine the project period. The maximum Award Period is 18 months.  In special cases, RakFond may allow a single 6-month no-cost extension request, which will be approved or disapproved at its discretion. (See "Terms & Conditions. Request for Budget Changes or Extensions.")

# 2. Terms & Conditions

By accepting RakFond's funding, the Award Recipient and Award Recipient's Organization (ARO)<sup>1</sup> accept the following Terms and Conditions:

#### A. Responsible Conduct of Research

- 1. The project must be conducted according to the highest scientific and ethical standards and in compliance with all applicable laws and regulations and with the policies of ARO. To the extent policies of ARO conflict with these Terms and Conditions and/or RakFond's policies, these Terms and Conditions will prevail.
- 2. Upon request of RakFond, the Recipient must provide copies of documentation of ARO approval for research (IRB and/or Ethical Committee) to RakFond prior to commencing research on human subjects.

## B. Funds: Payment, Use and Restrictions

3. The funds will be transferred to the ARO (preferably) or the Award Recipient directly.

<sup>&</sup>lt;sup>1</sup> Here and further, the Organization where the Award Recipient works full- or part-time.

- 4. The Recipient is not permitted to transfer the funds to any other person.
- 5. The funds will be used solely as detailed in the proposal and its budget.
- 6. Indirect or travel expenditures are not allowed. Funds cannot be used to pay salaries. No more than 20% of funds can be used for subcontracts and outsourced research.
- 7. Funds cannot be used for expenditures incurred prior to the first day of the Award Period or after the last day of the Award Period. No additional expenses may be paid from funds after RakFond has received the Recipient's final expenditure report or after any unexpended funds have been returned to RakFond.
- 8. At the end of the Award Period, any unexpended funds and any funds expended non-compliant with these terms and conditions, or inconsistent with the project must be returned to RakFond.

## C. Submission of Requests for Project Amendments

9. All change requests related to the project must be initiated by sending an email to: <a href="mailto:grant@rakfond.org">grant@rakfond.org</a>

### D. Requests for Budget Changes or Extensions

- 10. The Recipient may move funds of up to 10% of the total budget between budget categories or into new budget categories without prior written approval of RakFond. Notwithstanding the foregoing, indirect and travel costs cannot be introduced, neither can be salaries nor increase of subcontracts and outsourced research.
- 11. Budget changes of greater than 10% between budget categories must be approved in writing by RakFond before expenditure of funds. The Recipient must submit a re-budget request with a detailed justification of the proposed change by sending an email to: <a href="mailto:grant@rakfond.org">grant@rakfond.org</a>.
- 12. In exceptional cases, RakFond may allow a single 6-month no-cost project extension, which will be approved or disapproved at its discretion. The extension request, an updated financial expenditure and progress report, and a detailed explanation of why the request is being made must be emailed to: grant@rakfond.org.
- 13. Any request for a no-cost extension or budget change must be made at least 60 calendar days prior to the expiration of the Award Period. Requests received after that date will not be accepted and will automatically be disapproved.

#### E. Changes in Research Focus and Project Scope

14. Major changes in the overall research topic, approaches and methods are not allowed. However, some changes in the specific goals of the project may be allowed with prior written consent from RakFond. Any request for changes must be sent by email to: <a href="mailto:grant@rakfond.org">grant@rakfond.org</a>. An approval must be received prior to performing any changes to the project. RakFond will approve or disapprove the request at its discretion.

#### F. Institution Transfer

15. If the Recipient accepts an appointment at another institution during the Award Period, and desires to have the funds transferred to the new organization, the Recipient must submit a fund transfer request by email to: <a href="mailto:grant@rakfond.org">grant@rakfond.org</a> at least 30 calendar days before the anticipated date of transfer. Subject to RakFond's written approval and at RakFond's sole discretion, the funds may be transferred provided arrangements satisfactory to RakFond are implemented to continue the Research Project in a manner in which it was originally approved by RakFond, including establishing new organization's eligibility. Any transfer must be approved in writing by RakFond before any such transfer takes place. Upon approval of a

- transfer of the funds to a new organization, the original ARO must return any unexpended funds and any funds expended inconsistent with the project to RakFond. The new organization must agree to comply with these Terms and Conditions. RakFond will make arrangements to provide remaining funds to the new organization.
- 16. If the Recipient is unable or not permitted to transfer the funds to a new organization, the Recipient and the ARO will relinquish the funds and any unexpended funds or funds expended inconsistent with the Research Project must be returned to RakFond.

# G. Reporting

- 17. The final report consisting of expenditure (financial) and progress reports is due 2 months after project conclusion date. It is the responsibility of the Recipient to submit the report in a timely manner. RakFond may contact appropriate persons in the ARO to ensure the progress reports and expenditure reports are received as required. RakFond reserves the right to request an intermediate project progress report 9 months after the project start date or half-way through the Award period.
- 18. Noncompliance with any of these Terms and Conditions, including failure to submit progress or expenditure reports, may result in the withholding of payment on other RakFond-funded projects in effect at the ARO, or RakFond funding that may be awarded in the future, or such other action deemed appropriate by RakFond.

## H. Post-Award Reporting Obligation

- 19. The Award Recipient may be asked to respond to RakFond's requests for information on his/ her career progress following the Award Period and may be asked to provide his/her current Curriculum Vitae and/or publication list. The information may be used for program evaluation and alumni communications. The Award Recipient understands that this obligation survives the Award Period and that he/she has an obligation to provide this information during 5 (five) years after the project completion date.
- 20. RakFond reserves the right to include information relating to this Award in its periodic reports, annual reports, awardee directory, publicly accessible databases of funded research projects, or in any other materials issued by or on behalf of RakFond or its affiliates.

#### I. Publications, Other Public Release of Results, and Acknowledgments

- 21. RakFond strongly encourages the Award Recipient to submit the results of funded research project for publication or other public release. In the event the Award Recipient's results are published or otherwise publicly released either during or after the Award Period, the Recipient will provide RakFond with a copy of such publication or public release.
- 22. The Award Recipient and ARO agree that all abstracts, publications, presentations, and other intellectual property resulting from research supported by this funding must contain the acknowledgment, "This work was (partially) funded by the NPO "Foundation for Cancer Research Support" under Funding Program 2019-01. Any opinions, findings, and conclusions expressed in this material are those of the author(s) and do not necessarily reflect those of RakFond."

#### J. Intellectual Property Rights

23. RakFond will have no intellectual property rights or other rights in or to data collected or scientific discoveries made through any project funded by the program. RakFond encourages

the Award Recipient and ARO to report to RakFond any inventions, discoveries, or intellectual properties that result from the support of the research.

# Section III. Eligibility Information

RakFond reserves the right to evaluate and determine applicants' eligibility based on the information and justifications included in the application materials, publicly available information, and any other additional requests for information, if necessary.

# 1. Eligible Applicants

## A. Eligible Organizations

Applicants from any domestic public or private institutions of higher education, clinics, hospitals, research centers, non-profit or for-profit organizations, whose activities involve research in the area of oncology may be eligible to receive the Award.

Potential applicants should be prepared to establish eligibility of their organization to receive and administer funding, and RakFond reserves the right to reject application if an organization is determined not to satisfy eligibility criteria for this funding program. RakFond urges potential applicants to consider the following eligibility considerations:

- 1. Does your organization conduct scientific research?
- 2. What is the nature of the research and business that your organization performs? Are they related to oncology and fit within this RFP's objectives and scope?
- 3. Has your organization applied to and/or been funded to do oncology related research by any Federal agency or private foundation?
- 4. Have the results of any oncology related research papers been published by researchers from your organization?
- 5. Is your organization professionally responsible for the research?
- 6. Where physically is the proposed research to be conducted?

Forms and documentation submitted to RakFond must include the name of the Authorized Representative (AR) with the appropriate authority to sign and submit documentation on the organization's behalf. AR's signature certifies commitment of the organization to support the proposed project, that the organization will be accountable for the appropriate use of funds (in case the funds are transferred to the organization's account), and that the organization complies with the legislation of the Russian Federation, including required licenses and certifications, which are necessary for conducting the proposed research, and accepts the terms and conditions of RakFond's funding, which are described in the Request for Proposals.

#### B. Foreign Participation

Researchers based in foreign institutions and international organizations, including public or private non-profit or for-profit organizations, are not eligible to apply for this funding opportunity. Applicants must be affiliated with eligible domestic organizations only; however, an applicant may be a non-Russian citizen.

RakFond may support projects with a part performed outside Russia either by the Recipient or by researchers employed by a foreign institution, whether or not funds are expended. For this funding opportunity, the total expenditures for any outsourced research, including foreign, cannot exceed the total amount allocated for this category (20% of the budget).

### C. Registration

All applicants will have to complete a one-time registration process prior to submitting any proposal. Registration will help RakFond to make a preliminary assessment of applicant organization's eligibility.

Applicants are strongly encouraged to submit a registration form as soon as possible. This will help RakFond in timely determining applicant's organization eligibility prior to the full application submission deadline. Applications, for which organizational eligibility cannot be determined by the Formal Compliance Review deadline (July 15, 2019) will be automatically excluded from further consideration.

Registration form must be filled in on-line at: <a href="https://www.rakfond.org/rfp-2019-01-en/">www.rakfond.org/rfp-2019-01-en/</a>

The following information is required to complete the registration form:

#### **APPLICANT**

- 1. First Name (required)
- 2. Middle Name (optional)
- 3. Last Name (required)
- 4. Education and scientific degrees (required)
- 5. Current research appointment and organization (required). Full time or part-time (percentage of time spent on research, if part-time)
- 6. Primary Email to be used for all communications regarding this application (required)
- 7. Address (at least one, checked as primary) (required)
- 8. Phone (at least one, checked as primary) (required)
- 9. Website (optional)

#### ORGANIZATION(S)

- 1. Organizational Affiliations (single or multiple) (required)
- 2. Organization's addresses, both legal and actual (required). A primary organization must be designated, if affiliated with multiple organizations.
- 3. Website (required)
- 4. Name of primary organization's Authorized Representative (AR) (required)
- 5. AR's department and title (required)
- 6. AR's organizational email (required) and phone (optional)

#### **PROJECT**

- 1. Preliminary title (required)
- 2. Main goals (required)

Technical assistance with the registration form can be obtained by sending an email to: grant@rakfond.org.

## D. Eligible Applicants

Applicants must meet the following criteria to qualify for the Competition:

• Conduct scientific research in oncology or related areas.

• Work full-time or part-time (no less than 50%) in an eligible organization.

# 2. Cost Sharing

Cost sharing is not required. However, if the Award Recipient's organization commits to providing cost sharing, corresponding confirmation letter should be submitted with the application.

# 3. Additional Information on Eligibility

# A. Number of Applications

Each eligible organization may submit more than one application, provided that they are submitted by different applicants and each proposal is scientifically distinct. However, for this funding opportunity, RakFond strongly encourages to limit the total number of applications to two per organization.

Each applicant may submit only one proposal for this funding opportunity.

# Section IV. Application and Submission Information

All applications must be submitted in accordance with the requirements and instructions of this Request for Proposals (RFP). All application materials must be in English, must use RakFond's forms and templates, follow RakFond's guidelines, and must be submitted in a timely manner. Incomplete applications and applications submitted after deadlines will be automatically rejected.

# Obtaining an Application Package

Applicants must download application forms and templates associated with this funding opportunity from <a href="www.rakfond.org/rfp-2019-01-en/">www.rakfond.org/rfp-2019-01-en/</a>. Forms and templates contain all necessary instructions, including: required information, page limitations, budget categories, etc.

# 2. Content and Form of Application Submission

Applications should consist of a single PDF file or a set of PDF files containing the following documents assembled in the following order:

- 1. Cover letter signed by AR (required) in Russian or in English
- 2. Proposal form including brief rationale, scientific hypothesis, aim and goals, study design, sufficient resources, detailed budget and study timelines (7 pages maximum) (required) in English
- 3. Applicant's CV with the list of up to ten selected publications and link to Google Scholar or other relevant profile (2 pages maximum) (required) in English
- 4. Other supporting documentation (optional, if submitted, should not exceed 10 pages) letters of support should be submitted in English; all other information if necessary may be in Russian or in English

#### Formatting requirements:

Render and submit a single PDF file or a set of PDF files named "RFP-2019-01-[Your First Name]-[Your last name]-document index (if applicable)", that precisely follows the guidance of form and templates, and the order above. For example, «RFP-2019-01-Ivan-Petrov».

To ensure maximum protection of your information, please mark all pages of your application documents, where possible, with the footer "Confidential and Proprietary – Exempt from Disclosure."

Application PDF should be emailed before the submission deadline to: <a href="mailto:grant@rakfond.org">grant@rakfond.org</a> with the Application PDF file name as the Subject.

If the PDF file size exceeds 25 MB, send documentation in separate emails. Name those files "RFP-2019-01-[Your First Name]-[Your last name]-[Addendum (1, 2, 3, etc.)]" and use those names as the Subject.

#### 3. Submission Date and Time

Completed application and all supporting materials must be received via email by RakFond before 23:59 (Moscow time) on July 1, 2019. Applications received after this deadline will not be considered.

Winners must send to RakFond the originals of all documents, which were submitted in the electronic form during the application process, no later than 7 (seven) calendar days after the competition results are announced. Documents must be sent by Mail and include Confirmation of Delivery or any other certificate, which confirms receipt of the originals by RakFond.

The originals must be sent to:

# Foundation for Cancer Research Support (RakFond)

Rochdelskaya str. 15, bld. 17-18, 3rd floor, room III,

Moscow, 123022

If a winner fails to send the originals within the required period of time, RakFond reserves the right to withdraw the award and transfer it to another competition participant.

# 4. Other Requirements, Information Use and Sharing

# A. Application Changes

The applicant must notify RakFond within 3 (three) working days by sending an email to <a href="mailto:grant@rakfond.org">grant@rakfond.org</a> if any of the following conditions applies from application submission through award notification:

- 1. The applicant leaves his/her current position in the organization, changes organizations, or unable to meet the eligibility requirements stated in Section III.1.D.
- 2. Other significant changes in applicant's career plans or organization's conditions, which may affect goals, research strategy, timeline, and/or budget (organization ceases operation, loses funding, etc.).

If RakFond is notified of any of these changes in after the applicant is notified of an award, RakFond has the right to withdraw the award.

# Section V. Application Review Information

RakFond's core requirements for proposals are:

- Based on world-class science, that has the potential to provide significant advancement in cancer research and oncology
- Have goals that are clear, ambitious, and credible
- Yield practical, measurable outcomes
- Employ rigorous methodology
- Will achieve publishable results

Awards are given based on individual merit; proposals are not evaluated against one another.

# 1. Review Criteria

RakFond will select winners based on the following criteria:

	Explanation	Weight (0-1)
Significance	Does the proposal address an important problem to advance the field? Is there a strong scientific foundation for the proposal? If the goals of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? Is there a high probability of publishing project's research results in high-impact journals?	1
Investigator	Does the applicant have appropriate experience and training? Factors considered include the quality and extent of past education, scientific training, research experience, research originality and productivity.	1
Novelty	Does the proposal seek to utilize novel concepts, methodologies, instrumentation, or interventions?	2/3
Approach	Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific goals of the project? Have the investigators presented strategies to ensure a robust and unbiased approach? Are potential problems, risks, alternative strategies, and benchmarks for success presented?	
Are the institutional support, equipment and other resources available to the investigator adequate for the project proposed? Will the project benefit from some unique features of the scientific environment?		1/3

Total Maximum Score 33	Total Maximum Score 33
------------------------	------------------------

RakFond uses a 9-point scale (from 1 to 9, with 9 being the highest mark) for all individual review criteria. Scores for each criterion will be accompanied by the review critique. RakFond expects, that only proposals with scores of at least 5 ("good") for each criterion will be considered for funding.

The table below provides a guide for individual criterion scores:

Criterion Strength	Score	Descriptor
	9	Exceptional
High	8	Outstanding
	7	Excellent
Medium	6	Very Good
	5	Good
	4	Satisfactory
	3	Fair
Low	2	Marginal
	1	Poor

## 2. Review and Selection Process

The competition may be considered failed in case by the registration due date (June 20, 2019) less than 10 applicants are registered, or if by the submission Due Date (July 1, 2019) less than 5 applications are submitted for the competition. The decision will be made RakFond's discretion. In this case, RakFond immediately informs all applicants about the competition cancellation and the return of the submitted applications.

At its discretion, RakFond may change the competition timelines. Corresponding announcements will be published on RakFond's web-site and sent to all registered applicants or those who have submitted applications by the decision date.

RakFond employs a rigorous scientific review process to evaluate proposals received in response to the RFP.

Submitted applications are first evaluated for completeness and formal compliance with the RFP by RakFond. Applications that comply with the requirements of the RFP will undergo further scientific review.

RakFond will assign each proposal for scientific review to a minimum of three Reviewers.

Once scientific reviews are complete, the reviewers' evaluation reports are forwarded to RakFond. RakFond will review each proposal and associated evaluation reports to ensure that the evaluation reports adequately document the review conducted. It is the RakFond's responsibility to ensure that the Reviewers have provided sufficient, substantive rationale for their review findings.

RakFond then compiles a full recommendation package, which includes reviews and texts of all of the selectable proposals. The recommendation is sent to the members of the Scientific Advisory Board. They review the complete evaluation package and give their funding recommendations for each selectable proposal.

Finally, the recommendation package is forwarded to the Board of Directors for the funding approval.

# 3. Anticipated Announcement and Award Dates

After proposal evaluations are complete, applicants will be notified as to whether their proposal was deemed selectable as a result of the review process. Applicants can expect to be notified no later than September 20, 2019, via email to their primary email address on file. Notification may also be sent by email to the Applicant's organization Administrative Representative identified on the application Cover sheet. Applicants should ensure that their and their organization's AR primary email addresses on file are updated prior to September, 2019.

Applicants should add <a href="mailto:grant@rakfond.org">grant@rakfond.org</a> to their safe senders list to ensure they receive timely notifications such as document submission notifications, application submission confirmations, etc. If applicants are not receiving notifications, they should check their junk/spam folders first, then contact <a href="mailto:grant@rakfond.org">grant@rakfond.org</a> for additional assistance.

# Section VI. Award Administration Information

# 1. Additional Administrative Requirements

None for this RFP.

# 2. Reporting

The number and types of technical and financial reports required under the project are specified in Section II.2 "Terms & Conditions", Subsections G and H.

# Section VII. Foundation Contacts

RakFond will use email for all technical and administrative correspondence regarding this funding opportunity.

Technical Point of Contact: <a href="mailto:grant@rakfond.org">grant@rakfond.org</a>

# Mailing address:

Foundation for Cancer Research Support (RakFond) Rochdelskaya str. 15, bld. 17-18, 3rd floor, room III, Moscow, 123022 Russia

Solicitation Website: <a href="https://www.rakfond.org/rfp-2019-01-en/">www.rakfond.org/rfp-2019-01-en/</a>

# Section VIII. Application Form and Templates

#### **APPLICATION FORM**

APPLICATION FOR	RAKFOND'S	COMPETITION	OF	CLINICAL	RESEARCH
FUNDING OPPOR-	PROJECTS IN	ONCOLOGY			
TUNITY RFP # 2019-01					

Use 11 pt or larger font and single or larger line spacing. Application length not to exceed 7 pages.

1. GENERAL INFORMATION	
1.1. Title	
1.2. Applicant's Name	Last, First, Middle
1.3. Applicant's Degrees	Year, Degree, Organization
1.4. Link to the Applicant's public publication activity profile	Google Scholar, ResearchGate or eLibrary link, or research group's page with up-to-date publications list, etc.  Please indicate h-index or similar.
1.5. Applicant's Contact Information	Email: Address for all communications regarding this application.  Phone: Number for all communications regarding this application.
1.6. Applicant's Principal Organization and Title	Your Principal organization's name and location (city or town, do not enter full address). Your title in the Principal organization.

#### 2. PROJECT DESCRIPTION

## 2.1. Brief Scientific Rationale

Include a short summary of results and conclusions from previous trials, or from a systematic review as appropriate.

Recommended maximum length - 2000 characters including spaces or approximately  $\frac{2}{3}$  of a page.

## 2.2. Scientific Hypothesis

In one sentence.

#### 2.2. Phase

2 or 3 (for drugs and biologics), or N/A

#### 2.3. Objectives

Include the primary and secondary objectives.

Recommended maximum length - 1000 characters including spaces or approximately  $\frac{1}{2}$  of a page.

#### 2.4. Endpoints

Include the primary endpoint, secondary and exploratory endpoints.

Recommended maximum length - 1000 characters including spaces or approximately  $\frac{1}{3}$  of a page.

#### 2.5. Statistical Hypothesis

Please state the formal and testable null and alternative hypotheses for primary and key secondary endpoints, specify the type of comparison (e.g., superiority, equivalence or non-inferiority), sample size determination, statistical analyses, etc.

Recommended maximum length - 2000 characters including spaces or approximately  $\frac{2}{3}$  of a page.

#### 2.6. Study Population

Please describe inclusion and exclusion criteria, demographics, etc.

Recommended maximum length - 1500 characters including spaces or approximately  $\frac{1}{2}$  of a page.

#### 2.7. Intervention

Please describe the study intervention. If the study intervention is a drug or biologic, include name, dose and route of administration, as well as the origin (ownership).

Recommended maximum length - 1000 characters including spaces or approximately  $\frac{1}{3}$  of a page.

#### 2.8. Study Design and Methodology

Please provide the schema of the study. You may insert figures, diagrams or tables. Recommended maximum length - 3000 characters including spaces or approximately one page.

#### 2.9. Research Environment

Describe team, organizational support, and other resources available for this study, including unique features of the scientific environment, if any.

Recommended maximum length - 1500 characters including spaces or approximately  $\frac{1}{2}$  of a page.

## **3.BUDGET AND SCHEDULE**

#### 3.1. Detailed budget

Insert your budget assumptions in the table below and combine the expenditures into categories. Examples of eligible expenditures include: disposables, instrumentation, research services, etc.

Note that no salaries/consultancy fees, indirect or travel expenses are allowed and no more than 20% of

funds may be allocated to subcontracts and outsourced research, which must be mentioned explicitly.

Expenditure	Amount, RUR
1.	
1.1.	
2.	
2.2.	
· •	
Total:	Not to exceed 500 000 rubles

## Co-funding:

Please describe here any additional funding you either received or plan to receive, including source, amount and expenditures. If no additional funding is available, enter "None".

3.2. Proposed project schedule		
Research Activity For each Research Activity, enter the month number from the project start date when it is supposed to begin and its estimated duration in months.	Begins, month#	Duration, months
1.		
2.		

#### 4. NEXT STEPS

4.1. What are your next steps after this study is completed?

Maximum length - 500 characters including spaces or approximately % of a page.

4.2. In your opinion, how will the anticipated results influence oncology research and patients' care?

Maximum length - 500 characters including spaces or approximately % of a page.

# **5. ADDITIONAL INFORMATION**

Record here any additional information, which, in your opinion, is important for your project's scientific evaluation, or put "N/A".

Maximum length - 500 characters including spaces or approximately % of a page.

#### **COVER LETTER TEMPLATE**

## PRINTED ON YOUR PRINCIPAL ORGANIZATION LETTERHEAD

#### "DATE"

## Foundation for Cancer Research Support (RakFond)

Rochdelskaya str. 15, bld. 17-18, room III Moscow, 123022 Russia

#### Application for the RakFond's Competition of Clinical Research Projects in Oncology

I am pleased to submit a proposal titled "Proposal Title" for consideration under the RakFond's Competition of Clinical Research Projects in Oncology (Funding Opportunity RFP number 2019-01).

I certify, that I am a researcher, and work full-time [or part-time, specify percentage] in the [specify the official name in English] (the Organization), which activities include cancer research.

I certify the consent that my application is to be reviewed by RakFond, RakFond's Scientific Advisory Board and invited reviewers.

#### **OPTIONAL**:

List of individuals (e.g., competitors) who should not review the application.

The reasons for this request are [provide a narrative explanation for the request(s)].

Thank you for your consideration.

Sincerely,

## [SIGNATURE]

First, Middle and Last Name Department and Title

#### Approval by an Authorized Representative

I certify that I have authority to sign and submit documentation on the Organization's behalf, commitment of the Organization to support the proposed project, that the Organization will be accountable for the appropriate use of funds (in case the funds are transferred to the Organization's account), and that the Organization complies with the legislation of the Russian Federation, including required licenses and certifications, which are necessary for conducting the proposed research, and accepts the terms and conditions of RakFond's funding, which are described in the Request for Proposals "RakFond's Competition of Clinical Research Projects in Oncology" placed on the RakFond's official website.

### [SIGNATURE, STAMP]

First, Middle and Last Name Department and Title Organizational e-mail Organizational phone (optional)