งานบริหารและส่งเสริมการวิจัย
กองบริหารงานวิจัย มหาวิทยาลัยมหิดล
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ที่ อว 78.016/๗๑๗๕
วันที่ 24 ตุลาคม 2566
เรื่อง ประชาสัมพันธ์ทุน Opportunities to Advance Women's Health Innovation

เรียน คณบดี / ผู้อำนวยการ

ตามที่ แหล่งทุน Bill & Melinda Gates Foundation เปิดรับข้อเสนอโครงการในหัวข้อ Opportunities to Advance Women's Health Innovation โดยเปิดรับสมัครจนถึงวันที่ 6 ธันวาคม 2566 เพื่อสนับสนุนงานวิจัยที่แก้ไขช่องว่างในการทำงานวิจัยและพัฒนาด้านสุขภาพของผู้หญิง โดยอาจารย์/นักวิจัย ที่สนใจสมัครขอรับทุนขอให้จัดทำข้อเสนอโครงการผ่านระบบออนไลน์ของแหล่งทุน Bill & Melinda Gates Foundation ได้ที่เว็บไซต์ https://submit.gatesfoundation.org/prog/opportunities_to_advance_womens_health_innovation/ ทั้งนี้ โครงการที่เสนอขอทุนให้ปฏิบัติตามประกาศมหาวิทยาลัยมหิดลเรื่อง หลักเกณฑ์และอัตราเงินค่าธรรมเนียมพัฒนาการวิจัยของมหาวิทยาลัยและส่วนงาน ที่จัดเก็บจากโครงการวิจัยที่ได้รับเงินอุดหนุนจากแหล่งทุนภายนอกมหาวิทยาลัย พ.ศ. 2560 โดยระบุหมวดค่าธรรมเนียมอุดหนุนสถาบันในอัตราร้อยละ 10 และขอให้ดำเนินการตามที่ระบุในหนังสือชักซ้อมแนวปฏิบัติ เรื่องมาตรฐานการวิจัยของโครงการวิจัย รายละเอียดดังเอกสารที่แนบมาด้วยนี้ อาจารย์/นักวิจัย ที่สนใจสมัครรับทุนสามารถศึกษารายละเอียดของทุนดังกล่าวเพิ่มเติมได้ตามเอกสาร Rules and Guidelines ที่แนบมาด้วยนี้หรือเว็บไซต์ของแหล่งทุนที่ https://gcgh.grandchallenges.org/challenge/opportunities-advance-womens-health-innovation

ในการนี้ กองบริหารงานวิจัย มหาวิทยาลัยมหิดล จึงขอแจ้งข่าวประกาศทุนมายังท่าน เพื่อโปรดประชาสัมพันธ์ทุนวิจัยดังกล่าวให้บุคลากรในหน่วยงานของท่านทราบโดยทั่วกัน และขอให้อาจารย์/นักวิจัย โปรดส่งเอกสารข้อเสนอโครงการผ่านส่วนงานต้นสังกัดมายังกองบริหารงานวิจัยภายใน 5 วันทำการก่อนปิดรับสมัครทุน เพื่อขออนุมัติการจัดส่งข้อเสนอโครงการและตรวจสอบเอกสารก่อนจัดส่งไปยังแหล่งทุน ทั้งนี้หากส่วนงานจัดส่งเอกสารมายังมหาวิทยาลัยหลังจากวันที่มหาวิทยาลัยกำหนด มหาวิทยาลัยขอสงวนสิทธิ์ในการส่งข้อเสนอโครงการเพื่อสมัครรับทุนดังกล่าว

จึงเรียนมาเพื่อโปรดทราบและโปรดประชาสัมพันธ์ข่าวต่อไป จักเป็นพระคุณยิ่ง

(ศาสตราจารย์ ดร. นายแพทย์ภัทรชัย กีรติสิน)
รองอธิการบดีฝ่ายวิจัย

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Opportunities to Advance Women's Health Innovation

Grand Challenges

Request for Proposals

Background

The conventional understanding of women's health - which mainly centers on reproductive and maternal health - must be redefined: the health of women includes the overall health and well-being of women's bodies and minds across their life course, as well as the consideration of sex and gender in all aspects of disease and treatment. When using the term women in the context of 'women's health' we are also inclusive of both sex as a biological variable and gender as a social variable across the life course (including girls and adolescents) and people assigned female at birth, transgender women, transgender men, and non-binary people.

Tailoring prevention, screening, diagnostics, and treatments for diseases and conditions to account for sex and gender differences, as well as for women's context and environment, is crucial to support their health and well-being. By addressing intersectional and underlying social and structural factors, we can empower women to make informed decisions, pursue their ambitions, and live healthier lives. When women globally have access to appropriate, high-quality care, they can plan their families, increase their households' resilience to shocks, and advance their education. As women frequently serve as family caregivers, healthy mothers contribute to healthier households with better nutrition, improved child development and education, and higher household earnings. Healthy women transform societies.

Women's health is currently an underserved area for innovation, facing disproportionately low R&D funding relative to its burden. As recently as 2020, the Bill & Melinda Gates Foundation (BMGF) and the U.S. National Institutes of Health (NIH) represented nearly 60% of funding for sexual and reproductive health R&D.[1] While stakeholders are beginning to address innovation gaps in women's health, no coordinated agenda across sectors with a global focus exists to align their efforts. The result is less innovation in the women's health space and limited data to support business cases for new products.

To address this need, the Bill & Melinda Gates Foundation and the U.S. National Institutes of Health initiated an inclusive, consultative, cross-sector effort to generate a **Women's Health Innovation Opportunity Map 2023** as a collaborative framework to advance women's health innovation. The Opportunity Map was created by the **Innovation Equity Forum (IEF)** - a group of 250 stakeholders in women's health from across sectors and over 50 countries. The aim of the IEF was to bring a broad range of multidisciplinary expertise from various levels and sectors of the biomedical enterprise to provide diverse viewpoints in order to develop an inclusive, globally-focused, and widely accepted Opportunity Map of topics in women's health R&D.

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[1] The NIH and the Bill & Melinda Gates Foundation contributed a total of $1.13B, out of $2.1B in funding for sexual and reproductive health from 2018-2021 (Policy Cures Research). At the time of this RFP, there is no comprehensive figure estimating total funding across all of women's health.

The Opportunity Map has three main components. First, it establishes broad topics of women's health R&D with unique challenges, needs, and goals. Topics fall into two categories -

- **Cross-cutting topics** include data and modeling, research design and methodologies, regulatory and science policy, innovation introduction, social and structural determinants, and training and careers.
- **Issue-specific topics** include communicable diseases, non-communicable diseases and chronic conditions, and female-specific conditions.

Second, each topic identifies leading opportunities based on their potential for impact, readiness to scale, innovation feasibility, focus on women's unmet health needs, and ability to improve health equity. Finally, example specific solution strategies articulate actionable ways to realize each opportunity and create impact within the next 15 years. The full Opportunity Map can be found here.

The Challenge

The Women's Health Innovation team at the Bill & Melinda Gates Foundation is looking for innovations and ideas that address opportunities outlined in the Opportunity Map. While not all opportunities in the Opportunity Map are in scope for this RFP (see list below and Table 1), we are looking to fund proposals that address a wide range of issues.

The ultimate goal of this RFP is to kickstart work to address gaps in women's health R&D. The overall objectives are to:

- **Advance bold ideas** that address opportunities in the Opportunity Map
- **Enhance overall funding** and resources for women's health R&D
- **Demonstrate effectiveness** of investments in women's health R&D

What We Are Looking For:

We are looking for proposals that address opportunities for the following topic areas in the Opportunity Map:

1. **Data and modeling** – Collecting more granular data, strengthening capacity for sex- and gender-informed data collection, and filling critical data gaps.
2. **Research design and methodologies** – Advancing sex- and gender-intentional research design, methods, and analysis.
3. **Regulatory and science policy** – Implementing sex- and gender-intentional regulatory and science policy frameworks that promote the development of innovations that improve the health of women.
4. **Innovation Introduction** – Strengthening the innovation ecosystem and pathways for women's health solutions to scale.
5. **Social and structural determinants** – Including social determinants of health in R&D in women's health research agendas to develop more equitable and appropriate women's health products.
6. **Training and careers** – Embedding a sex and gender lens throughout education and supporting women's career advancement to develop a workforce able to drive innovation in women's health.
7. **Communicable diseases** – Evaluating the burden of infectious diseases and their direct and indirect costs, exploring associations between microbes and chronic

conditions, and developing innovations for infections that disproportionately impact women and that can benefit pregnant women.

8. **Female-specific conditions** – Researching the etiology and progression of gynecological, reproductive, maternal, and life stage conditions, supporting new methods for data collection and sharing, and developing innovations to prevent, diagnose, monitor and treat female-specific conditions.

Please note: The Non-communicable Diseases and Partnership topic areas of the Opportunity Map are not in scope for this RFP. Additionally, not all opportunities within each topic area listed above are in-scope for this RFP. Please refer to Table 1 for details on which specific opportunities will be accepted for this RFP.

Proposals that address a given in-scope opportunity **do not have to adhere to specific solution strategies outlined in the Opportunity Map** but can take inspiration from the examples listed in the Opportunity Map.

Eligibility

This initiative is open to nonprofit organizations, for-profit companies, international organizations, government agencies and academic institutions. We particularly encourage applications involving projects led by women or from women-led organizations and applications from institutions based in low- and middle-income countries. Proposals should be aligned to local public health systems. Additionally, collaborations are highly encouraged.

We will not consider funding for:

- Proposals not related to improving women's health
- Proposals that do not consider health conditions based on gender differences
- Proposals that do not have a clear link to at least one opportunity outlined in the Opportunity Map, even if the proposal still applies to a specific topic area.
- Proposals related to the two out-of-scope topic areas of the Opportunity Map for this RFP:
    - Non-Communicable Diseases
    - Partnerships
- Specific opportunities not explicitly included in Table 1
- Proposals that only address needs for high-income countries
- Proposals that focus on lobbying efforts
- Proposals that are not easily scalable or not aligned to local needs for uptake

Award

The funding level for each **award is a total of up to USD $150,000 for a project lasting up to 2 years,** based on the scope of the proposed project. We intend to fund up to 3 proposals for each of the 8 in-scope Opportunity Areas listed above and in Table 1. The proposed budget must realistically reflect the technical work and project deliverables within a time frame of up to 2 years; in some cases, a smaller budget and/or shorter grant period may be justified. Budgets and scope may be negotiated with applicants as part of the review process to ensure the foundation's ability to fund a robust and balanced portfolio with good geographic scope with the existing available budget.

Table 1 – In-Scope Topic Areas and Opportunities

Topic area	Opportunity
1. Data and modeling	A. Collect, harmonize, utilize, and report granular data (qualitative and quantitative) for health elements and determinants to inform prioritization, develop models, and innovate products for women's health across the life course.
	B. Support capacity to collect, harmonize, utilize, and report granular data (qualitative and quantitative) for health elements and determinants to inform prioritization, develop models, and develop products for women's health across the life course.
	C. Update and expand burden of disease metrics to better account for sex and gender-related conditions, long-term sequelae, and socio-cultural gender biases (including input data gaps, disability weighting, and duration assumptions).
	D. Identify and fill data gaps related to calculating return on investment (ROI) in women's health R&D, including economic models and ROI for disease-specific areas.
	E. Develop approaches for incorporating qualitative information and proxy indicators into models, including unstructured narrative data.
2. Research design and methodologies	A. Advance sex- and gender-intentional research design and analysis during all stages of research (including preclinical and clinical) to generate endpoints, outcome measures, and evidence relevant for women across the life course, and to evaluate heterogeneity of treatment effects by sex and gender.
	B. Promote knowledge- and resource-sharing on the preclinical and clinical research landscape in LMICs and other under-resourced settings to strengthen research activities and promote collaborations that advance women's health.
	C. Strengthen the use of computational and bioinformatics modeling (reducing the use of animal models) and machine and deep learning approaches to better understand the biological basis of diseases affecting women and inform product development, risk identification, and treatment approaches—including by leveraging existing datasets and unbiased common data elements.
	D. Support in vitro translational model development—such as organoids and 'organ on a chip' systems—to ensure more extensive clinical and translational characterization of diseases, conditions, and differences by sex and gender.
3. Regulatory and science policy	A. Ensure the implementation of sex- and gender-intentional science policy frameworks that cover all aspects of the R&D lifecycle for medical products and healthcare innovations—including ethical, legal, and societal implications—with harmonization and collaboration mechanisms to accelerate their development.
	B. Require legal and/or regulatory frameworks covering all aspects of the R&D lifecycle for medical products and healthcare innovations to systematically apply sex- and gender-intentional approaches and evidence at all stages of development to drive sex- and gender-specific interventions (e.g., ensuring clinical studies capture relevant differences in disease trajectory and outcomes across sex and gender, including novel endpoints).
	C. Require reporting and timely updates of sex- and gender-specific outcomes in healthcare product labeling and package inserts.
	D. Advance data harmonization and standardization efforts to drive sex-, gender-, and age-disaggregated post-market surveillance with common indicators specific to women's health.
	E. Assess and implement regulatory and policy incentives that will promote investment and address barriers and disincentives, to accelerate the pace and volume of development, de-risk R&D in women's health, ease market authorization, and improve access to innovations that improve women's health.

Topic area	Opportunity
4. Innovation introduction	A. Create robust and ongoing data repositories to catalyze women's health product development and accelerate the successful introduction of these products into new markets.
	B. Establish centralized innovation hubs specifically focused on the design and commercialization of solutions for women's health and well-being.
	C. Improve pathways to market for women's health solutions by accelerating commercialization, regulatory review, reimbursement, and access.
	D. Create new pathways to fund innovation
	E. Support market shaping approaches that enable suppliers to develop innovations accessible in LMIC settings by incentivizing payors and market entry and addressing demand and scale issues.
5. Social and structural determinants	A. Ensure that women's needs and voices guide national and global research agendas through broad representation and reflection of different communities.
	B. Conduct a global review of social determinants of health interventions with an emphasis on those that focus on vulnerable populations of women; based on review, develop equitable standards for inclusion of social determinants of health considerations for women's health research.
	C. Research the intersectional impacts of gender roles, power dynamics, and economic agency (e.g., decision-making, unpaid work) on women's health.
	D. Increase representation of women, SGM, and other marginalized populations in the review of research grants in women's health R&D.
	E. Research traditional and cultural practices that promote women's health outcomes and well-being.
6. Training and careers	A. Create and implement resources for educating the current and future research and healthcare workforce on women's health and sex and gender influences on health.
	B. Advocate among educational policymakers and institutional decision-makers for the integration of women's health and sex and gender considerations into education and training.
	C. Investigate barriers and enablers for the participation, progression, and leadership of women in R&D, entrepreneurship, and healthcare careers, and use successful practices to create reference tools.
	D. Establish safeguards for women's rights within countries globally to receive STEMM education and pursue STEMM, R&D, and entrepreneurship careers and leadership positions.
	E. Enhance men's allyship to activate opportunities for women to pursue STEMM, R&D, and entrepreneurship careers and leadership positions

Topic area	Opportunity
7. Communicable diseases	A. Assess the burden of disease and costs resulting from infections that affect women disproportionately or differently, including reproductive tract infections, infections in pregnancy, and pathogens with outbreak potential.
	B. Stimulate R&D to explore associations between microbes and conditions that primarily or disproportionately affect women.
	C. Develop and evaluate vaccines and other prevention interventions for infections that disproportionately impact women and evaluate maternal immunization to protect the mother-infant dyad.
	D. Develop improved diagnostic tests for STIs and other reproductive tract infections, including affordable point-of-care and self-testing products.
	E. Expand therapeutic options for infections in women, including during pregnancy and breastfeeding.
8. Female-specific conditions	A. Investigate the biological and external mechanisms of female gynecological health conditions and develop tools and therapies for prevention, diagnosis, treatment, and non-invasive monitoring of conditions, including normal menstruation and disorders such as polycystic ovarian syndrome, endometriosis, adenomyosis, and fibroids.
	B. Stimulate R&D on the role of the vaginal microbiome in health and illness and develop interventions to address vaginal dysbiosis and foster a low-risk vaginal microbiome.
	C. Increase research on prenatal, intrapartum, and postpartum conditions and risk factors associated with adverse maternal health outcomes to enable the development of diagnostics, treatments, and prevention, including artificial intelligence/machine learning tools. Please note - special consideration will be given to proposals that link to the WHO PPH Roadmap: https://cdn.who.int/media/docs/default-source/reproductive-health/maternal-health/pph-roadmap.pdf?sfvrsn=db36b511_3
	A. Investigate evidence gaps in understanding the role of micronutrients, including iron and folic acid, and their formulation for improving maternal outcomes.
	B. Create and support biobanks with diverse, linked milk and blood samples that can be accessed for research, including assessing the safety of prescription and over-the-counter medication use during pregnancy and breastfeeding.
	C. Develop improved, accessible contraceptive technology with fewer side effects and more prolonged efficacy.
	D. Understand how policies that influence reproductive care impact women's health to support the development of new modalities for the full range of reproductive care.
	E. Develop self-administered solutions and/or new biomaterials (such as mesh products, stem cells) to support safe and effective treatment options for gyn conditions. Please note - this is a narrower opportunity than listed in the Opportunity Map

Please note: Partnerships and Non-Communicable Disease Topic Areas are not in scope for this RFP; Female-Specific Conditions - Opportunities 8 and 10 in the Opportunity Map are not in scope for this RFP

Opportunities to Advance Women's Health Innovation

Grand Challenges

Rules and Guidelines

Applications due no later than December 6, 2023, 11:30 a.m. U.S. Pacific Time

Supporting Materials

1) Full RFP – Opportunities to Advance Women's Health Innovation
2) Application Instructions
3) Budget Template and Narrative
4) Frequently Asked Questions (FAQ) Document

Key Dates and Deadlines*

Key Dates	Event
October 7, 2023	Application period opens
December 6, 2023, **11:30 a.m. US PT**	Application period closes, deadline to submit
March 2024	Proposal review completed
By June 1, 2024	Estimated start dates

**Any changes to the Key Dates and Deadlines will be updated on the Grand Challenges website.*

Eligibility Criteria

This initiative is open to nonprofit organizations, for-profit companies, international organizations, government agencies and academic institutions. We particularly encourage applications involving projects led by women or from women-led organizations and applications from institutions based in low- and middle-income countries. Proposals should be aligned to local public health systems. Additionally, collaborations are highly encouraged. Individuals and organizations classified as individuals for U.S. tax purposes are not eligible to receive an award from the foundation as part of this initiative.

Upon registration, applicants must provide information about the tax status of their organization as different terms and conditions may apply. You should confirm your organization's tax status with the appropriate advisor or entity within your organization such as your grants or contracts department, finance, or office of sponsored research. The foundation may request additional information regarding your tax status. For information about tax statuses, you may check with your own advisors and review information provided on the Internal Revenue Service web site at: www.irs.gov.

How to Apply

Please review the Application Instructions as you develop your proposal. You are required to submit either a Microsoft Word® or PDF document no more than 2 pages in length for your Proposal. You will also upload a completed Budget Table and Narrative, template provided in the Application Instructions. Please do not include a cover sheet with your proposal, a cover sheet will be automatically generated from your registration data.

Changes to the Rules and Guidelines and to the Frequently Asked Questions (FAQ) document will be posted periodically, including any changes to the dates listed above. Please read the FAQ document before submitting any questions or concerns.

Proposals must be submitted prior to the deadline of December 6, 2023, 11:30 a.m. U.S. Pacific Time

Awards

The funding level for each **award is a total of up to USD $150,000 for a project lasting up to 2 years,** based on the scope of the proposed project. We intend to fund up to 3 proposals for each of the 8 in-scope Opportunity Areas listed above and in Table 1. The proposed budget must realistically reflect the technical work and project deliverables within a time frame of up to 2 years; in some cases, a smaller budget and/or shorter grant period may be justified. Budgets and scope may be negotiated with applicants as part of the review process to ensure the foundation's ability to fund a robust and balanced portfolio with good geographic scope with the existing available budget. Indirect costs will be considered, and should be included as part of the total $150,000 USD award (subject to the Bill & Melinda Gates Foundation's indirect cost policy).

Review Process

The Grand Challenges application review process is executed in four steps:

1. The first step consists of screening applications to evaluate whether proposals address the key needs described in the topic. We screen for responses that are completely unrelated or specifically excluded in thetopic description. Excluded responses encompass ideas related to the topic but that, for strategic reasons, weare not funding under the Grand Challenges initiative. In addition, we exclude proposals considered incremental advances, appropriate responses that are similar to work in which the foundation or other GrandChallenges programs are already investing, or avenues of inquiry we deem ill-suited to the Grand Challengesinitiative. Applicants with proposals removed from consideration during the screening process will be notified that their proposals were declined but will not receive specific feedback.

2. In the second step, reviews are chaired or co-chaired by technical leads from the foundation and, in some cases, other funding partners and are conducted by reviewers both outside and within the foundation. Reviewers are selected from the world's leading researchers and comprise both experts in the topic area andexperts in complementary areas. Not all reviewers have deep expertise in the topic; please consider this information when drafting your proposal.

The criteria considered in these reviews are:

- Potential to lead to solutions with substantial impact related to the specific topic
- Scientific and technical excellence & innovation, including:
  - creativity of the project's approach and clear differentiation from existing approaches
  - a clear and rigorous conceptual framework for the activities
- Project Plan, including:
  - investigator and organization capabilities and potential for collaboration
  - value in terms of appropriateness of the budget and timeline relative to project complexity, risk, and potential impact

3. The third step is the validation and final selection of the proposals to be funded by the Executive Committee. The Executive Committee may recommend the proposal be funded, subject to specific modifications which will be negotiated as part of the award process. Organizations invited to submit full proposals will be provided additional technical instructions at that time.

4. The fourth and final step is a due diligence review and to directly discuss and negotiate any adjustments to the proposed project recommended by the Executive Committee. Investigators will be contacted as part of the due diligence review.

Management of Conflict of Interest

To identify and avoid conflicts of interest among application reviewers, such reviewers will not be permitted to review proposals from organizations with which the reviewer has self-identified conflicts of interest.

Eligibility and Notifications

Please review the Bill & Melinda Gates Foundation's sample terms and conditions. Please note that depending on the tax status of your organization, alternate terms and conditions may apply. Please also review the Bill & Melinda Gates Foundation's standard Request for Proposal (RFP) Terms and Conditions.

Privacy Notice and Terms of Use

When submitting materials to the Foundation please keep in mind that because we have a focus on achieving charitable outcomes, we view information that we obtain through our grantmaking as a public good. Subject to the Foundation's Privacy & Cookies Notice, the Foundation may also share information you provide to us (either orally or in writing) with third parties, including external reviewers, consultants, contingent workers, key partners and co-funders. **You should assume that nothing will be kept confidential and should not include any information in the proposal, budget, supplemental materials, or reports that you consider proprietary.**

Additionally, the foundation is required by the IRS to publish a list of its grants. The foundation also provides general descriptions of its grants on its web sites, in press releases, and in other marketing materials.

For more information, please review the Grand Challenges Privacy and Terms of Use.

Representation

By providing any Submission Materials, you represent to the Bill & Melinda Gates Foundation that (i) you have the right to provide any personal information submitted; and (ii) you are a duly authorized representative of the Applicant and agree to be bound by the terms set forth above, without amendment.

Frequently Asked Questions

Answers to many application questions can be found on the Frequently Asked Questions (FAQ) document.

Inquiries

Please direct all questions about this initiative, selection criteria or application instructions by e-mail to the following address: grandchallenges@gatesfoundation.org.