

Kingdom of Saudi Arabia
Ministry of Health
GDRS
IRB



المملكة العربية السعودية
وزارة الصحة
الإدارة العامة للبحوث والدراسات
اللجنة المحلية لأخلاقيات البحوث

National Registration Number with NCBE-KACST, KSA: (H-01-R-009)

Approval Letter

Date: 14/5/2026

Category of Approval: Expedited

IRB log No: 26-25M

Dear Haytham sheerah

The IRB pleased to inform you that your study mentioned below has been reviewed and approved. This letter gives you an ethical clearance to implement your study according to the approved documents and you still need to obtain administrative approval from the site/s where the study will be conducted.

Protocol Title	Determinants of User Engagement with the Sehhaty Mobile Health Application in Saudi Arabia: A Cross-Sectional Analysis of Perceived Barriers		
PI name	Haytham sheerah	PI ID	51586878
PI affiliation	MOH	PI E-mail	Hasheerah@moh.gov.sa
The tool that will be used in the study		Questionnaire	

Approval Conditions:

1. The approval is valid for one year from the date of this letter.
2. The PI is required to submit a progress report every six months.
3. The PI must apply for an extension from the IRB if the research has not been completed within the validation period.
4. The research team should follow the IRB approved study documents unless amendments are requested and approved by the IRB.
5. A publication approval letter is required before submitting any manuscript resulting from this research to journals for publication.
6. The PI should maintain the data securely, and it should only be used for this research.
7. The PI should obtain only the data has been approved by the data office.

Sincerely

Dr. Eman El Desouky

Co-Chairman of IRB, MOH, KSA



الاستبيان :محددات استخدام تطبيق صحي في المملكة العربية السعودية

الباحث الرئيسي:

د. هيثم عبدالوهاب شيره

استشاري صحة عامة

وزارة الصحة

hasheerah@moh.gov.sa

أنت مدعو للمشاركة الطوعية في دراسة بحثية عن محددات استخدام تطبيق صحي في المملكة العربية السعودية تهدف إلى الهدف الرئيسي من هذه الدراسة هو فحص الحواجز التي تمنع استخدام تطبيق صحي بين عامة السكان في المملكة العربية السعودية .

الوقت المتوقع لتعبئة الاستبيان: ٥ دقائق.

تُخزن الإجابات رقميًا على خوادم مشفرة، ويقتصر الوصول عليها للباحثين المعتمدين فقط.

النتائج المنشورة ستكون بشكل إحصائي عام دون إشارة لأفراد.

تعبئتك للاستبيان تعتبر موافقة على المشاركة في البحث.

المشاركة طوعيه محضة ويمكنك أن تنهيها في أي وقت تشاء.

القسم الأول: أسئلة التأكد من الأهلية:

١- هل سبق لك استخدام تطبيق صحي ؟

نعم ☐ لا ☐ (إنهاء الاستبيان) ☐

٢- هل عمرك 18 سنة أو أكثر؟

نعم ☐ لا ☐ (إنهاء الاستبيان) ☐

٣- هل تقيم حالياً في المملكة العربية السعودية؟

نعم ☐ لا ☐ (إنهاء الاستبيان) ☐

القسم الثاني: البيانات الديموغرافية

٤- العمر:

☐ 18-29 ☐ 30-39 ☐ 40-49 ☐ 50-59 ☐ ≥60

٥- الجنس:

ذكر ☐ أنثى ☐

٦- الجنسية:

سعودي ☐ غير سعودي ☐

٧- مستوى التعليم:

أقل من الثانوية ☐ الثانوية العامة ☐ دبلوم ☐ بكالوريوس ☐ دراسات عليا ☐

٨- الحالة الوظيفية:

موظف حكومي ☐ موظف قطاع خاص ☐ عمل حر ☐ طالب ☐ غير موظف ☐ متقاعد ☐

٩- منطقة الإقامة:

الوسطى ☐ الغربية ☐ الشرقية ☐ الشمالية ☐ الجنوبية ☐

١٠- مكان السكن:

مدينة ☐ قرية ☐

١١- هل تعمل في المجال الصحي:

نعم ☐ لا ☐

القسم الثالث: نمط استخدام تطبيق صحي

١٢- منذ متى تستخدم تطبيق صحي؟

أقل من 6 أشهر ☐ 6-12 شهر ☐ سنة-سنتان ☐ أكثر من سنتين ☐

١٣- كم مرة تستخدم تطبيق صحي؟

أسبوعياً ☐ شهرياً ☐ أحياناً ☐ نادراً ☐

١٤- ما الخدمات التي تستخدمها غالباً؟ (يمكن اختيار أكثر من إجابة)

☐ حجز المواعيد

☐ نتائج التحاليل

☐ خدمات التطعيم

☐ الاستشارات الطبية عن بعد

☐ الإجازات المرضية

☐ الوصفات الطبية

☐ خدمات كوفيد-19

☐ أخرى

العبارة	أوافق بشدة	أوافق	محايد	أعارض بشدة	أعارض
يتعطل تطبيق صحي بشكل متكرر أثناء الاستخدام.					
يستغرق التطبيق وقتاً طويلاً للتحميل أو الاستجابة.					
أواجه أخطاء تقنية أثناء استخدام التطبيق					

					بعض خدمات التطبيق لا تعمل بشكل صحيح
					ضعف الاتصال بالإنترنت يحد من قدرتي على استخدام التطبيق بشكل فعال
					واجهة تطبيق صحي واضحة وسهلة الفهم
					من السهل التنقل بين أقسام التطبيق
					تنفيذ المهام داخل التطبيق سهل بالنسبة لي
					التعليمات داخل التطبيق واضحة وسهلة المتابعة
					تعلم استخدام تطبيق صحي كان سهلاً بالنسبة لي
					يساعدني تطبيق صحي على توفير الوقت عند الحصول على الخدمات الصحية
					يسهل تطبيق صحي الوصول إلى الخدمات الصحية
					يساعدني تطبيق صحي في إدارة حالتي الصحية بشكل أفضل
					يقلل تطبيق صحي من الحاجة إلى زيارة المرافق الصحية حضورياً
					يحسن تطبيق صحي التواصل مع مقدمي الرعاية الصحية

					أثق في الخدمات الرقمية المقدمة من وزارة الصحة عبر تطبيق صحي.
					أعتقد أن معلوماتي الصحية الشخصية آمنة داخل التطبيق.
					أشعر بالقلق من احتمال إساءة استخدام معلوماتي الشخصية عبر التطبيق.
					أشعر بالثقة عند إدخال معلوماتي الصحية في تطبيق صحي.
					يوفر تطبيق صحي حماية كافية لخصوصية المستخدمين.

Haytham A. Sheerah

Senior Advisor – International Health, Global Security & Strategic Development



+966 55 069 6515



Hasheerah@moh.gov.sa



| Riyadh



PROFESSIONAL SUMMARY

Accomplished Public Health Consultant and Global Health Advisor with over a decade of progressive experience in international health systems, policy development, and cross-sector collaboration. Recognized for leading complex public health initiatives at the ministerial level and representing Saudi Arabia on global platforms including the WHO, G20, and SDG forums. Skilled in translating research into action, shaping national policy, and driving innovation across preventive, therapeutic, and regulatory domains. Published extensively in peer-reviewed journals, with a strong track record of delivering evidence-based strategies in international collaboration, global health security, and intergovernmental negotiations. Adept at navigating multicultural environments, advising senior leadership, and fostering high-level partnerships that improve health outcomes at scale.

SKILLS & EXPERTISE

Soft Skills

Leadership | Cross-Functional Collaboration | Problem Solving | Negotiation | Strategic Thinking | Public Speaking | Relationship Building | Presentation Skills | Critical Thinking | Strong Communication

Professional Skills

Microsoft Office | SPSS | STATA | SAS | Infectious Disease Prevention | Travel Medicine Consultation | Scientific Writing | Biostatistical Analysis | Epidemiological Research | Strategic Public Health Planning | Regulatory Compliance | Public Health Awareness Campaigns

WORK EXPERIENCE

Health expert – International Cooperation

July 2025 – Present

Public Health Authority – Office of the CEO | Riyadh

- Collaboration with various sectors to produce scientific research that informed decision-making aligned with the Authority's priorities.
- Coordination operations of the Authority's WHO Collaborating Centers, ensuring compliance and efficiency.
- Engaging in building strategic international partnerships, enhancing the Authority's influence in global health policy.
- Facilitation of participation of Authority personnel in international programs, aligning with strategic health initiatives.

Travel Medicine Doctor

Jan 2024 – Present

Ministry of Health – Primary Health Care, Almuhammadiyah | Riyadh

- Provided comprehensive travel-related medical assessments, including individualized risk profiles for infectious diseases and vaccine recommendations.
- Managed the operational delivery of travel clinics serving high-volume pilgrims and international travelers.
- Disseminated up-to-date global epidemiological alerts and disease-specific briefings to frontline healthcare professionals.

Manager, Consultation & Research Unit | Advisor to Deputyship**Jan 2025 – Jun 2025****Ministry of Health – Deputyship of Therapeutic Affairs | Riyadh**

- Served as a strategic advisor to the Deputyship, contributing to the planning and early implementation of nationwide consultation initiatives aimed at improving therapeutic care in public hospitals and clinics.
- Supported the translation of scientific literature into policy-oriented summaries to inform senior health leadership and guide decision-making processes.
- Played a key role in fostering collaboration between government health officials, clinical professionals, and academic researchers to co-create national clinical guidelines rooted in evidence-based practices.
- Advised on the direction and focus of applied research projects designed to strengthen the quality, accessibility, and effectiveness of therapeutic health services.

General Secretariat – Ministerial Committee on Health in All Policies (HiAP)**Jan 2024 – Dec 2024****Global Health Advisor | Riyadh**

- Managed operational delivery of inter-ministerial partnerships to embed health equity considerations into policies across non-health sectors.
- Crafted technical reports outlining the public health impact of proposed government programs in areas such as transport and environment.

Public Health Consultant**Jan 2024 – Dec 2024****Ministry of Health – Office of the Vice Minister | Riyadh**

- Formulated national public health policies designed to tackle emerging threats and chronic health system challenges.
- Represented the Ministry in high-level regional forums and international delegations.
- Advised on risk communication strategies for outbreaks and public awareness campaigns aligned with national priorities.
- Championed cross-sectoral collaboration by coordinating multi-agency working groups on public health preparedness.

International Health Advisor**Nov 2022 – Dec 2024****Ministry of Health – Assistant Deputyship for International Collaborations | Riyadh**

- Negotiated multi-year frameworks with global institutions such as WHO and the G20 Health Working Group.
- Mapped alignment between Saudi health strategies and global public health priorities to strengthen cooperative initiatives.
- Introduced monitoring systems to track the outcomes of cross-border partnerships and knowledge-sharing activities.

International Health Officer**Jun 2022 – Oct 2022****Ministry of Health – International Health Regulation (IHR) Program | Riyadh**

- Appraised national readiness across IHR core capacities using WHO benchmarks and assessment tools.
- Managed operational scenario-based exercises simulating public health emergencies to evaluate the national response.
- Delivered targeted training sessions on early warning systems, contact tracing, and disease reporting protocols.

Postdoctoral Research Fellow**Jan 2021 – Jan 2022****National Cerebral and Cardiovascular Center – Department of Preventive Cardiology Program | Osaka, Japan**

- Explored complex associations between lifestyle factors and cardiovascular disease outcomes using national-level data sets.
- Published original peer-reviewed articles contributing to global knowledge on preventive cardiology and public health.
- Guided early-career researchers and interns on academic writing, research design, and data visualization techniques.

Research Fellow**Oct 2020 – Mar 2022****Osaka University – Graduate School of Medicine, Department of Social Medicine | Osaka, Japan**

- Investigated public health policy implementation challenges through comparative case studies in East Asia.
- Co-authored journal articles focused on aging populations, universal health coverage, and system resilience.
- Delivered keynote presentations and poster sessions at global public health academic forums.

Teaching Assistant**Apr 2017 – Mar 2018****Osaka University – Graduate School of Medicine, Department of Social Medicine | Osaka, Japan**

- Instructed postgraduate students in applied epidemiology, population health management, and research methods.
- Mentored thesis students from project formulation through to defense, with a focus on ethical research practices.
- Evaluated coursework and statistical analyses to support academic progression in biostatistics modules.

Teaching Assistant**Oct 2015 – Mar 2016****Keio University – Graduate School of Medicine, Department of Social Medicine | Tokyo, Japan**

- Managed educational content for public health modules covering disease burden, global health issues, and systems design.
- Supported faculty in creating interdisciplinary learning materials bridging epidemiology and policy.

Public Health Consultant | Part-time**Oct 2015 – Mar 2016****Japan Medical Prime – Department of Health Product | Tokyo, Japan**

- Collaborated with teams to align marketing with scientific data and public health goals.
- Facilitated Saudi Japanese health collaboration, advancing cross-border knowledge exchange.

E D U C A T I O N

Diploma in Travel Medicine | Ministry of National Guard Health Affairs, Saudi Arabia- 2025**Diploma in Global Clinical Scholars Research Training**- Harvard Medical School, USA-2021**Doctoral Studies in Medical Sciences** - Osaka University, Japan-2020**Exchange Program in Medical Sciences** - Karolinska Institute, Sweden-2017**Research Fellowship**- Keio University, Japan-2016**Bachelor of Medicine, Bachelor of Surgery (MBBS)**- King Saud University, College of Medicine, Saudi Arabia-2012

PROFESSIONAL DEVELOPMENT

- Certificate of WHO Rapid Response Teams Advanced Training Package (RRT ATP)
- Certificate of WHO Rapid Response Teams Training of Trainers Package (RRT TOT)
- Certificate of WHO Rapid Response Teams Country Pilot-Testing Team (RRT CPTT)
- Certificate of WHO Rapid Response Teams Essentials Online Learning Program (RRT ELP)
- Certificate of Imperial College of London Emergency Preparedness & Planning Training course
- Certificate of Liaquat National Hospital and Medical College Research Certificate Course 2020
- Certificate of MiSK Foundation Youth Voice course
- Certificate of MiSK Foundation Preparation Program Future Career Course

MEMBERSHIP

- Member of the Saudi Arabia official delegates at the Intergovernmental Negotiating Body (INB) 2022 – 2024.
- Member of the the Saudi Arabia official delegates at the Working Group on Amendments to the International Health Regulations (2005) 2022 – 2024.
- Member of the Health Working Group in Saudi Arabia official delegates at the G20 INDIA PRESIDENCY.
- Member of the Health Working Group in Saudi Arabia official delegates at the Sustainable Development Goals 2023.
- Associate Member (AM) alumni status by Harvard University 2021 – present.
- Member of the American Heart Association 2021 – present.

SELECTED PUBLICATIONS

- 1- Strengthening global health security through antimicrobial resistance control: Insights from Saudi Arabia. ([link](#)).
- 2- The Need for a Travel Medicine Diploma in Saudi Arabia: Addressing National and Global Health Priorities ([link](#)).
- 3- Assessing Population Well-Being in Saudi Arabia: A Comprehensive National Survey Using the WHO-05 Index and Self-Rated Health Metrics ([link](#)).
- 4- COVID-19 and influenza hospitalizations and the role of COVID-19 vaccination in the post-pandemic period: A cross-sectional study from Saudi Arabia ([link](#)).
- 5- Empowering Women in the Saudi Health Sector: Challenges, Opportunities, and Policy Interventions ([link](#)).
- 6- The Rise of Virtual Health Care: Transforming the Health Care Landscape in the Kingdom of Saudi Arabia: A Review Article ([link](#)).
- 7- Navigating Hurdles: A Review of the Obstacles Facing the Development of the Pandemic Treaty ([link](#)).
- 8- Public Health Challenges in Saudi Arabia during the COVID-19 Pandemic: A Literature Review ([link](#)).
- 9- Return of genomic results does not motivate intent to participate in research for all: Perspectives across 22 countries ([link](#)).
- 10- Global Perceptions of Genomic Data Sharing: What Shapes the Willingness to Donate DNA and Health Data? ([link](#)).

For the full list, please visit the ([link](#))

AWARDS

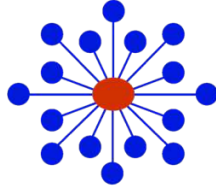
- ELSEVER Certificate for the article linked to the Sustainable Development Goals 2020-2022.
- AFHRE Award for Patient-Oriented or Clinical Research in Hypertension 2021.

PRESENTED POSTERS

- Presented a poster titled "Fruit and Vegetable Consumption and Inflammatory Bowel Disease: A Case-Control Study" at The First Nutritional Care Conference 2025
- Presented a poster titled "Incident of Hypertension According to Blood Pressure Categories in Non-Hypertensive Population in the Suita Study: An Urban Cohort Study" at Hypertension 2021 (P347).
- Presented a poster at the 12th APRU GHC 2018 with the title "Attracting Medical Students to Global Health" (Abstract ID:70).

PRESENTED SPEAKER

- Presented at the Campus Asia 2020 symposium in South Korea, Seoul, Yonsei University, Graduate School of Medicine, 12 – 15 Jan 2020.
- Presented at the 12th APRU Global Health conference, "Planetary Health," Faculty of Medicine, University of Malaya, Kuala Lumpur, Malaysia, 28 – 30 Oct 2018.
- Presented at the Empowerment for Health Promotion Scientific Symposium held at King Khaled Eye Specialist Hospital, 27- 28 Dec 2011.



NIDA Clinical Trials Network

Certificate of Completion

is hereby granted to

Haytham Sheerah

to certify your completion of the six-hour required course on:

GOOD CLINICAL PRACTICE

MODULE:

Introduction
Institutional Review Boards
Informed Consent
Confidentiality & Privacy
Participant Safety & Adverse Events
Quality Assurance
The Research Protocol
Documentation & Record-Keeping
Research Misconduct
Roles & Responsibilities
Recruitment & Retention
Investigational New Drugs

STATUS:

N/A
Passed
Passed
Passed
Passed
Passed
Passed
Passed
Passed
Passed
Passed
Passed

Course Completion Date: 16 May 2024

CTN Expiration Date: 16 May 2027

Eve Jelstrom

Eve Jelstrom, Principal Investigator
NDAT CTN Clinical Coordinating Center

Good Clinical Practice, Version 5, effective 03-Mar-2017

This training has been funded in whole or in part with Federal funds from the National Institute on Drug Abuse, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN2720120100024C.

نموذج مشاركة البيانات البحثية مكتب إدارة البيانات والذكاء الاصطناعي في وزارة الصحة

يشجع مكتب إدارة البيانات والذكاء الاصطناعي في وزارة الصحة بتعزيز ثقافة البحث والابتكار من خلال تمكين الباحثين للوصول إلى البيانات بطريقة سهلة وآمنة. هذا النموذج يحفز الباحثين ويسهل طلب البيانات المطلوبة لإجراء دراسات قيمة تساهم في تعزيز المعرفة وتعزيز المصلحة العامة.

الغرض من تعبئة النموذج

- تمكين مقدم الطلب من صياغة هدف الحصول على البيانات بوضوح.
- وصف وتحديد البيانات المطلوبة بوضوح.
- تحديد مستخدمي البيانات وكيفية استخدامها ونشرها.
- تحديد كيفية تبادل البيانات وإدارتها.

تعليمات الاستخدام

- التأكد من أن البيانات المطلوبة ليست ضمن البيانات الإحصائية المتاحة في البوابة الإلكترونية لوزارة الصحة قبل إرسال طلب البيانات.
- استخدام النموذج شرط للحصول على الموافقة لاستعمال البيانات.
- تعبئة جميع الحقول الإلزامية والتحقق من اكتمال النموذج وإرساله لبريد مكتب إدارة البيانات: Data-Office@moh.gov.sa
- الاقرار بأن جميع المعلومات المقدمة في النموذج دقيقة وحديثة.
- إرفاق جميع المستندات المطلوبة.
- في حال اعتماد الموافقة ولإكمال باقي الإجراءات مع لجنة أخلاقيات البحوث على البريد التالي GDRS-IRB@moh.gov.sa

تنويه

- مكتب إدارة البيانات معني بحوكمة وتشريع وتنظيم عمليات مشاركة البيانات، حصولك على موافقة المكتب على عملية مشاركة البيانات لا تعني بالضرورة مسؤولية المكتب بتوفير البيانات المطلوبة لطالب البيانات.

١. بيانات التواصل (*حقل إلزامي)

الاسم *	هيثم عبدالوهاب إبراهيم شيره
البريد الإلكتروني *	hasheerah@moh.gov.sa
رقم الجوال *	0550696515
مدينة السكن الحالية *	الرياض
جهة العمل / الدراسة *	وزارة الصحة (معار لوقاية)

٢. هدف الحصول على البيانات (*حقل إلزامي)

اسم البحث / المشروع *	Determinants of User Engagement with the Sehhaty Mobile Health Application in Saudi Arabia: A Cross-Sectional Analysis of Perceived Barriers
الغرض من البحث / المشروع *	To examine the determinants of user engagement with Sehhaty by assessing technical, behavioral, and trust-related factors influencing satisfaction and continued use.
وصف عام للخلاصة البحثية المتوقعة *	Mobile health (mHealth) applications are central to healthcare digitalization. In Saudi Arabia, the Sehhaty app plays a key role in service delivery; however, sustained user engagement remains uncertain. Importance: This study provides a comprehensive framework to understand mHealth engagement, offering practical insights for policymakers and developers to improve digital health systems and support Vision 2030 goals.
الإطار الزمني للبحث / للمشروع *	٩/٣٠ - ٥/٣١
الجهة الراعية للبحث / المشروع *	لا يوجد

٣. تفاصيل البيانات (*حقل إلزامي)

هل البيانات المطلوبة بيانات خام (Raw) أم تجميعية (Aggregates) *	☒ بيانات خام (Raw data) ☐ بيانات تجميعية (Aggregates)
عناصر البيانات المطلوبة بالتفصيل والوصف الواضح لكل عنصر *	☐ لا يوجد
فترة البيانات *	☐ لا يوجد
هل الدراسة/ البحث تستهدف منطقة محددة *	☐ نعم ☒ جميع مناطق المملكة إذا كان الجواب نعم ماهي المنطقة/المناطق
هل سيتم ربط البيانات مع بيانات من جهة أخرى *	☐ نعم ☒ لا ماهي الجهة؟
هل سيتم مشاركة البيانات أو التحليلات المبنية عليها مع جهة أو أشخاص آخرين قبل نشر البحث؟ *	☐ نعم ☒ لا إذا كان الجواب نعم ماهي الجهة / الأشخاص
هل نتيجة البحث قابلة للنشر أو المشاركة مع جهات أخرى *	☒ نعم ☐ لا إذا كان الجواب نعم ماهي الجهة مجلات علمية
ماهي الإدارة المالك للبيانات ؟	ماهي الجهة؟ ☐ لا يوجد

إقرار بصحة البيانات المقدمة

أقرّ أنا الموقع أدناه على صحة البيانات المقدمة وصحة المرفقات وأتعهد بأنها دقيقة ومحدثة، وأن أي تغيير على تفاصيل الطلب يستلزم موافقة جديدة. كما ألتزم بالتعليمات والبنود الواردة في النموذج المقدم من مكتب إدارة البيانات في وزارة الصحة. وفي حال وجود ما يخالف ذلك فإن هذا النموذج يعتبر لاغياً الفعالية.

الاسم	هيثم عبد الوهاب شيره
رقم الهوية	١٠٥٧٦٥٥٨٠٣
التاريخ	٢٠٢٦/٥/٧
التوقيع	

IRB Application Form

IRB Application Number: FOR IRB USE

IRB APPLICATION CHECKLIST

	#	Items	Choose	Notes
General Requirements	1	CVs of the research team (required from all investigators)	YES	Click or tap here to enter text.
	2	A valid research ethics certificate (required from all investigators)	YES	Click or tap here to enter text.
	3	The tools that will be used in the study 'e.g., questionnaire, data collection sheet, interview guide' (if applicable)	YES	Click or tap here to enter text.
	IRB Required Forms			
	4	IRB approval application form (to be completely filled and signed)	YES	Click or tap here to enter text.
	5	Informed consent form 'Arabic/English' (provide translation certificate if other languages)	YES	Click or tap here to enter text.
	6	Data sharing agreement form	YES	Click or tap here to enter text.
Only for Students	7	Non-disclosure agreement form (if applicable)	Choose an item.	Click or tap here to enter text.
	Additional Required Documents for Students			
	8	Supervisor letter	Choose an item.	Click or tap here to enter text.
	9	Cultural attaché letter (if studying abroad)	Choose an item.	Click or tap here to enter text.
	10	Enrollment letter from the academic institution	Choose an item.	Click or tap here to enter text.
	11	The supervisor's C.V.	Choose an item.	Click or tap here to enter text.

*N/A: not applicable

Section 1: SUBMISSION DETAILS

Study title in English:	Determinants of User Engagement with the Sehhaty Mobile Health Application in Saudi Arabia: A Cross-Sectional Analysis of Perceived Barriers		
Study title in Arabic:	الرجاء كتابة الموضوع مباشرة وديق		
Submission date:	5/7/2026	Starting date of the study:	5/31/2026
Study duration:	5 years		
Research Type:			
☐ A. Medical Primary Research ☐ 1. Basic Medical Research ☐ 2. Clinical Research ☒ 3. Epidemiological Research			
☐ B. Medical Secondary Research ☐ 1. Reviews ☐ 2. Meta-Analyses			
☐ C. Non-Medical			
*If you are unsure about your selection, please refer to this link for clarification.			
Research site:			
☐ Inside of MOH Institutions ☐ Outside of MOH Institutions ☒ Both Inside and Outside of MOH Institutions			

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Purpose of the research:		Research site affiliation:					
☒ Academic Purposes <i>Choose an item.</i> ☐ Professional Purposes		☐ Single Site or Center ☐ Multi-Sites or Centers					
Research specialty (please select one from the dropdown list):		Research site name/s (e.g., hospitals or locations)					
Choose an item. If others: please specify		<table border="1"> <tr> <th>#</th> <th>Site</th> </tr> <tr> <td>#</td> <td>Click or tap here to enter text.</td> </tr> </table> <i>* You can expand the table to add sites as necessary.</i>		#	Site	#	Click or tap here to enter text.
#	Site						
#	Click or tap here to enter text.						
Previous IRB Approval							
Did you apply to another IRB for this study? <i>Choose an item.</i> <i>* If yes, please attach a copy to the application.</i>							

Section 2: RESEARCH TEAM

Principal Investigator (PI)									
First, Middle Name:		Haytham		Last Name:		Sheerah			
PI ID* Number:		51586878		PI Specialty:		Public Health			
PI Degree:		Md, Ph.D		PI E-mail:		Hasheerah@moh.gov.sa			
PI Phone:		0550696515		Signature:					
PI Affiliation:		☒ MOH ☐ Non-MOH, specify Click or tap here to enter text.							
Supervisor name and degree (for students)			Click or tap here to enter text.			Supervisor E-mail:		Click or tap here to enter text.	
Please List Co-Investigator(s), if any:									
<i>* If the research supervisor is considered a co-investigator in this study, he/she must be included in this list.</i> <i>* By signing this section, all investigators agree to and will be responsible for all clauses in Section 6: Investigator Assurance.</i>									
#	Name	Degree	Affiliation	Email	Phone	ID*	Role	Signature	
1	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	please specify		
2	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	please specify		

** National ID or Iqama ID number (passport number for non-residents)*

*** You can expand the table and add co-investigators as necessary*

Section 3. FUNDING SOURCE

A. Is the Study Funded?	
☒ Study is Not Funded (continue to section 4). ☐ Study is Funded . Fund Number: Click or tap here to enter text. ☐ Study Applied for Funding (under process). Application Date: Click or tap here to enter text.	
B. Funding Source:	
☐ MOH: please specify ☐ Governmental: please specify ☐ Commercial Sponsorship: please specify	

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Section 4. CONFLICTS OF INTEREST

Do any of the research team or members of their immediate families have any financial interests related to the research or the research sponsor?

☐ Yes

☐ No

If yes, please write a conflict management plan

Section 5. PROPOSAL FORM

Part 1: SUMMARY AND BACKGROUND OF THE STUDY

A. Summary in English (max 150 words):

Introduction: Mobile health (mHealth) applications are central to healthcare digitalization. In Saudi Arabia, the Sehhaty app plays a key role in service delivery; however, sustained user engagement remains uncertain.

Purpose: To examine the determinants of user engagement with Sehhaty by assessing technical, behavioral, and trust-related factors influencing satisfaction and continued use.

Methods: A cross-sectional study will be conducted among adults in Saudi Arabia using an online questionnaire. Measures will include technical barriers, ease of use, perceived usefulness, trust, interoperability, satisfaction, and behavioral intention. Data will be analyzed using descriptive statistics and multiple linear regression.

Importance: This study provides a comprehensive framework to understand mHealth engagement, offering practical insights for policymakers and developers to improve digital health systems and support Vision 2030 goals.

B. Summary in Arabic (max 150 words):

المقدمة:

تعد تطبيقات الصحة المتنقلة جزءاً أساسياً من التحول الرقمي في الرعاية الصحية. في المملكة العربية السعودية، يمثل تطبيق "صحتي" أداة رئيسية لتقديم الخدمات، إلا أن استمرارية استخدامه ما زالت غير واضحة.

الهدف:

دراسة محددات تفاعل المستخدمين مع تطبيق "صحتي" من خلال تحليل العوامل التقنية والسلوكية وعوامل الثقة المؤثرة على الرضا.

منهجية البحث:

دراسة مقطعية تُجرى على البالغين في السعودية باستخدام استبيان إلكتروني. تشمل المتغيرات الحواجز التقنية، سهولة الاستخدام، الفائدة المدركة، الثقة، التكامل، الرضا، ونية الاستمرار. سيتم تحليل البيانات باستخدام الإحصاء الوصفي والانحدار الخطي المتعدد.

أهمية البحث:

تقدم الدراسة إطاراً تحليلياً شاملاً لفهم استخدام تطبيقات الصحة الرقمية، وتوفر أدلة عملية لصناع القرار لتحسين الأنظمة الصحية الرقمية ودعم أهداف رؤية 2030.

C. Background "summarize the relevant literature (max 400 words)" (references must be included)

Over the past two decades, healthcare systems worldwide have experienced rapid digital transformation driven by advances in information and communication technologies. Among the most significant developments has been the emergence of mobile health (mHealth), defined as the use of mobile devices and wireless technologies to support medical and public health practices (Istepanian & Al-Anzi, 2018). mHealth applications are increasingly integrated into national health systems to improve accessibility, enhance patient engagement, optimize resource allocation, and reduce operational costs. These applications allow users to schedule appointments, access medical records, receive teleconsultations, monitor chronic conditions, and manage prescriptions remotely (Istepanian & Al-Anzi, 2018). International research indicates that the adoption and sustained use of mHealth applications depend on multiple interacting technical, behavioral, and organizational factors. Evidence from systematic reviews shows that perceived usefulness, perceived ease of use, trust in digital systems, interoperability with healthcare providers, and technical reliability are among the strongest determinants of continued engagement with digital health platforms. At the same time, concerns related to privacy protection, digital literacy limitations, and system integration remain persistent barriers to effective implementation across different healthcare settings (Rahimi et al., 2018; Lee et al., 2025; Zakerabasali et al., 2021).

In Saudi Arabia, digital health transformation represents a central pillar of Vision 2030, which emphasizes modernization, efficiency, and sustainability in public services (Suleiman & Ming, 2025). As part of this national strategy, the Ministry of Health has introduced several digital platforms to enhance healthcare accessibility and service delivery. Among these initiatives, the Sehhaty mobile application represents one of the most important national digital health tools. Sehhaty provides users with access to primary healthcare appointment booking, virtual medical consultations, laboratory results, vaccination records, prescription management, and health monitoring services. During the COVID-19 pandemic, the application played a critical role in managing testing and vaccination appointments, which significantly increased public familiarity with digital healthcare platforms (Alharthi, 2025).

Despite the widespread availability and strategic importance of Sehhaty, the effectiveness of digital health platforms depends not only on access but also on sustained user engagement and satisfaction. Previous research suggests that technological availability alone does not guarantee continued usage, as adoption decisions are strongly influenced by usability, perceived usefulness, trust, interoperability, and technical performance (Zakerabasali et al., 2021). Within the Saudi context, existing studies examining Sehhaty have primarily focused on specific user groups such as healthcare providers or young adults, or have evaluated isolated aspects such as usability or technical performance rather than examining multiple determinants simultaneously (Alzghaibi, 2025a, 2025b; Al-Edresee & Alrabaily, 2025; Ali et al., 2022; Dawood & Alkadi, 2022).

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Accordingly, there remains a need for a comprehensive analytical framework that integrates technical, behavioral, and trust-related determinants to better understand sustained engagement with the Sehhaty application among the general adult population in Saudi Arabia. Therefore, the objective of this study is to examine the determinants of user engagement with the Sehhaty mobile health application among adults in Saudi Arabia by investigating how technical barriers, perceived ease of use, perceived usefulness, trust, and interoperability influence user satisfaction and behavioral intention to continue using the application.

D. Aims and objectives/research question(s)

The primary objective of this study is to examine the barriers to using the Sehhaty mHealth application among the general population in Saudi Arabia.

More specifically, the study aims to:

1. Identify technical barriers affecting Sehhaty usage.
2. Assess perceived ease of use and perceived usefulness of the application.
3. Measure levels of trust and privacy concerns.
4. Evaluate the role of system interoperability.
5. Examine the relationship between these factors and user satisfaction.
6. Determine predictors of behavioral intention to continue using Sehhaty.

E. Rationale and importance (max 150 words)

This study is significant at multiple levels.

- Academically, it contributes to the growing literature on digital health adoption in the Middle East by developing and empirically testing a multidimensional explanatory model within the Saudi context.
- Practically, the study provides actionable insights for healthcare policymakers, system developers, and digital transformation leaders. Understanding the relative impact of technical barriers, perceived usefulness, trust, and interoperability can guide resource allocation and improvement strategies.
- Strategically, the study supports Saudi Arabia's Vision 2030 objectives by strengthening evidence-based digital transformation. Sustainable digital health systems require not only technological infrastructure but also public confidence and satisfaction. By identifying modifiable barriers, the research supports long-term digital health sustainability.

Part 2. METHODS

A. Study design

This study will employ a cross-sectional analytical design to investigate barriers associated with the use of the Sehhaty mobile health application among adults in Saudi Arabia.

B. Study site and target population

The study will be conducted across Saudi Arabia using a fully online recruitment strategy. Data will be collected through a structured electronic questionnaire distributed via digital platforms, including social media networks (e.g., Facebook, Twitter/X, WhatsApp, Telegram, Instagram), community groups, university mailing lists, and professional networks. The study population consists of adults residing in Saudi Arabia who have used the Sehhaty mobile application at least once. The unit of analysis is the individual user of the application.

C. Sample size and sampling technique "provide justification for the required sample"

Sample size is calculated using Cochran's formula for cross-sectional studies:

$$n = (Z^2 \times p \times (1 - p)) / e^2$$

Assuming:

- $Z = 1.96$ (95% confidence level)
- $p = 0.50$ (maximum variability)
- $e = 0.05$ (margin of error)

The minimum required sample size is 384 participants.

To account for incomplete responses and improve analytical stability in multivariable modeling, the study will target at least 400 completed responses.

D. Tools and Procedures

1. Select study tools (all that apply)

- ☒ Questionnaire(s): ☐ Paper ☐ Telephone ☒ Online
- ☐ Data Collection Sheet
- ☐ Interviews
- ☐ Intervention: please specify

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☐ Test(s): please specify

☐ Other: please specify

2. Please list and describe all the selected tools (include references if needed)

Click or tap here to enter text.

E. Recruitment

1. Planned recruitment procedures (select all that apply)

☐ Phone Call or SMS: please specify

☒ Social Media: Facebook, Twitter/X, WhatsApp, Telegram, Instagram

☐ Email

☐ Flyers/Brochures

☐ Online Announcement: please specify

☐ Other: please specify

☐ Not Applicable (secondary data only)

2. Describe the recruitment process in details (for each group of the participants, if applicable)

**please attach copies of any advertisement materials, if applicable.*

Click or tap here to enter text.

3. Study populations (select who will be recruited)

Age:

☒ Adults (≥18 years)

☐ Children (<18 years)

☐ Particular Age Range: please specify

Gender:

☒ Both Males and Females

☐ Targeted Gender: ☐ Males or ☐ Females

Race/Ethnicity:

☒ All Races and Ethnicities

☐ Targeted Race/Ethnicity: please indicate

Other:

☐ Pregnant or Lactating Women, Fetuses, and Neonates

☐ Prisoners

☐ People with Low-Income Status

☐ People with Physical Disabilities

☐ People with Mental Issues: please specify

☐ People Who Are Illiterate

☐ People Who Are Non-Arabic Speakers

☐ Other: please specify

4. Please provide a scientific rationale if you are targeting one gender, race, ethnic group, or groups from the "other" category

Click or tap here to enter text.

5. Describe the measures the study will take to protect the rights and welfare of the populations selected above

Click or tap here to enter text.

6. Describe the ethical issues that may arise from the study and the methods to handle such issues

Click or tap here to enter text.

F. Inclusion/Exclusion

1. Inclusion criteria:

Click or tap here to enter text. Participants must meet all of the following criteria:

1. Aged 18 years or older.
2. Currently residing in Saudi Arabia.
3. Have used the Sehhaty application at least once.
4. Able to read and understand Arabic or English.
5. Provide electronic informed consent.

2. Exclusion criteria:

Participants will be excluded if:

1. They have never used Sehhaty.
2. They submit incomplete questionnaires, missing primary outcome variables.
3. They provide clearly inconsistent or duplicate responses.

G. Analysis plan

Data will be analyzed using SPSS.

1. Data cleaning

- Removal of duplicate responses.
- Assessment of missing data.
- Logical consistency checks.

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2. Descriptive analysis

- Means and standard deviations for continuous variables.
- Frequencies and percentages for categorical variables.
- Ranking of most commonly reported barriers.

3. Bivariate analysis

- Independent t-tests or ANOVA for comparison of mean barrier scores across demographic groups.
- Pearson correlation coefficients to examine relationships between continuous constructs.

4. Multivariable analysis

Multiple linear regression will be used to examine predictors of behavioral intention. The behavioral intention score will be treated as a continuous dependent variable.

Independent variables will include:

- Technical barriers score
- Ease of use score
- Perceived usefulness score
- Trust score
- Interoperability score
- Satisfaction score

Demographic variables (age, gender, education, and region) will be entered as covariates.

Model assumptions will be assessed:

1. Normality of residuals
2. Linearity
3. Homoscedasticity
4. Multicollinearity (Variance Inflation Factor < 5)

Adjusted beta coefficients with 95% confidence intervals will be reported. A p-value < 0.05 will be considered statistically significant.

Part 3. PAYMENTS & INCENTIVES

A. Will you provide financial incentives or compensation to the study participants?

☐ Yes ☒ No, if no, continue to part 4

B. Describe the payment plan including the amount of money (SAR) to be given to each participant

Click or tap here to enter text.

Part 4. RISKS & BENEFITS

A. Does the study present any risk and benefits to the participants?

☐ Yes ☒ No, if no, continue to part 5

B. What risks are expected from carrying out this study?

(examples of risk areas: physical well-being, privacy, emotions, reputation, employability, and/or criminal/legal status)

Click or tap here to enter text.

C. How will the risks be minimized?

Click or tap here to enter text.

D. What are the expected benefits from the study?

Click or tap here to enter text.

E. Balance risks and benefits (do the benefits outweigh the risks?):

Click or tap here to enter text.

Part 5. INFORMED CONSENT

A. Select the informed consent process that will be used:

☒ The informed consent form will be **Signed** by the: ☒ Adult(s) ☐ Children ☐ Parent(s)/Guardian(s)

OR

☐ The PI would like to request a **Waiver of Documentation** of informed consent for the: ☐ Adult(s) ☐ Children ☐ Parent(s)/Guardian(s)

Explain Why: Click or tap here to enter text.

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OR

☐ The PI would like to request a **Waiver of Informed Consent** for the: ☐ Adult(s) ☐ Children ☐ Parent(s)/Guardian(s)

Explain Why: [Click or tap here to enter text.](#)

Part 6. PRIVACY & CONFIDENTIALITY

A. Will the participants' data be identified?

- ☐ Yes, with direct identifiers
☐ Yes, with indirect identifiers (e.g., assigning codes)
☒ No, it will be anonymous

B. How will you protect the privacy of the research data? (select all that apply)

- ☐ Storage of consent forms and data in separate places
☒ Data is collected anonymously
☐ Use of participant codes on all data (codes will be stored in a separate location)
☒ The study data will be stored securely (e.g., secured office, password protected computer) please explain
☐ Other: please describe

C. How long will the study data be kept after the completion of the study? (minimum period is 5 years)

- ☒ 5 years OR ☐ > 5 years please indicate the duration

Part 7. DISSEMINATION

A. How will the study be disseminated?

- ☒ Scientific Journal
☒ Conference Presentation
☐ Other: please describe

B. Will participants' identifying information be published or shared?

- ☐ Yes ☒ No * If yes: please specify

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Section 6. INVESTIGATOR ASSURANCE

I certify that:

1. The information filled out in this application form is complete and correct.
2. The research team will follow the IRB approved proposal (study details, methods, and procedures), unless amendment(s) are requested and approved by the IRB.
3. The research team will follow MOH and NCBE regulations.
4. The research team will not disclose personally identifiable data of the participants to any other party.
5. The PI will keep the study data securely for at least five years after the completion of the study.
6. The collected data will only be used for this proposal.
7. The PI is responsible for the safe and ethical conduct of the research.
8. The PI will perform and/or supervise the conduct of study-related procedures and monitor the safety of the study subjects and investigational staff.
9. The research team will collect three copies of informed consent forms (unless waived):
 - I. one copy to be kept with the PI.
 - II. one copy to be kept with the study participant.
 - III. one copy for the IRB committee OR to be kept in the participant's file in case of clinical research.
10. The research team will provide periodic progress reports as requested by the IRB.
11. The PI will notify the IRB as soon as possible in the case of:
 - I. any amendment to the project protocol, CRF, IC or IB or other related documents.
 - II. any serious unexpected adverse events in accordance with the NCBE regulations.
 - III. any event or new information that may affect the benefit/risk ratio of the proposal.
12. The PI will ensure adequate close-out of the study.
13. The final report will be submitted for approval by the IRB before publication.

The application must be signed by the PI before submission (electronic signatures are accepted)

Principal Investigator name: Click or tap here to enter text.

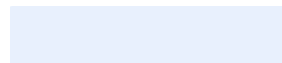
Signature:



Date: Click or tap to enter a date.

Supervisor name (for students): Click or tap here to enter text.

Signature:



Date: Click or tap to enter a date.

Informed Consent Form

IRB Log Number:			رقم البحث العلمي:
Subject or Study Number:		هيثم عبد الوهاب شيره	اسم المشارك:
Medical Record Number:			رقم السجل الطبي:
Study Title E:			
Determinants of User Engagement with the Sehhaty Mobile Health Application in Saudi Arabia: A Cross-Sectional Analysis of Perceived Barriers			عنوان البحث العلمي بالعربي:
Principal Investigator:		هيثم شيره	الباحث الرئيس:
Affiliation:		وكالة الصحة السكانية (معار وقاية)	مكان العمل :
Telephone or Mobile No.:		٠٥٥٠٦٩٦٥١٥	رقم الهاتف أو الجوال:

Why this study is being done?	ما سبب القيام بهذا البحث العلمي؟
This study is significant at multiple levels. - Academically, it contributes to the growing literature on digital health adoption in the Middle East by developing and empirically testing a multidimensional explanatory model within the Saudi context. - Practically, the study provides actionable insights for healthcare policymakers, system developers, and digital transformation leaders. Understanding the relative impact of technical barriers, perceived usefulness, trust, and interoperability can guide resource allocation and improvement strategies. - Strategically, the study supports Saudi Arabia's Vision 2030 objectives by strengthening evidence-based digital transformation. Sustainable digital health systems require not only technological infrastructure but also public confidence and satisfaction. By identifying modifiable barriers, the research supports long-term digital health sustainability.	

How many people will take part in this study? Sample size	كم عدد الأشخاص المفترض مشاركتهم في هذا البحث العلمي؟ حجم عينة البحث
Sample size is calculated using Cochran's formula for cross-sectional studies: $n = (Z^2 \times p \times (1 - p)) / e^2$ Assuming: $Z = 1.96$ (95% confidence level) $p = 0.50$ (maximum variability) $e = 0.05$ (margin of error) The minimum required sample size is 384 participants. To account for incomplete responses and improve analytical stability in multivariable modeling, the study will target at least 400 completed responses.	

What are the objectives of the Study?	ما هي أهداف هذا البحث العلمي؟
The primary objective of this study is to examine the barriers to using the Sehhaty mHealth application among the general population in Saudi Arabia. More specifically, the study aims to: - Identify technical barriers affecting Sehhaty usage. - Assess perceived ease of use and perceived usefulness of the application.	

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3. Measure levels of trust and privacy concerns.
4. Evaluate the role of system interoperability.
5. Examine the relationship between these factors and user satisfaction.
6. Determine predictors of behavioral intention to continue using Sehhaty.

Study location: MOH facilities

General population

موقع إجراء هذا البحث العلمي: منشآت وزارة الصحة

What is expected of me as participant during the study?

ما المطلوب مني كمشارك خلال هذا البحث العلمي؟

The study will be conducted across Saudi Arabia using a fully online recruitment strategy.

How long will the participant last?

مدة المشاركة في البحث؟

5 years

Can I stop being in this study?

هل يمكنني إنهاء المشاركة في هذا البحث العلمي؟

You can decide to stop at any time. Taking part is purely voluntary.

المشاركة طوعه محضة ويمكنك أن تنهيها في أي وقت تشاء.

What are the benefits of this study?

ما هي فوائد هذا البحث العلمي؟

This study provides a comprehensive framework to understand mHealth engagement, offering practical insights for policymakers and developers to improve digital health systems and support Vision 2030 goals.

[على سبيل المثال، لا توجد فوائد]:
لن تكون هناك أي فائدة مباشرة لك من المشاركة في هذا البحث العلمي. نتائج هذا البحث قد تكون مفيدة للمرضى في المستقبل.

What are the risks of this study?

ما هي المخاطر المتوقعة من المشاركة في هذا البحث العلمي؟

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Non	
What if I am injured because I took part in this study?	ماذا سيحدث إذا أصابني ضرر جراء المشاركة في هذا البحث العلمي؟
Not applicable	إذا حدث أن أصبت بضرر نتيجة مشاركتك في هذا البحث العلمي، ستقدم لك مستشفى.....العلاج دون أي تكلفة لك.
What are the costs of this study?	وما هي تكاليف المشاركة في هذا البحث العلمي؟
There are no costs to you if you take part in this study.	لا توجد تكاليف للمشاركة في هذه البحث العلمي.
Will I be paid for taking part in this study?	هل هنالك اجر مقابل المشاركة في هذا البحث العلمي؟
No	
What are the alternatives?	ما هي البدائل؟
Non	
Will my information be kept private?	هل سيتم الحفاظ على معلوماتي بسرية؟
Your personal information will be kept private. It will be given out only if required by law. Your personal information will not be used in any reports.	معلوماتك الشخصية سيتم الحفاظ عليها بسرية تامة. ولا تعطي إلا إذا اقتضى الأمر وذلك في حدود النظم والقوانين المطبقة بهذا الخصوص. معلوماتك الشخصية لن تستخدم في أي تقارير.
What are my rights if I take part in this study?	ما هي حقوقي إذا شاركت في هذا البحث العلمي؟
Taking part in this study is your choice. You may choose to take part or not to take part. If you decide to take part in the study, you can quit at any time. There will be no penalty to you for your decision. Your medical care will not change.	المشاركة في هذا البحث العلمي هي بمحض اختيارك. يمكنك أن تختار المشاركة أو لا. إذا قررت أن تشارك في هذا البحث العلمي، يمكنك التوقف في أي وقت تشاء. وإذا لم تشارك لن تكون هناك أي عقوبة لك، ولا تتأثر الرعاية الطبية المقدمة لك بسبب هذا القرار.
Who do I call if I have questions or problems?	بمن يمكنني الاتصال إذا كان لدي أسئلة أو مشاكل؟
If you have questions about the study, you can call PI (PI name) at [] or email([]) If you have any questions about “rights of human subjects,” or If you have an emergency you may call the Chairman of the Central IRB at extension 011 2125555 ext.4337 or (gdrs-irb@moh.gov.sa).	إذا كانت لديك أسئلة عن هذا البحث العلمي ، يمكنك الاتصال بالباحث الرئيس(اسم الباحث الرئيس) على هذا الرقم [] أو الايميل () وإذا كانت لديك أي تساؤلات حول "حقوق الأشخاص موضوع البحث، “ أو إذا كان لديك مكالمة طارئة يمكنك الاتصال برئيس اللجنة المركزية لأخلاقيات البحوث (Central IRB) على 011 2125555 ext.4337 أو ايميل اللجنة (gdrs-irb@moh.gov.sa).

Informed Consent Form

CONSENT:

Subject:

I will receive a signed copy of this consent form.

إقرار بالموافقة:

المشارك:

أقر أنا بأن هذا البحث العلمي وإجراءاته قد تم شرحها لي. لقد سمح لي بأن أسأل كل سؤال لدي الآن. ويمكنني أن أسأل أي أسئلة إضافية في أي وقت لاحق. كما يمكنني إنهاء المشاركة في هذا البحث العلمي في أي وقت دون أن تتأثر الرعاية الصحية المقدمة لي. سأحصل على نسخة موقعة من الإقرار بالموافقة.

Subject Signature: _____

Date: _____

Time: _____ ☐ AM ☐ PM

توقيع المشارك: _____

التاريخ: _____

الوقت: _____ ☐ م ☐ ص

Person Obtaining Consent:

I have explained the nature and purpose of the study and the risks involved. I have answered and will answer questions to the best of my ability. I will give a signed copy of the consent form to the subject.

الشخص الحاصل علي الإقرار بالموافقة:

أقر بأنني قد شرحت بصورة كاملة طبيعة هذا البحث العلمي والغرض منه وما ينطوي عليه من مخاطر. ولقد أجبت على جميع الأسئلة بقدر الإمكان. سأعطي نسخة موقعة من الإقرار بالموافقة للمشارك المذكور أعلاه.

Signature of Person Obtaining Consent: _____

Date: _____

Time: _____ ☐ AM ☐ PM

توقيع الشخص الحاصل علي الإقرار بالموافقة: _____

التاريخ: _____

الوقت: _____ ☐ م ☐ ص

Principal Investigator:

Name: Haytham Abdulwhab sheerah

Date: 7/5/2026

Time: 3.35 ☐ AM ☒ PM

Signature _____

الباحث الرئيس:

الاسم :

التاريخ:

الوقت: _____ ☐ م ☐ ص

التوقيع :

Stamp

Stamp

RS-MOH Data Sharing Agreement

This Agreement sets forth the terms and conditions under which the Provider will disclose certain data and protected health information, the party holding the data ("Provider") you request will be shared with you, the Data Recipient, for purposes outlined in study proposal

[Determinants of User Engagement with the Sehhaty Mobile Health Application in Saudi Arabia: A Cross-Sectional Analysis of Perceived Barriers]

The PI will keep the study data for at least 5 years after completion of study

Study Information:

- **Provider Name** : MOH
- **Recipient Name PI** : Haytham Abdulwaleed Sheerah
- **Date** : 7/5/2026
- **Brief description of the research:**

Introduction: Mobile health (mHealth) applications are central to healthcare digitalization. In Saudi Arabia, the Sehhaty app plays a key role in service delivery; however, sustained user engagement remains uncertain.

Methods: A cross-sectional study will be conducted among adults in Saudi Arabia using an online questionnaire. Measures will include technical barriers, ease of use, perceived usefulness, trust, interoperability, satisfaction, and behavioral intention. Data

اتفاقية تبادل بيانات الدراسات البحثية - وزارة الصحة

تستعرض هذه الاتفاقية الشروط والأحكام التي سيقوم بموجبها المزود بالكشف عن بعض البيانات ومعلومات الصحة المحمية، ويتم تبادل البيانات التي يتم طلبها بين الطرف الحاصل عليها ("المزود") ومتلقي البيانات للأغراض التي تم بيانها في المقترح البحثي

[عنوان المشروع]

أقل مدة لإحتفاظ الباحث الرئيس بالبيانات بعد انتهاء البحث هي
٥ سنوات

معلومات الدراسة:

- اسم المزود: وزارة الصحة
- اسم المتلقي (الباحث الرئيس):
- التاريخ:
- وصف مختصر للبحث:

will be analyzed using descriptive statistics and multiple linear regression.

Importance: This study provides a comprehensive framework to understand mHealth engagement, offering practical insights for policymakers and developers to improve digital health systems and support Vision 2030 goals.

- The purpose of this research is to: Provide complete description of the purpose of the research project:

Purpose: To examine the determinants of user engagement with Sehhaty by assessing technical, behavioral, and trust-related factors influencing satisfaction and continued use.

- The recipient agrees to use the information solely in the following manner: Provide complete description of all proposed uses of the data set:

The primary objective of this study is to examine the barriers to using the Sehhaty mHealth application among the general population in Saudi Arabia.

More specifically, the study aims to:

1. Identify technical barriers affecting Sehhaty usage.
2. Assess perceived ease of use and perceived usefulness of the application.

- الغرض من هذا البحث هو:
يتم تقديم وصف كامل للغرض من المشروع البحثي:

- يوافق المتلقي على استخدام المعلومات فقط بالطريقة التالية:
يتم إدراج وصف كامل للاستخدامات المقترحة لمجموعة البيانات

To be filled by one language only

3. Measure levels of trust and privacy concerns.
4. Evaluate the role of system interoperability.
5. Examine the relationship between these factors and user satisfaction.
6. Determine predictors of behavior intention to continue using Sehhaty.

- **Recipient agree to limit access to the information to the following individuals or classes of individuals:** Provide complete list of all individuals, or classes of individuals, who will access the limited data set:

Age:

☒ Adults (≥ 18 years)

Gender:

☒ Both Males and Females

Race/Ethnicity:

☒ All Races and Ethnicities

- **يوافق المتلقي على الحد من الاطلاع على المعلومات على الأفراد و فئات الأفراد التالية:** يتم إدراج قائمة كاملة بكافة الأفراد، أو فئات الأفراد، الذين سيطلعون على مجموعة البيانات المحدودة:

To be filled by one language only

Conditions and Stipulations:	الشروط و الاشتراطات:
Recipient further agrees to the following conditions and stipulations:	يوافق المتلقي أيضا على الشروط و الاشتراطات التالية:
1. The information will not be used or further disclosed other than as permitted by this agreement or as otherwise required by Saudi Law.	١. لن يتم استخدام المعلومات أو الكشف عنها بخلاف ما هو مسموح بهذه الاتفاقية أو بخلاف ذلك على النحو المطلوب بالقانون السعودي.
2. Appropriate safeguards will be implemented as described above to prevent use or disclosure of information other than as provided for by this agreement.	٢. سيتم تطبيق الضمانات المناسبة على النحو الموضح أعلاه للحيلولة دون استخدام المعلومات أو الكشف عنها بخلاف ما هو منصوص عليه في هذه الاتفاقية.
3. Information set will not be re-identified.	٣. لن يُعاد تحديد مجموعة المعلومات.
4. Individuals whose information is contained in the information will not be contacted.	٤. لن يتم التواصل مع الأفراد المدرجة معلوماتهم في المعلومات.
5. You will use the information only for the research purposes described above.	٥. سيتم استخدام المعلومات فقط للأغراض البحثية الموضحة أعلاه.
6. Recipient-investigator agrees to take the appropriate safeguards to prevent unauthorized use or disclosure of the information.	٦. يوافق الباحث المتلقي على اتخاذ الضمانات المناسبة للحيلولة دون الاستخدام أو الكشف غير المصرح به للمعلومات.
7. Upon learning of any use or disclosure of information not provided for by this agreement, such unauthorized use or disclosure will be reported to the holder within 15 days of becoming aware of such use a disclosure.	٧. عند العلم بأي استخدام أو كشف للمعلومات غير منصوص عليه في هذه الاتفاقية، يتم الإبلاغ عن ذلك الاستخدام أو الكشف غير المصرح للمالك خلال ١٥ يوما من علمه بذلك الاستخدام أو الكشف.

To be filled by one language only

8. Any individuals or organizations, including subcontractors, to whom the information is provided, must first agree to the same restrictions and conditions set forth in this agreement.	٨. يجب على أي أفراد أو مؤسسات، بما في ذلك المقاولين من الباطن، الذين يتم تقديم المعلومات لهم، الموافقة أولاً على نفس القيود والشروط المنصوص عليها في هذه الاتفاقية.
10. Recipient and Provider understand and agree that individuals who are the subject of PHI are not intended to be third party beneficiaries of this agreement.	٩. يفهم ويوافق المتلقي والمزود بأن الأفراد موضوع المعلومات الصحية المحمية لا يقصد بهم أن يكونوا أطرافاً أخرى مستفيدة في هذه الاتفاقية.
11. Each party agrees that it will be responsible for its own acts and the results thereof to the extent authorized by law and shall not be responsible for the acts of the other party or the results thereof.	١٠. يوافق كل طرف على أنه سيكون مسؤولاً عن تصرفاته والنتائج المترتبة عليها إلى الحد المصرح به قانوناً وأنه لن يكون مسؤولاً عن تصرفات الطرف الآخر أو النتائج المترتبة عليها.
Term and Termination: 1. The term of this agreement shall be effective as the study approved, and shall remain in effect until the research proposed is completed, after which you agree to destroy or return safely and promptly to Provider all information.	المدة والإنهاء: ١. يبدأ سريان مفعول هذه الاتفاقية اعتباراً من تاريخ اخذ الموافقة الأخلاقية وتبقى سارية المفعول وناظرة حتى يتم إكمال البحث المقترح، و بعد ذلك يوافق الطرف على إتلاف أو إعادة كافة المعلومات للمزود بشكل سليم و على الفور.
2. Upon the Provider's knowledge of a material breach of this agreement by the Data Recipient, the Provider shall provide an opportunity for Data Recipient to cure the breach or end the violation. If efforts to cure the breach or end the violation are not successful within the 15 days period specified by the Provider, the Provider shall discontinue disclosure of PHI to the Data Recipient.	٢. عند علم المزود بأي مخالفة مادية لهذه الاتفاقية من قبل متلقي البيانات، يمنح المزود لمتلقي البيانات الفرصة لتصحيح المخالفة أو إنهاء الإنتهاك. و إذا لم تنجح جهود تصحيح المخالفة أو إنهاء الإنتهاك خلال فترة الـ ١٥ يوما التي يحددها المزود، يتوقف المزود عن الكشف عن المعلومات الصحية المحمية لمتلقي البيانات.

To be filled by one language only

3. The Data Recipient agrees to destroy study data according to the following specifications:	٣. يوافق متلقي البيانات على إتلاف بيانات الدراسة وفقا للمواصفات التالية:
• [Insert any specifications regarding the destruction of data pieces here].	• [يتم إدراج أي مواصفات تتعلق بإتلاف البيانات].
• Unless otherwise required by Saudi law, the Data Recipient will destroy Data Set(s) not less than ٥ year(s) of the study end date. The Data Recipient will notify the Holder with written confirmation of the destruction via email or other memo.	• ما لم يُنص على خلاف ذلك بالقانون السعودي، سيقوم متلقي البيانات بتدمير مجموعة (مجموعات) البيانات في مدة لا تقل عن ٥ (أعوام) من تاريخ إنتهاء الدراسة. و سيقوم متلقي البيانات بإبلاغ المزود بتأكيد خطي بالإتلاف عبر البريد الإلكتروني أو أي مذكرة أخرى.
• When printed material containing confidential information is discarded, it is loaded, transported and stored under supervision (using a chain of custody control process) until the material can be recycled into paper pulp.	• عندما يتم التخلص من المواد المطبوعة التي تحتوي على معلومات سرية، فيتم تحميلها، و نقلها و تخزينها تحت إشراف (باستخدام سلسلة من عملية مراقبة العهدة) إلى أن يتم إعادة تدوير المواد إلى لب ورق.
4. This agreement shall not be amended, altered, or changed except by written documentation agreed to and executed by both parties.	٤. لا يتم تعديل هذه الإتفاقية، أو تغييرها، أو تبديلها إلا بوثيقة خطية تتم الموافقة عليها و توقيعها من قبل الطرفين.
Ownership of Data: All data shall remain exclusively owned by the disclosing party and its use by other parties shall be governed by the following:	ملكية البيانات: تبقى كافة البيانات ملكا خالصا و حصريا للطرف المصرح و ينظم إستخدامها من قبل الطرف الآخر بالتالي:

To be filled by one language only

1. Information may be disclosed to study sites provided solely as necessary to perform obligations in connection with the research project for which such data are provided under this agreement. Such uses and disclosures shall also be in compliance with applicable laws and regulations, protocols, consent forms, if any, IRB approvals.
 2. No party shall use the names, logos, symbols or trademarks of another party or the other party's affiliates or related entities, without the express written permission of the other party, except that parties may identify each other in annual reports and like documents that generally describe or refer to the research project.
 3. The Provider retains any and all tangible and intangible rights to the information.
 - 4- Recipient abides to submit a final draft of the research including the results (or published paper) to the provider or uploading it to the research data base at MOH electronic site.
 5. The Products created by the Data Recipient shall be owned by the Data Recipient. Products jointly created by both the Data Recipient and the Holder shall be jointly owned.
 6. The Data Recipient agrees not to use or disclose the Data Set for any purpose or secondary use other than the reporting purposes outlined above or as required by Saudi law.
١. يجوز الكشف عن المعلومات لمواقع الدراسة المنصوص عليها حصراً على أنها ضرورية لأداء الإلتزامات المتصلة بالمشروع البحثي و الذي يتم تقديم هذه البيانات له بموجب هذه الإتفاقية. و تكون عمليات الإستخدام و الكشف هذه متفقة مع القوانين و الأنظمة و المطبقة، و البروتوكولات، و نماذج الموافقة، إن وجدت، و موافقات لجنة أخلاقيات البحوث.
 ٢. لا يقوم أي طرف بإستخدام الأسماء، و الشعارات، و الرموز و العلامات التجارية الخاصة بالطرف الآخر أو التابعين للطرف الآخر أو الكيانات ذات العلاقة دون الإذن الخطي الصريح من الطرف الآخر، بإستثناء أنه يجوز للأطراف تمييز بعضهم البعض في التقارير السنوية و الوثائق المماثلة التي تصف بشكل عام المشروع البحثي أو تشير إليه.
 ٣. يحتفظ المزود بأي من وكافة الحقوق المادية و غير المادية للمعلومات.
 ٤. يلتزم الطرف المتلقي بتزويد الطرف المزود بنسخة نهائية من البحث أو الدراسة شاملة النتائج (أو نسخة من البحث منشورة بإحدى الدوريات العلمية) أو رفعها بقاعدة البيانات البحثية بموقع وزارة الصحة.
 ٥. تكون المنتجات التي يتم إنشاؤها من قبل متلقي البيانات ملكاً لمتلقي البيانات. و بالنسبة للمنتجات التي يتم إنشاؤها بشكل مشترك من قبل كل من من متلقي البيانات و مالكيها ، فتبقى مملوكة بشكل مشترك.
 ٦. يوافق متلقي البيانات على عدم إستخدام مجموعة البيانات أو الكشف عنها لأي غرض أو إستخدام ثانوي بخلاف أغراض الإبلاغ المحددة أعلاه أو على النحو المطلوب بالقانون السعودي.

To be filled by one language only

7. The Data Recipient agrees to report to the Provider any use or disclosure of the Data Set not provided for by this agreement, of which it becomes aware, including without limitation, any disclosure of PHI to an unauthorized subcontractor, within ten (10) business days of its discovery.

٧. يوافق متلقي البيانات على إبلاغ المزود بأي استخدام أو كشف لمجموعة البيانات غير منصوص عليه بهذه الاتفاقية، قد يطلع عليه، بما في ذلك على سبيل المثال لا الحصر، أي كشف للمعلومات الصحية المحمية لأي مقاول من الباطن غير مصرح له، خلال عشرة (١٠) أيام عمل من إكتشافه لذلك.

8. The Data Recipient agrees not to identify the information contained in the Data Set, contact the individual, or publish or disclose publically any PHI.

٨. يوافق متلقي البيانات على عدم تحديد المعلومات المدرجة في مجموعة البيانات، أو التواصل مع الفرد، أو نشر أي معلومات صحية محمية أو الكشف عنها للعامة.

Security

The Data Recipient agrees to use appropriate administrative, physical, and technical safeguards to prevent use or disclosure of the Data Set other than as provided for by this agreement.

الأمن

يوافق متلقي البيانات على استخدام الضمانات الإدارية، و المادية و الفنية المناسبة للحيلولة دون استخدام مجموعة البيانات أو الكشف عنها بخلاف ما هو منصوص عليه في هذه الاتفاقية.

- All data will be stored in secure storage areas or on digital media that has been password protected, encrypted, or otherwise secured for storage and transfer.]

- [سيتم تخزين كافة البيانات في مناطق تخزين آمنة أو على وسائل إلكترونية تتم حمايتها بكلمة مرور، أو تشفيرها أو بخلاف ذلك تأمينها للتخزين و النقل].

To be filled by one language only

Publications and Presentations

The Data Recipient should submit an application for publication to the General Directorate for Research and Studies –MOH prior to publication in local or international journals.

النشر والمطبوعات

لا يحق للطرف المتلقي بنشر نتائج الدراسة في المجلات العلمية المحلية أو العالمية إلا بعد الحصول على موافقة خطية على النشر من الإدارة العامة للبحوث والدراسات بوزارة الصحة .

The parties signing below agree to the conditions enumerated above.

Authorized representative of the Provider or the facility releasing the data set:

Data Provider in MOH Facilities

Signature of authorized representative of the provider or the facility releasing the data set

يوافق الأطراف الموقعون أدناه على الشروط التي تم تعدادها أعلاه.

الممثل المخول من قبل المزود أو المنشأة المصدرة لمجموعة البيانات:

هذا الجزء خاص بمزود البيانات بمنشآت وزارة الصحة

توقيع الممثل المخول من قبل المزود أو المنشأة المصدرة لمجموعة البيانات

Name of authorized representative:.....

Title of authorized representative

Recipient:.....

Name of facility:.....

Address:.....

Phone:.....

e-mail:.....

Fax:.....

Date:

إسم الممثل المخول:

منصب الممثل المخول:

المتلقي:

إسم المنشأة:

العنوان:

رقم الهاتف:

البريد الإلكتروني:

الفاكس:

التاريخ:

To be filled by one language only

To be fulfilled by Principle Investigator

Recipient Name: ...Haytham Abdulwhab
Sheerah
Recipient Institution:MoH
Address:Digital city
Phone:0550696515
e-mail:Hasheerah@moh.gov.sa
Fax:
Date:7/5/2026.

.....
Signature of Recipient

يملأ بمعرفة الباحث الرئيس:

.....إسم المتلقي:
.....مؤسسة المتلقي:
.....العنوان:
.....رقم الهاتف:
.....البريد الإلكتروني:
.....الفاكس:
.....التاريخ:

.....
توقيع المتلقي