UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	Using Digital Data to Predict CHD
Principal Investigator/ Emergency Contact	Raina Merchant, MD 3400 Spruce St, Philadelphia, PA 19104 215-746-8681 Raina.Merchant@pennmedicine.upenn.edu
Study Contact	Megan Bradley (215) 615-2806 Dydhearthealth@Pennmedicine.upenn.edu

Research Study Summary for Potential Subjects
You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted to learn more about how digital data (social media, online search, mobile media) are associated with coronary heart disease (CHD) and related risk factors, and health care utilization.

If you agree to join the study, you will be asked to complete the following research procedures:
- Share data from any or all of the following digital data sources: social media data (Facebook, Instagram, and/or Twitter), Google search history, or step tracking data
- Complete a survey that asks about diet behavior, physical activity and physical fitness, smoking and tobacco use, and digital data use
- Share information about your insurance provider and share information about your medical history

Your participation could last between 15-60 minutes or up to one week or more for study enrollment, and your data will be stored during the duration of the study. If you decide to participate in the optional focus group part of the study, follow-up is necessary.

There is no direct benefit to your participation. However, your participation could help us understand how digital data and health record information can be used to predict heart health and health care use. This study has minimal risks, but the most common risks of participation include the disclosure of potentially sensitive information. Another potential risk in permitting your data to be stored in our research database is the potential risk of loss of confidentiality.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Why am I being asked to volunteer?
You are being invited to participate in a research study because you are between the ages of 40 and 74 and you use and post on digital data types that we are studying.

If you decide to participate, you will be asked to sign this form. Your doctor may be an investigator in this research study. You do not have to participate in any research study offered by your doctor. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. You may also decide to discuss the study with your family, friends, or family doctor. Being in a research study is different from being a patient. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study.

What is the purpose of the study?
The purpose of the study is to learn more about how digital data (social media, online search, steps) can give doctors a better understanding of cardiovascular risk by providing insights about an individuals' daily habits.

Why was I asked to participate in the study?
You are being asked to join this study because you are between the ages of 40 and 74, English is your primary language, use digital data types that we are studying.

How long will I be in the study?
The study will take place over a period of 5 years, but your participation will end after you complete all the enrollment steps. The study enrollment will last approximately 15-60 minutes during one session. The enrollment process could take up to a week or more depending on completion of all enrollment steps. You will complete all enrollment steps, completing surveys and downloading digital data, online through email, over the phone, or via text messaging on your own device or a study team members' device remotely or in-person on a secure study laptop with a study team member.

What will I be asked to do?
- You will first complete a survey that takes approximately 10-15 minutes to complete. The survey will ask questions about your diet behavior and nutrition, physical activity and fitness, smoking and tobacco use, digital data use, and basic demographic information.
- After completing the survey, you will be asked to share whatever digital data sources you have decided to donate.
- If you decide to share Facebook or Instagram, you will then be directed to the study app that was designed for the purposes of this study.
    - If sharing Facebook, you will be asked to sign in to your Facebook account using our secure application. When you sign into your account, you grant access to a Facebook application called Penn Image Station that was designed for the

purposes of this study. The Penn Image Station application will gather information from your Facebook public profile, status updates, personal description, and "likes". The application will not affect your usual use of Facebook nor will it post to your page. Penn Image Station will collect historical Facebook data (for example, when you created your account) and for the duration of the study, 60 days or until you no longer wish to participate. Data extracted from Facebook may include bio (about me section) text and image posts, time of posting, pages liked, and image captions. The application will not affect your usual use of Facebook nor will it post to your page.

- OF NOTE: If there are technical difficulties with our application pulling Facebook data, we will re-contact you via email, text message or telephone call (your preference) at a later point once the application is running.

- If you share your Instagram posts, you will be asked to sign into your Instagram account on our secure application. When you sign into your account, you grant access to an Instagram application called Penn Social Mediome. You will read a brief statement, either agree or disagree with the statement, and then log on to your Instagram account. Your Instagram posts and photos will be extracted by the Penn Social Mediome application. Penn Social Mediome will collect historical Instagram data and for the duration of the study, 60 days or until you no longer wish to participate. You may notify us in writing that you no longer wish to participate in the study. Data from Instagram will include image posts, time of posting, and image captions. Instagram data will only include your past data.
- OF NOTE: If there are technical issues with our secure data collection application, we may ask you to share you Instagram username with us so we can extract the data manually.

- If you share your Twitter posts, you will provide the study team with your Twitter username or "handle." Data from Twitter will include: handle, number of followers/following, tweets, geography, time/date, profile. Your Twitter data will be extracted and de-identified by researchers. Twitter data will be collected for the duration of the study (5 years) or until you no longer wish to participate
- If you share your Reddit posts, you will provide your Reddit username/handle with the study team. Your Reddit posts comments to posts, their votes "up" or "down" to posts, and the sub-reddits (forums) that they've joined will be extracted and de-identified by researchers. Reddit data will be collected for the duration of the study (5 years) or until you no longer wish to participate
- If you decide to share your Google takeout (online searches and tracking information) data with us, you will receive directions either in-person or via email from one of our team members. You will receive a document explaining how to download your data through Google take-out. Please note, the study will not affect your Google use. Your search history, YouTube histories, and other activities will be only retrospective. Data extracted from Google takeout includes the search terms, website visited with the URL, YouTube search history, date, and Google fit that includes activities and daily aggregations.

- If you decide to share your daily step count with us. This can be done different ways depending on what step-tracking platform you have an account on. The research assistant will guide you through this process.
- As part of the study, we will also collect health information from your electronic medical record to be used for research purposes. Data from the medical record will include but not be limited to: demographic information (e.g. date of birth, insurance type, height, weight), medical diagnoses (e.g. history of hypertension, diabetes, cancer, depression), mode of arrival to the hospital (e.g. ambulance or other), labs (e.g. cholesterol, lipid panel, HbA1c), vital signs, mediations, procedures, dates and diagnoses from outpatient visits, emergency room visits, and hospitalizations. Your authorization for your personal health information for this specific study will last the duration of the study. You may notify us in writing that you no longer wish to participate in the study. If you are not a patient within the University of Pennsylvania Health System, also known as Penn Medicine, we will ask you to upload screenshots and/or self-report information from their office visit summaries, labs, vital signs, ED and inpatient hospital admission information since we will not have access to your electronic medical record.
- We are asking permission to collect information on your Medicare and/or insurance coverage and on your cost of care. This information will be collected directly from your insurance and medical record. Information will be collected for up to 5 years. If you agree to participate in the study, the following information will be collected in regards to your health insurance: type of health insurance, health insurance provider, health insurance policy, health insurance group number, and the policy holder's name and date of birth will be collected. OF NOTE: If we aren't able to obtain your health insurance policy number, we will either call you to obtain your policy number or you can fill out a secure survey through REDcap that will allow you to input your policy number.
- If you decide to participate in the optional additional survey part of the study, we will ask you questions related to your health status perceptions, perceptions of social media use, and engagement on social media.
- If you decide to participate in the optional focus group part of the study, we will ask you to virtually join a group of 15-20 patients via conference video or phone call. You will receive a date and time with video conference login information to join the focus group session. The focus group is a one-time occurrence. The focus group will be recorded. All recordings will be transcribed and the original recording will be erased to protect your identity.

For this study we may need to contact you via email to provide you information about scheduling or send you information about your participation in the study. Email communications are often not secure and may be seen by others as a result. By signing below, you accept this risk. If you wish for us to use a different means to communicate with you during the course of this trial please discuss this with the research team and alternative methods can be arranged.

Additionally, we may be reaching out via text messaging to send you information about your participation in the study. Since texting technology was not built for secure communications, the privacy of information sent through text messaging cannot be guaranteed. Texting should not be your primary source of communication for your healthcare needs. You and your provider can use text messaging as a convenient way to stay in touch. However, we cannot promise that your

text message will be read and responded to within a certain time. By signing below, you accept this risk. Text messaging should never be used for urgent issues or emergencies and you waive any and all claims that may arise against the University of Pennsylvania Health System, employees, contractors, interns, and students resulting from the use or misuse of text messaging. Your provider will make her/his best efforts to use the minimum information necessary in the text messages to reduce the chance of someone else seeing details about you and your health. You can also help reduce privacy risks by putting a screen lock on your device and not sharing your "PIN" or other password to unlock it. I understand that message and data rates may apply. If you wish for us to use a different means to communicate with you during the course of this trial please discuss this with the research team and alternative methods can be arranged.

If you are unable to complete the enrollment process during a virtual or in-person encounter with a study team member, due to not having your social media login credentials at hand or encountering an interruption during your enrollment, the study team will send you up to 4 email reminders in month (using a pennmedicine.upenn.edu email address), with additional phone calls and text messages, if necessary, to share your digital data and social media information and/or complete the baseline survey remotely. To assist you in donating your digital data remotely, we will call or videoconference through Doximity, a HIPAA compliant platform to provide personalized instructions or to troubleshoot any concern or issue.

What are the risks?
The study has minimal risks. Possible risks include the disclosure of potentially sensitive information. Another potential risk in permitting your data to be stored in our research database is the potential risk of loss of confidentiality.

How will I benefit from the study?
There is no benefit to you. However, your participation could help us understand coronary heart disease (CHD) risk factors, which can benefit you indirectly. In the future, this may help other people to prevent CHD.

Will I receive the results of research testing?
Most tests done in research studies are only for research and have no clear meaning for participants. Research results will not be returned to you because the findings are exploratory and are not intended to change the standard of care.

What other choices do I have?
Your alternative to being in the study is to not be in the study.

What happens if I do not choose to join the research study?
You may choose to join the study or you may choose not to join the study. Your participation is voluntary.

There is no penalty if you choose not to join the research study. You will lose no benefits or advantages that are now coming to you, or would come to you in the future. Your primary care doctor will not be upset with your decision.

If you are currently receiving services and you choose not to volunteer in the research study, your services will continue.

When is the study over? Can I leave the study before it ends?
The study is expected to end after all participants have completed all visits and all the information has been collected. The study may be stopped without your consent for the following reasons:

- The PI feels it is best for your safety and/or health-you will be informed of the reasons why.
- You have not followed the study instructions
- The PI, the sponsor or the Institutional Review Board (IRB) at the University of Pennsylvania can stop the study anytime

You have the right to drop out of the research study at any time during your participation. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so. Withdrawal will not interfere with your future care.

You may remove your data by visiting https://donate.centerfordigitalhealth.upenn.edu/participant/login. First you will sign into your account and then select the 'Opt Out' button under Actions in the Manage Donated Data. This action removes your data from our database. However, any information gathered before you un-install the application may still be used for analysis.

If you no longer wish to share your social media or health record information with the study, please contact the research team, at Dydhearthealth@Pennmedicine.upenn.edu to ensure you are removed from the study.

To remove your google takeout file and step tracking data, please email Dydhearthealth@Pennmedicine.upenn.edu to permanently delete your file.

If you experience medical or emotional changes related to your involvement in the study, please contact the investigator, Raina Merchant, MD, 3400 Spruce St, Philadelphia, PA 19104, 215-746-8681, raina.merchant@pennmedicine.upenn.edu.

If you no longer wish to be in the research study, please send an email or written notice to the research team, Dydhearthealth@Pennmedicine.upenn.edu

How will my personal information be protected during the study?
We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records.

An exception to confidentiality is if you report child or elder abuse or neglect, or if you report suicidal or homicidal ideation or intent to the research team. Any information about child or elder abuse or intent to harm yourself or others will be reported to the authorities, as required by law.

What may happen to my information collected on this study?
All identifiable data will be kept in a secure, password protected database behind a firewall.

Future Use of Data
Your information will be de-identified. De-identified means that all identifiers have been removed. The information could be stored and shared for future research in this de-identified fashion. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected on this study.

Electronic Medical Record and Release of Study Related Information

What is an Electronic Medical Record and/or a Clinical Trial Management System?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS), Penn Medicine, (outpatient or inpatient) and are participating in a Penn Medicine research study, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by Penn Medicine Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care at Penn Medicine and are participating in a Penn Medicine research study that uses Penn Medicine services, an EMR will be created for you for the purpose of maintaining any information produced from your participation in this research study. The creation of this EMR is a requirement of your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in clinical research will also be contained in the CTMS. If you have been a patient at Penn Medicine, information from your research participation will be added to your existing medical record.

What may be placed in the EMR?
Information related to your participation in the study (i.e. research enrollment status and contact outreach) will be placed in this EMR maintained by Penn Medicine.

Once placed in your EMR or in the CTMS, your information may be accessible to appropriate Penn Medicine workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by Penn Medicine to be appropriate to have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

UPHS also participates in automated information sharing through Health Information Exchanges (HIEs). HIEs securely share parts of your electronic health record, including research information, with other healthcare organizations involved in your care. This information is shared to improve the quality, safety and efficiency of your healthcare. To request that your health information not be shared through HIEs, please call 215-662-4484.

Will I, as a subject, have access to research related information within the EMR?

The 21st Century Cures Act requires healthcare institutions to allow patients increased access to their electronic medical record. As part of your participation in this research, you will have access to research related information within your EMR through Penn Medicine's patient portal – called MyPennMedicine (MPM).

Will I receive the results of research testing that may be relevant to my health?
Many of tests done in research studies are only for research and have no clear impact on your healthcare. Research results for this study will not be returned to you because they would not be relevant to your healthcare.

Will I have to pay for anything?
You will not have to pay to participate in this study.

Will I be paid for being in this study?
Patients who consent to complete the survey and share digital data will receive $50 in the form of a Greenphire clincard.

Additionally, if you opt to participate in the optional additional survey part of the study, you will receive an extra $10.

If you opt to participate in the optional focus group part of the study, you will receive an additional $50.

You will be entered into a raffle to win an iPad or equivalent device valued at approximately $500. Raffle winners will be chosen at random every 300 study participants enrolled and notified by email and/or phone

What information about me may be collected, used or shared with others?

Data extracted from Facebook may include bio (about me section) text and image posts, time of posting, pages liked, and image captions. Facebook can change privacy settings for applications at any time. Data from Twitter will include: handle, number of followers/following, tweets, geography, time/date, profile. Data extracted from Reddit will include: Reddit posts, comments to posts, your votes "up" or "down" to posts, and the sub-reddits (forums) that you've joined. Data from Instagram will include image posts, time of posting, and image captions. Data extracted from Google takeout includes the search terms, website visited with the URL, YouTube search history, date, and Google fit that includes activities and daily aggregations. If sharing Apple Health, data extracted will include: any data stored or gathered by the Health app and any associated devices, including any Medical ID data, the native iPhone step counter and distance tracker, any data from an Apple Watch, and any data gathered from any third party devices that are syncing to Health app, like a smart scale or blood pressure monitor. (http://osxdaily.com/2019/05/20/export-health-data-from-iphone/). If sharing Fitbit, data extracted will include: Activity, Exercise , Social, Sleep, Coach, Corporate, Logs, Profile, Direct messages, Female health, Sleep score, Friends, Subscriptions. If sharing Garmin, data extracted will include: steps per month for the past 12 months. If sharing S Health, data extracted will include: Daily step count for 34 days prior to export date (https://medium.com/@dimshik100/how-to-extract-your-personal-samsung-health-data-514bbe2331f7). Data extracted from MapMyFitness will include: Date Submitted, Workout Date, Activity Type, Calories Burned, Distance, Workout Time, Average Pace, Max Pace, Average Speed, Max Speed, Average Heart, Rate, Steps, Source, Link *we do not use this as it requires user login to view link results* Data from the medical record will include but not be limited to: demographic information (e.g. date of birth, insurance type, height, weight), medical diagnoses (e.g. history of hypertension, diabetes, cancer, depression), mode of arrival to the hospital (e.g. ambulance or other), labs (e.g. cholesterol, lipid panel, HbA1c), vital signs, medications, procedures, dates and diagnoses from outpatient visits, emergency room visits, hospitalizations. OF NOTE: If you are not a Penn Medicine patient, we will ask you to self-report, in a secure survey link, some of your medical record data as stated above. Health insurance data extracted will include: type of health insurance, health insurance provider, health insurance policy, health insurance group number, and the policy holders name and date of birth will be collected. OF NOTE: If we aren't able to obtain your health insurance policy number, we will either call you to obtain your policy number or you can fill out a secure survey through REDcap that will allow you to input your policy number.

Additional data extracted from our secure data collection platform: device IP addresses.

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right
- to evaluate and manage research functions.

Who may use and share information about me?
The following individuals may use or share your information for this research study:

- The Principal Investigator and the Investigator's study team
- Penn researchers and collaborating researchers at other academic institutions with approval from the study team and approval from the Institutional Review Board (IRB)
- Authorized members of the workforce of the UPHS and the School of Medicine and the University of Pennsylvania support offices who may need to access your information in the performance of their duties (for example for research oversight and monitoring)

Who, outside of the School of Medicine, might receive my information?

- No individual or organization

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the study. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

How long may the School of Medicine use or disclose my personal health information?
Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?
Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?
If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with Dr. Raina Merchant, (215) 746-8681. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the IRB at (215) 898 2614.

When you sign this form, you are agreeing to take part in this research study. If you have any questions or there is something you do not understand, please ask. You will receive a copy of this consent document.

Printed Name of Subject	Signature of Subject	Date
Printed Name of Witness	Signature of Witness	Date