Translating Scientific Evidence Into Practice Using Digital Medicine and Electronic Patient Reported Outcomes

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INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI

Sponsor / Study Title:	**Rx. Health / "Translating Scientific Evidence into Practice Using Digital Medicine and Electronic Patient Reported Outcomes"**
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Summary of this Research Study

In medicine there are many unanswered questions. A research study is when scientists try to answer a question about something that we don't know enough about. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. It is completely up to you whether or not you take part or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled. You can also change your mind at any time and it will not affect your ability to get medical care within the Mount Sinai Health System.

The Investigator or the sponsor can stop your participation at any time without your consent for the following reasons:

- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

The purpose of this research study is to help patients manage chronic illnesses like Inflammatory Bowel Disease (IBD). We believe that the use of digital medicine (text messages, telemedicine, apps, etc.) can help people manage their health. However, we want to evaluate and better understand how to best implement these digital tools in the mainstream clinical practice to be a part of the standard care given to patients managing the IBD. In this study, we will be creating an investigational Digital Transformation Network (DTN), which will provide subjects with various digital medicine study tools.

If you choose to participate, you will be asked to first complete a series of electronic assessments. You will then enter the investigational DTN and receive digital study tools in a timely manner based on the responses you provided for the different electronic assessment tools. The study team will evaluate how these digital medicine study tools play a role in managing your IBD status and the ease of using these types of study tools.

If you choose to participate, you will be asked to:

- Complete an initial set of electronic assessment tools
- Continue interacting with various digital study tools related to your IBD care
- There are no costs associated with participation
- There is compensation for participating in this study.

The study will last 4 years and about 1500 subjects will participate in this study.

The main risks to you if you choose to participate are minimal. The procedures to be implemented in this study are noninvasive and pose minimal risk to study subjects. Data collection sessions will be purposefully restricted to minimize fatigue to the subjects.

You may also benefit from participation in this research. A potential benefit of this study is that it may enhance patient provider communication and improve patient outcomes. Although this study may not directly benefit all those who participate, it may provide important information to develop interventions to improve outcomes of patients with IBD.

If you are interested in learning more about this study, please continue to read below.

USE OF YOUR DATA AND/OR SPECIMENS:

In the future, your identifiable information may be removed from the private information and/or samples that are collected as part of this research. After this removal, the information and/or samples could be used for future research studies or shared with other research teams for future research studies. The private information and/or samples collected as part of this research will never be used or shared for future research unrelated to ***IBD*** or ***digital medicine tools / Digital Transformation Network (DTN),*** even if the identifiable information is removed. You will not be informed of the details of specific research that is done with your medical information and biospecimens. That means that a research project might be done that you would not consent to if provided with the details of that research project.

No personally-identifiable information from the study will be released to any unauthorized third party without prior written approval of the sponsor/funding agency. All study subject research data will be secured and password protected. All study databases will be de-identified and archived at the AppLab Data Coordinating Center, Icanh School of Medicine at Mount Sinai. After the study is completed, future related and/ or not related research use of this data by other researchers including those outside of the study. The data will remain in a password encrypted secured database online (for example, Microsoft Azure Cloud) where it will be archived and stored. This cloud database will be maintained and provisioned by Rx. Health and AppLab.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS

Risk of loss of private information; this risk always exists, but, there are procedures in place to minimize the risk.

As part of this research, you may be required to use one or more of the following: a phone or web app/site, an electronic study diary (eDiary), or a device that tracks information about you. While using these, information about you may be collected and shared with the researchers or people outside of the study. This data might include personal health information, location, call logs, text message history, web browsing history, or social media use. A complete description of the data collection and sharing for an app, eDiary, or device can commonly be found in the Terms of Use, End User License Agreement, or Privacy Policy associated with the device. If you would like to read these documents, request a copy or instructions about how to access this information from the study doctor.

While the Terms of Use, End User License Agreement, or Privacy Policy may include statements limiting your rights if you are harmed as a result of your use of the app/site, eDiary, or device in this study, you do not release the study doctor, sponsor, institution, or agents for responsibilities from mistakes. You also do not waive any of your rights as a research participant."

There may be other risks that are unknown.

ALTERNATIVES TO PARTICIPATION

This research study is for research purposes only. The only alternative is to not participate in this study.

NEW FINDINGS

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

COMPENSATION FOR PARTICIPATION

You will be paid up to a total of $40.00 in gift cards if you complete this study. You will be paid for your enrollment will be compensated at the completion of the first assessment and final assessment. according to the following schedule:

- $20.00 for enrollment and first (baseline) survey assessment
- $20.00 for final assessment

In addition, if you are among the top most engaged patients every month, you will be eligible to receive $10 gift cards (not to exceed more than $100 total for the entire duration of the study)

If you do not complete the study, for any reason, you will be paid for each study survey assessment you do complete. Gift cards will be sent electronically following each completed survey assessment.

If you have any questions regarding your compensation for participation, please contact the study staff.

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS). Generally this reporting would take place if you receive payments that equal $600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

DISCLOSURE OF FINANCIAL INTERESTS

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

One or more researchers has a financial interest that could be affected by the outcome of this research study.

Dr. Ashish Atreja (Principal Investigator at UC Davis and Adjunct Associate Professor of Gastroenterology at Mount Sinai), Mr. Sarthak Kakkar (Senior Software Developer for the Mount Sinai Mobile App Studio and software architect in this study) are named inventors of the HealthPromise App being evaluated in this study. The HealthPromise App is filed through the Icahn School of Medicine at Mount Sinai and licensed to the private company, Rx.Health. In addition, Mount Sinai holds equity in Rx.Health.

Dr. Atreja is a co-founder of, Chairman of the Board of Directors for, and holds equity in Rx.Health.

Mr. Kakkar is the Chief Technical Advisor for and holds equity in Rx.Health.

Mr. Shashank Garg (Lead Data Scientist for the Mount Sinai Mobile App Studio and data scientist in this study) is the Chief Data Science Advisor for and holds equity in Rx.Health.

IN CASE OF INJURY DURING THIS RESEARCH STUDY

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the study Investigator.

ENDING PARTICIPATION IN THE RESEARCH STUDY

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or

complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00046503.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

What protected health information is collected and used in this study, and might also be disclosed (shared) with others?

As part of this research project, the research team at the hospital(s) involved in the research will collect your telephone, email, dates related to hospitalizations and medical record number.

The researchers will also get information from your medical record in the Mount Sinai Health System.

During the study the researchers will gather information by:

- Medical and laboratory records (includes current and past medications or therapies, illnesses, conditions or symptoms, laboratory records, emergency room visits, hospitalization, endoscopy [procedure to look inside the body] or imaging reports, family medical history, allergies, etc.)
- Completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.

Why is your protected health information being used?

Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

The Principal Investigator may also use and share the results of these tests and procedures to treat you in collaboration with others in the Mount Sinai Health System.

The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or

accreditation requirements. For example, the School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your information. If you receive any payments for taking part in this study, the study site may need your name, address, social security number, payment amount, and related information for tax reporting purposes. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside the study site, might receive your protected health information?

As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- Other collaborating research center(s) and their associated research/clinical staff who are working with the investigators on this project: Cleveland Clinic and Northwestern. This is a multi site trial and we will be evaluating the use of this DTN across the IBD Centers at all three sites including Mount Sinai.
- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.
- The United States Department of Health and Human Services and the Office of Human Research Protection.
- AppLab at Icahn School of Medicine at Mount Sinai, our Data Coordinating Center.
- Advarra IRB, our central IRB of record.
- Rx.Health, our technology partner.

In almost all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier.. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. It is possible that a sponsor or their representatives, a data coordinating office, or a contract research organization, will come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. They are authorized to remove information with identifiers if necessary to complete their task. By signing and dating this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose your protected health information?

Your authorization for use of your protected health information for this specific study does not expire. In California and any other state that requires an expiration date, the Authorization will expire 50 years after you sign the authorization document.

Will you be able to access your records?

During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?

NO! If you decide not to let us obtain, use or share your health information you should not sign and date this form, and you will not be allowed to volunteer in the research study. If you do not sign and date, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may

receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

Certificate of Confidentiality:

To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This Certificate does not mean that the Department of Health and Human Services approves of this research. Rather, this is intended to ensure that your identity as a participant in this research study will not have to be disclosed as a result from a subpoena, for the purpose of identifying you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above.

The research staff will not share any of your research information and/or biospecimens with anyone who is not a member of the research team, including any family members or friends, other than to those identified above. However, you should know that if we learn that you or someone else is threatened with serious harm, such as a child or an elderly person being abused, the investigators may notify the appropriate authorities if necessary to protect you or others. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. This means that you and your family must also actively protect your own privacy. If an insurer or employer learns about your research participation, and you agree that they can have your research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

Signature Block for Capable Adult

Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

Signature of subject	Date
Printed name of subject	Time

Person Explaining Study and Obtaining Consent

I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study and this form. I have been available to answer any questions that the subject has about this study and this form.

Signature of person obtaining consent	Date
Printed name of person obtaining consent	Time