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STUDY INFORMATION:

Study Title: IBD Forecast

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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. 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 purpose of this research study is to assess whether markers measured from wearable devices, such as the Apple Watch or Fitbit, can identify the development and predict the development of a flare of ulcerative colitis.

If you choose to participate, you will be asked to download the study app to your smartphone and wear your wearable device for the duration of the study. In addition, you will be asked to complete surveys throughout the study, and then at the time of worsening symptoms. There is no cost associated with participating in the study. To participate in this study you must own a smartphone and a wearable device. Some participants at Mount Sinai will be provided with an Apple Watch to use for the duration of the study, if they have an iPhone.

The main risks to you if you choose to participate is loss of confidentiality. Participating in this research will not benefit you. If you are interested in learning more about this study, please continue to read below.

PARTICIPATION IN THIS RESEARCH STUDY:

Feel free to ask all the questions you want before you make a decision about whether or not to participate. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

You may qualify to take part in this research study because you have ulcerative colitis or Crohn's disease. If you have an iPhone and you would like to share your electronic health record data as part of the study, you can choose to do this. This is optional and not required to participate.

Funds for conducting this research are provided by the Mount Sinai Hospital and the National Institute of Health.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your participation in this research study is ongoing. You can participate in the study for as long as you would like, though if possible, should last up to 12 months.. The total number of people expected to take part in this research study is several thousand people.

DESCRIPTION OF WHAT'S INVOLVED:

Research will take place remotely with no in-person visits required. If you agree to participate in this research study, the following information describes what may be involved.

- You will download a study App (eHive App) on your phone in which you will answer survey questions at least every day about how you are feeling, with slightly more questions being asked every 2 weeks (the surveys should take several seconds to complete each day) and a few minutes every 2 weeks.
- You will wear your wearable device for the duration of the study.
- If you have an iPhone and link your electronic health records to your smart phone, you can choose to share these records with the researchers. This is optional and not required to participate.

USE OF YOUR DATA AND/OR SPECIMENS:

In the future, your identifiable information may be removed from the private information that is collected as part of this research. After this removal, the information could be used for future research studies or shared with other research teams for future research studies. You will not be informed of the details of specific research that is done with your medical information. That means that a research project might be done that you would not consent to if provided with the details of that research project.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for the following things:

- Downloading the custom smartphone App.
- Answering survey questions.
- Wearing your wearable device (ie. Apple Watch, Fitbit, Our ring etc)

If you are provided an Apple Watch as part of your participation in the study at Mount Sinai, you are responsible for returning it at the end of the study, if you withdraw from the study, or if you are withdrawn from the study. You are not responsible for lost or damaged Apple Watches.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to take part in this research study you will not receive compensation. There may be cellular data fees associated with the use of your wearable device and the study app which you will be responsible for.

POSSIBLE BENEFITS:

You are not expected to get any benefit from taking part in this research study. Others may not benefit either. However, if the signatures generated from wearable devices are able to identify and predict disease flares then in the future others may benefit from improved disease control.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

There are potentially risks and discomforts associated with participation in this study:

1. Risk of loss of private or health information; this risk always exists, but there are procedures in place to minimize the risk.
2. If you are being provided with an Apple Watch you should understand that you are agreeing to data sharing and privacy agreements with Apple. You will read through and agree to this as part of the setup of this device. This agreement is the same agreement you would enter into with Apple as would take place if you bought the device yourself. If you already have your own device you have already entered into a privacy and data use agreement with the device company. You should review this.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you.

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 Principal 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.

If you decide to stop being in the research study, please contact the Principal Investigator or the research staff. You will be required to return the Apple Watch if you were provided one as part of your participation at Mount Sinai.

If you decide you don't want your data to be used for research anymore, you can contact the researcher and ask to have your data removed from future use. If any data have already been shared without your identity, it won't be possible to retrieve them because no one will know who you are. Data that have already been used or collected will not be affected by your decision. Any data that are still linked to your identity by a code the researcher has will be withdrawn so that no future sharing of your data will take place. Data that has already been collected for this study will be analyzed and will not be removed if you decide to withdraw.

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If data have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT INFORMATION:

If you have any questions, concerns, or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Principal Investigator at the email address ibdforecast@mssm.edu or phone number 212-241-4500.

If you experience an emergency during your participation in this research, contact 212-241-4500.

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

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.

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 shared with others?

As part of this research project, the research team at the hospital(s) involved in the research will collect your name, date of birth, dates related to your medical history including diagnoses, admissions, discharges, procedures, imaging and potential surgeries.

The researchers will also get information from your medical record in the hospital and clinic.

During the study the researchers will gather information by:

- Your completion of questionnaires explained in the description section of this consent.
- Your using a wearable device.

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 Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. I*f the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.*

Who, outside Mount Sinai, 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.)

- The United States Department of Health and Human Services and the Office of Human Research Protection.
- The National Institute of Health.

In all disclosures outside of Mount Sinai, you will not be identified by name or using other direct personal identifier unless disclosure of the direct identifier is required by law. 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 law requires it, or rarely if the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may 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. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing 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.

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 this form, and you will not be allowed to volunteer in the research study. If you do not sign, 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.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

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.

ADULT PARTICIPANT:

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	Printed Name of Subject	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

_____	_____	_____	_____
Signature of consent delegate	Printed Name of consent delegate	Date	Time