REQUEST FOR APPLICATIONS

Opportunity Title: Health Research Priorities:

Clinical Trials

Code: SNIH-RO-HRP-CG01-2505

FUNDING YEAR(s): FYs 2025-2026

OPEN APPLICATION SUBMISSION: 01 July 2025

2025

Research Office

Saudi National Institute of Health

Saudi NIH
المعهد الوطني لأبحاث الصحة

Synopsis

General information

		Note
Funding Organization	Saudi NIH	
Administration Information	Research Office	
Application Type	Ready to Initiate and Ongoing Clinical Trials	
Funding Mechanism	Clinical Trials Grant	Mechanism Code: CG01
Opportunity Title	Health Research Priorities: Clinical Trials	Opportunity ID: SNIH-RO-HRP-CG01-2505
Opportunity Announcement	01-07-2025	
Open Application Submission	01-07-2025	
Opportunity Expiration	30-06-2026	Applications may be submitted at any time prior to the opportunity expiration date; however, applications will be processed quarterly.
Notice of Award	Within 3-5 months of submission	
Earliest Project Start	Within 1 month of Notice of Award	
Targeted Priority Fields	All fields under Saudi NIH Health Research Priorities	

Eligibility

Eligible Applicants	• The applicant must be affiliated with a Saudi organization, including academic institutions, research organizations, and hospitals. • The applicant must hold a doctorate degree or an equivalent qualification in a relevant field. • The applicant must have publication history and a minimum of four years of experience in the proposed research area. • Both Saudi citizens and non-Saudi residents are eligible to apply.
Additional Eligibility Requirements	• The applicant must serve as the Principal Investigator (PI) for the proposed research project. • The PI must not be leading any other currently active project funded by Saudi NIH. • The PI's organization must have an Authorized Organization Representative. • Each PI is permitted to submit only one research proposal under this funding opportunity.

	• A Co-Investigator may participate in up to five active Saudi NIH-funded research projects across all grants. • Institutional Review Board approval must be obtained before submission. • Saudi Food and Drug Authority approval must be obtained before submission. • Collaboration with organizations/entities (including non-governmental, national, or international organizations) is allowed, subject to terms and conditions.

Additional information	
Description and Scope	Saudi National Institute of Health (Saudi NIH) invites research applications under its Health Research Priorities Strategic Plan in alignment with Vision 2030 and national research and development priorities. This opportunity is designed to support clinical trials that address diseases with significant public health relevance in the Kingdom of Saudi Arabia within the fields specified in the Saudi NIH Health Research Priorities. Researchers awarded under this funding opportunity will play a pivotal role in advancing the national health research agenda.
Clinical Trial Allowability	Clinical Trial Required: Only applications that propose clinical trial(s) are considered.
Eligible Types of Studies	Ready to initiate or ongoing clinical trials that investigate novel or existing pharmacologic therapies, vaccines, medical devices, and intervention modalities across the health research priority fields identified by Saudi NIH. Phase IV and post-marketing surveillance clinical trials are not eligible.
Maximum Duration	Up to 36 months, subject to extension.
Maximum Budget	Up to 4,000,000 SAR per project, subject to case-by-case negotiation.
Contact Information	GRANTS@SNIH.GOV.SA

Executive Summary

The Saudi National Institute of Health (Saudi NIH) invites applications under the Health Research Priorities: Clinical Trials to support investigator-initiated clinical trials addressing national health priorities. This opportunity aims to generate high-quality clinical evidence through clinical trials that may include pharmaceuticals, vaccines, medical devices, diagnostics, surgical procedures, or behavioral interventions.

Trials must align with the research priority fields identified by the Saudi NIH and demonstrate strong scientific merit, feasibility, and potential for health impact. The funding mechanism supports both new and ongoing trials that are ready to initiate or expand. Researchers applying for this opportunity must thoroughly read this funding opportunity announcement and ensure to follow the application guidelines and eligibility criteria. Eligible applicants must be based in the Kingdom of Saudi Arabia and capable of conducting regulated clinical research in accordance with ethical and operational standards.

Awards may reach up to 4 million SAR, with final budgets subject to case-by-case negotiation based on project scope and justification. The duration of projects is up to 36 months, with the possibility of extension upon review. Applications are accepted on a rolling basis for FYs 2025-2026 and are processed quarterly.

Contents

Background

Saudi National Institute of Health

Saudi National Institute of Health (Saudi NIH) focuses on implementing a strategy based directly on prioritizing translational research and clinical trials to meet public health needs while working to identify and mitigate challenges that hinder the development of effective and high-quality research, strengthening coordination and scientific collaboration, and improving the impact of the research and innovation system in the health sector. Therefore, one of the ways through which Saudi NIH aims to achieve its goals is to create funding opportunities for promising clinical and translational health research.

Research Office

The Saudi NIH Research Office is responsible for overseeing the design, implementation, and evaluation of Saudi NIH's funding programs and opportunities. It manages the full grant lifecycle, including announcing funding opportunities, processing applications, overseeing peer-review processes, contracting, and monitoring funded research projects. Additionally, the Research Office establishes administrative, technical, and financial policies for Saudi NIH-funded research projects, ensuring alignment with both the needs of researchers and regulatory frameworks within the Kingdom and internationally.

Opportunity Description and Scope

Description

Clinical trials are essential pillars of health research that generate high-quality evidence on the safety, efficacy, and effectiveness of medical interventions. They provide critical data that guides healthcare providers, regulatory agencies, and policymakers in decision-making, ultimately improving patient outcomes and informing clinical guidelines. The Saudi NIH plays a critical role in supporting and advancing clinical trials in the Kingdom.

In addition, this opportunity contributes to advancing translational research by promoting the translation of scientific discoveries from the bench to the bedside, facilitating the movement of research innovations to market, supporting the integration of research evidence into clinical practice, and enhancing national research capabilities.

Eligible types of studies include ready-to-initiate or ongoing clinical trials that investigate novel or existing pharmacologic therapies, vaccines, medical devices, and intervention modalities across the health research priority fields identified by the Saudi NIH.

Phase IV and post-marketing surveillance clinical trials are not eligible.

Scope

This opportunity is designed to support clinical trials that address diseases with significant public health relevance in the Kingdom within the fields specified in the Saudi NIH Health Research Priorities, to answer clinical questions that address unmet clinical needs, and have the potential to improve health outcomes or inform clinical practice.

Applicants must demonstrate alignment with the pre-specified priority fields in their research applications. However, applications addressing other areas may be considered if a strong and well-justified rationale is provided. Applications should address scientifically sound and unanswered research questions with potential for significant clinical or public health impact.

Eligibility

Minimum Eligibility Requirements:

- The applicant must be affiliated with a Saudi organization, including academic institutions, research organizations, and hospitals.
- The applicant must hold a doctorate degree or an equivalent qualification in a relevant field.
- The applicant must have publication history and a minimum of four years of experience in the proposed research area.
- Both Saudi citizens and non-Saudi residents are eligible to apply.

Additional Requirements:

- The applicant must serve as the Principal Investigator (PI) for the proposed research project.
- The PI must not be leading any other currently active project funded by Saudi NIH.
- The PI's organization must have an established grant management process with an Authorized Organization Representative (See Authorized Organization Representative)
- Each PI is permitted to submit only one research proposal under this funding opportunity.
- A Co-Investigator may participate in up to five active Saudi NIH-funded research projects across all grants.
- Institutional Review Board approval must be obtained before submission.
- Saudi Food and Drug Authority approval must be obtained before submission.
- Collaboration with organizations/entities (including non-governmental, national, or international organizations) is allowed, subject to terms and conditions (See Funding Allocation).

Funding Allocation

Awardees will receive the funding amount according to their signed contract. The Saudi NIH has the authority to determine the allocation of funding in accordance with its policies and regulations. The budget limit for each research project is 4,000,000 Saudi Riyals, subject to case-by-case negotiation, with a maximum proposed project period of 36 months (extendable upon review).

In the case of collaboration, no part of the funding allocation may be disbursed through this opportunity to private or international collaborating organizations. Additional conditions for collaboration apply in accordance with Saudi NIH policies and regulations.

Allowable Costs and Budget Guidelines

Detailed allowable costs and budget guidelines are available in the Saudi NIH Policies and Regulations.

Review Process and Timeline

Table 1: Saudi NIH proposal review process.

Stage	Description
Proposal Submission	• Applicants will submit their applications through the Saudi NIH Application Platform.
Prescreening	• Saudi NIH will begin prescreening applications as soon as they are submitted. • Applications are screened for eligibility, originality, completion, and compliance with Saudi NIH Grants Policy.
Technical Review	• Saudi NIH will conduct a technical review of applications that have passed the prescreening stage. • Applications will be reviewed to ascertain that all requirements have been fulfilled.
Scientific Review	• A scientific review committee will assess applications and nominate them for funding based on scientific merit.
Ethical Review	• The Saudi NIH will review all submitted documents and approvals, including Institutional Review Board approval, to ensure they are in accordance with the National Committee of Bioethics' requirements.
Notice of Award	• The final approval is made by the Chief Executive Officer (CEO) of Saudi NIH. • Saudi NIH will communicate with the applicants to inform them that they have been nominated to receive the award.
Contracting	• Following the receipt of the notice of award, the awardees and their affiliated organization's Authorized Organizational Representative are

	required to sign the contract and submit all required documentation to facilitate the disbursement of the award.
Project Start	• Projects may commence after receiving the Project Execution Notice from Saudi NIH.
Reporting and Monitoring	• After receiving the Notice of Award, awardees are required to agree to undergo monitoring by Saudi NIH for the duration of the research project. • Systems will be in place for monitoring all activities involving human subjects. • Saudi NIH has the right to conduct periodic visits to the awardee's organization's research site(s) to conduct evaluations. • Awardees will be required to submit periodic reports throughout the duration of the project, and a final report at the end of the project according to deadlines determined in the signed project contract.
Award Close-out	• Saudi NIH will end the award period after ensuring that agreed-upon milestones have been reached. • The awardee must present all the necessary documentation for the scientific review committee and the Ethics and Compliance Department to issue approvals for award close-out. • The results of the research project are subject to disclosure according to Saudi NIH Grants Policy.

Timeline and Important Dates

Applications will be processed through funding cycles, each with its own important dates (See Table 2: Opportunity Timeline and Important Dates).

Table 2: Opportunity Timeline and Important Dates

	Submission period	Notice of Award	Earliest Project Start
Cycle 1	1 July, 2025 - 30 September, 2025	Within 3-5 months of submission	Within 1 month of Notice of Award
Cycle 2	1 October, 2025 - 31 December, 2025		
Cycle 3	1 January, 2026 - 31 March, 2026		
Cycle 4	1 April, 2026 - 30 June, 2026		

Evaluation Criteria

Applications will be evaluated based on the following criteria:

- Completeness of Clinical Trial related documents
- Relevance to the priority research fields defined by Saudi NIH
- Scientific and technical merit

- The integrity of the work
- Significance of the problem
- Approach to addressing the problem
- The soundness of the rationale.
- The realistic estimation of outcomes
- Risk management criteria
- Alignment with Saudi NIH strategy and the National Vision 2030

Expected Research Outcomes

- Products, such as diagnostic and preventative healthcare equipment and AI-based software solutions
- Technology transfer or commercialization plans
- Proposed policies, guidelines, and recommendations
- Measurable improvements in service delivery, access, or health outcomes
- Awards and acknowledgments
- Publications in scientific journals and scientific meetings (i.e. research papers, scientific reports, abstracts, scientific lectures, etc.)

Reporting and Monitoring

Saudi NIH will monitor awarded projects. The monitoring process includes the submission of periodic progress reports by awardees and may involve periodic site visits. A final report will be required upon completion of the project.

Other Information

How to Apply

Researchers interested in applying must register on the Saudi NIH Application Platform to submit their application, then apply through the following link: Start an application.

Saudi NIH will only accept applications submitted through its application platform. Please take advantage of the submission manual tool provided to you here to guide you through the registration and submission processes.

Confidentiality

All information submitted by applicants is confidential. In accordance with Saudi NIH Grants Policy, all application reviewers must adhere to the confidentiality guidelines set forth by Saudi NIH.

Authorized Organization Representative (AOR) Criteria

An Authorized Organization Representative is the designated individual within the organization responsible for overseeing all aspects of the grant administration. This person ensures that the organization meets key eligibility and compliance requirements, including:

- Financial management systems and operational capacity
- Availability of an organizational bank account

The AOR also serves as the primary point of contact with Saudi NIH during the contracting stage.

Sub-Grants

Sub-grants to collaborating organizations are permitted within this opportunity only to local organizations. Sub-grants to private and international organizations are not permitted. However, organizational diversity within the research team is accepted. Additional conditions for collaboration apply in accordance with Saudi NIH policies and regulations.

Related Required Documents

All required documents should be uploaded to the online application form. Applications will only be considered if key clinical trial-related documents are prepared at the time of submission.

Applicants will be required to submit relevant documentation, the following documents are required:

- Saudi Food and Drug Authority (SFDA) approval
- Informed Consent Form
- Case Report Form (CRF)
- Data and Safety Monitoring Board (DSMB)
- Good Clinical Practice (GCP) certificates for all research team members
- Institutional Review Board (IRB) approval
- For multi-site trials, site-specific IRB and SFDA approvals may also be required

End of Request for Applications