

**THE MOUNT SINAI HEALTH SYSTEM  
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY  
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**  
Icahn School of Medicine at Mount Sinai,



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Study ID #: [GCO# 15-0063]

Form Version Date: 20 Nov 2015

**TITLE OF RESEARCH STUDY:**

Title: Asthma Mobile Health Application 2.0

**PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:**

Name: Yu-Feng Yvonne Chan, MD, PhD

Mailing Address: One Gustave L. Levy Place Box 1498, New York, NY 10029

Phone: 212-241-7526

Email: [asthmamobilehealth@mssm.edu](mailto:asthmamobilehealth@mssm.edu)

**WHAT IS A RESEARCH STUDY?**

A research study is when scientists try to answer a question about something that we don't know enough about. Participating may not help you or others. People volunteer to be in a research study. The decision about whether or not to take part is totally up to you. You can also agree to take part now and later change your mind. Whatever you decide is okay. It will not affect your ability to get medical care at Mount Sinai.

We have provided the contact information for the study's principal investigator above. If you have questions, please ask them. Feel free to ask all the questions you want before you decide. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

Basic information about this study will appear on the website <http://www.ClinicalTrials.gov>. There are a few reasons for this: the National Institutes of Health (NIH) encourages all researchers to post their research; some medical journals only accept articles if the research was posted on the website; and, for research studies the U.S. Food and Drug Administration (FDA) calls "applicable clinical trials" 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.

**PURPOSE OF THIS RESEARCH STUDY:**

The purpose of this study is to understand whether using an asthma mobile health application (AMHA or "asthma app") that you download onto your iPhone will help you to monitor your asthma. Although "apps" have been made to help people monitor certain health problems, medical researchers still do not know if they really work well or if they really can help improve your health. Unlike typical research studies, you will not need to come to a hospital clinic or a study center. Part of this research is to see

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if we can study the use of the “asthma app” completely by phone without visits to a study center or clinic. This first part of our research is to see if we can do this study by phone alone and to study how well the “asthma app” features work. Since you will only be using the app for a short period of time, we do not expect that the app will help you with your asthma. We will use information about how you use the app to make the app better. We hope to do another study later to see if the “asthma app” helps you with your asthma. If you join this study you will still be able to join the later study if you choose.

Funds for conducting this research are provided by the Icahn School of Medicine at Mount Sinai, with technology support from Apple, Sage Bionetworks, and LifeMap Solutions.

**LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE**

Your participation in this research study is expected to last for up to 2 years.

The number of people expected to take part in this research study is difficult to predict, but may be hundreds to tens of thousands of people.

**DESCRIPTION OF WHAT'S INVOLVED:**

This consent form tells you about the study to help you make your choice on whether or not to take part. Please take the time to read this carefully before making your choice. If you have any questions or anything is unclear please contact the study team. If you choose to participate in this study you will be asked to give permission by using your phone to sign the consent form electronically. You should not give consent or start any part of the study until your questions are answered and you are ready and able to begin. If you participate in this research study, you should also tell any health care providers who treat you that you are in the study.

Asthma is a very common condition and patients with asthma do best if they monitor or take care of their asthma. Some things patients can do to take care of their asthma is to use regular medication as prescribed by their doctor, keep track of their own symptoms, and stay away from certain situations that may make their asthma symptoms worse (we sometimes call these asthma triggers). The “asthma app” is designed to help you do all of these things. The “asthma app” will help you learn more about your asthma, take your asthma medicine as prescribed, and learn what triggers your asthma. The “asthma app” does not replace your usual medical care. Our goal is that you will be able to use

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the “asthma app” to learn more about asthma. This consent will give you more details below about what types of things you will be asked to do in this study. The information about your asthma that you give us through this “asthma app” will be joined together with information from other study participants so researchers can learn more about asthma and how an app can help monitor asthma. This information will be collected without your name or other ways for researchers to identify you or know it is you.

You may qualify to take part in this research study because you are 18 years of age or older, have asthma that has been diagnosed by a doctor, own an iPhone, do not currently smoke, are not currently pregnant, and do not have a lung disease other than asthma.

If you agree to participate in this research study, this is what you will be asked to do:

- ☐ Download a mobile app (free): You need to have the AMHA app on your iPhone in order to participate in this study
- ☐ View a brief video that describes the purpose of the study and introduces the study team
- ☐ Complete a screening questionnaire on the iPhone.
- ☐ **Register an account:** Once you give your consent, everyone who enrolls will complete an electronic registration process through the “asthma app.” Registration will include entering your email address and other general information about yourself.
- ☐ **Health Surveys:** We will ask you to answer questions about yourself, your asthma, what types of things trigger your asthma symptoms (that is, make them worse), what asthma medicines you take, other medical problems you may have, and your current health. You may choose to leave most questions you do not wish to answer blank. Of course, the more information you can give us, the more we may learn about how the app works. For certain features of the app to work, you will need to enter what asthma medicine you are taking so that the app can send you reminders about your medicine and keep track of any changes in your medicine. Those functions will not work unless you put in that information. When you fill out a daily or weekly survey, you will have to fill out most of the questions in order to complete the survey. Other

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than that, you may choose to not answer any question that makes you uncomfortable. You can opt not to have this function enabled.

- ☐ **Things you will be asked to do:** We will ask you to do certain things or tasks. Some things you will be asked to do every day (daily), other things every week (weekly), and some just at the beginning and end of the study.

We will randomly assign users to one of two different groups. Some may receive the full daily survey each day, while some will be asked a few questions and based on the answers, either proceed to the rest of the daily survey or be done for the day.

You may be asked to perform the following daily tasks using a tab in the app called “Activities (Task and Surveys)”. You can set a time preference in the app when you want to do these each day. If you don’t complete your task in the time frame you picked, you will get an automatic reminder on your iPhone.

1. If you are prescribed daily asthma medicine, you will be asked whether you took it in the past 24 hours
2. You will be asked about daytime and nighttime asthma symptoms in the past 24 hours
3. You will be asked if you took your quick relief medication or inhaler (such as albuterol, Proventil, or Ventolin) in the past 24 hours
4. You will be asked about your lung function as measured by a peak flow meter.

Once each week you will be asked several questions about whether you have had any major things happen in terms of your asthma, such as visits to your doctor, the emergency room, or the hospital, or if you were prescribed any new asthma medication.

At the beginning, 3 months, 6 months, and end of this study you may be asked to complete certain sets of questions about your asthma and overall health that we use in medical research, such as the EQ-5D, a survey that assesses how you feel about your overall health. The asthma app will prompt you to take these at the correct time.

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Your dashboard will have your information compiled in a way that you can show your doctor, if you choose. Though this is not a therapeutic tool, this dashboard may allow you to better keep track of information you would be reporting in your doctor's office.

You may have the choice to use the AMHA to receive information about pollen and air quality in your area. If this functionality is available to you and you choose to ~~de~~ use it, the AMHA will use the location of your phone to send you information about your general area. Location information will not be stored by the AMHA. It will only be used to provide you with your location-specific information. You are free to turn off the AMHA's access to your location and not receive the information, and directions for doing so may be found [details].

If you use a personal health device with your iPhone (such as Nike Fuel Band) and you use iOS8 or later (which includes Apple HealthKit), you can choose to include the data from the health device in the study. You will be asked if you would like our AMHA to get all, some, or none of the data, and you may change your preference from time to time during the study should you wish to do so. You can also choose not to do this and still participate in the study. Directions for doing this may be found [details].

The app will track your use of the app and features in the app. This way the researchers can find out more about how many participants drop out of the study, how often the app is typically used by participants, which specific features of the app are used, etc. This functionality is critical to the study, and these tracking devices are strictly necessary in order for you to use the app and to participate in the study.

Watching the introduction and consent video and giving electronic consent, registering for the study on your mobile phone, and answering the first set of questions should take about 20 minutes. The daily tasks and weekly questions that we ask you to do should take only a few minutes each time. At 6 months, and the end of the study we will ask you to repeat the surveys

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you did at the start. We think that your participation in this study will on average take about 15 minutes each week. Your study participation is expected to last four weeks.

We will send notices on your phone asking you to complete these tasks and surveys. You may choose to complete the surveys at your convenience, either then or later. You can use the notification settings on the iPhone for the asthma app to control or turn off the notifications if you don't want anyone else to become aware you are in the study (by hearing a notification tone, for example).

23andMe has partnered with Apple, Mount Sinai, and LifeMaps Solutions to build an app feature that allows you to easily transfer 23andMe genetic data to the asthma mobile health app study. You will be asked in this AMHA2.0 consent process if you would like our app to receive your 23andMe genetics data. You can choose not to do this and still participate in the asthma mobile health study. If you choose to participate in the Genetics Sub-study you must review and sign an additional consent document. If you consent and enroll in the Genetics Sub-study your encrypted genetic data will securely pass through your phone when being transferred from 23andMe computers to the asthma mobile health application computers maintained by Sage Bionetworks.

**What we will and will not do with your data?**

- **De-identification:** In order to protect your privacy, we will use a random code instead of your name on all your study data. This unique code cannot be used to directly re-identify you. Any survey or device data that identifies you (including name, birthdate, mobile phone number, etc.) will be removed before the data is transferred to researchers for study. You will be given an option to let researchers contact you for this study or for other research studies in the future. You can choose whether or not you will permit them to do so. This permission will not be connected to your study data.

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• **Use in research:** We will combine your study data including survey response and task measurements with those of other study participants. The combined data will be transferred to a computer program where all of the information can be used by researchers who have obtained permission to use the AMHA Study data. Your study data may be shared with other researchers outside of the Icahn School of Medicine at Mount Sinai and the Mount Sinai Hospital ("Mount Sinai") without survey or device information that can be linked to identify you, but we will not share your information with any advertisers or other commercial third parties. We will NOT access your personal contacts, other applications, phone use habits, text message content, personal photos, or websites visited. Data will be stored in a manner that maintains strict information technology procedures to safeguard participant information and to prevent improper access.

**YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:**

- ☐ If you decide to take part in this research study we ask you to try to complete as many of the tasks and surveys as you feel comfortable doing and to try as best as you can to do them in the scheduled time period
- ☐ If there is any major change in your asthma or your asthma medications, please make sure to record them when you get your weekly prompt. You may need to have the medicine in front of you to do this correctly
- ☐ You should not smoke or use other tobacco products
- ☐ Having good asthma control is very important if you are pregnant or planning to become pregnant. However since this is a research study, if you are pregnant or considering becoming pregnant during the study period, you should not participate in the study
- ☐ If you have any lung condition other than asthma, or if you have congestive heart failure, you should not participate in this study
- ☐ You should not participate in any other study while you are enrolled in this one. This is because we do not want a research intervention manipulating the results of this study.

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**COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:**

You will not be paid for participating in this research study. Being in this research study will not lead to extra costs to you other than usage of your mobile data plan if applicable. Data collected in this study will count against your existing mobile data plan but you can set up the “asthma app” to only use Wi-Fi connections to limit impact on your data plan.

**POSSIBLE BENEFITS:**

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits may be that what we learn from the study may help doctors better understand asthma and design better mobile applications. During the study you will be able to track what is happening with your asthma and your health overall. You may learn more about asthma and monitoring your health that may possibly help you and your doctor to keep you healthy.

**REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:**

There are risks, discomforts, and inconveniences associated with any research study.

In this study, we are not changing or recommending any changes in your asthma medicine so we do not expect any medical side effects from participating.

Inconveniences associated with participation include spending time outlined above in performing the surveys and tasks in the “asthma app.”

Some survey questions may make you may feel uncomfortable. Know that the information you provide is entirely up to you. We ask that you complete the daily and weekly reminders but otherwise you are free to keep other questions blank.

Other people may glimpse the study notifications and/or reminders on your phone and realize you are enrolled in this study and that you have asthma. This could cause some embarrassment or self-consciousness.

Be safe. Do not do study tasks while driving. Wait until you are in a safe place to perform tasks.

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You may have concerns about data security, privacy and confidentiality. Your study data, including this consent, will be maintained in an encrypted database. Only a limited number of researchers will have access to any personally identifying survey or device information. Although we will use state-of-the-art technology to protect your information, there is a slight risk of loss of confidentiality. This is low risk because we separate your personal information (information that can directly identify you, such as your name or phone number) from the app use data that you provide to respect your privacy. However, even with removal of this information, it is sometimes possible to re-identify an individual. This risk, while very low, should still be considered before enrolling.

There is the possibility that the genetic data you provide us through this study may, even when presented without other identifying factors, allow you to be re-identified, and therefore this research study cannot promise anonymity. If you chose to participate in the Genetics Sub-study, your risks will be explained in further detail in a separate consent.

Participation in this study may involve risks that are not known at this time.

**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. You should continue your asthma care with your usual doctor if you participate in the study and if you choose not participate in the study.

**IN CASE OF INJURY DURING THIS RESEARCH STUDY:**

This study does not provide any compensation, health or medical care to participants. If you are injured as a direct result of your participation in this study, the Principal Investigator and the research study staff will assist you in obtaining appropriate medical treatment. Your medical insurance, managed care plan, or other benefits program will be billed for this treatment. You will be responsible for any associated co-payment or deductibles as required by your insurance.

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If costs of care related to such an injury are not covered by your medical insurance, managed care plan or other benefits program, you may be responsible for these costs. The sponsor will not pay charges that your insurance does not cover. No payment is available from the study sponsor.

**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 Mount Sinai or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, delete the "asthma app" from your phone or contact the Principal Investigator or the research staff by email, phone or in writing, using the contact details set out in the "CONTACT PERSON(S)" section below.

If you stop being in the research study, already collected information which is no longer tied to you personally will in most cases be retained in the research study database and will continue to be used to complete the research analysis.

You may also withdraw your permission for the use and disclosure of any of your private protected health information (see the section titled "MAINTAINING CONFIDENTIALITY – HIPPA AUTHORIZATION" below for the meaning of this term) 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 the information that was already collected if that information is necessary to complete the research study, although it will not be associated personally with you. 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 participating in the research study.

Withdrawal without your consent: Principal Investigator 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 researcher believes it is in your best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your consent. More possible reasons for removal from the study

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include if the Principal Investigator believes it is in your or the study's best interest or if the study is cancelled.

You are free to remove the app from your mobile phone at any time. If you remove the research study app from your mobile phone and do not promptly reinstall it, you will stop being in the research study.

- You should not feel obligated to agree to participate.
- Your questions should be answered clearly and to your satisfaction.
- You have a right to view your data through the asthma app.
- By agreeing to participate you do not waive any of your legal rights.

If you withdraw from the study, we will stop collecting new data, but any data already collected will remain as part of the study.

The Study Director may also withdraw you from the study without your consent at any time for any reasons, including if it is in your or the study's best interest or if the study is cancelled.

**CONTACT PERSON(S):**

If you have any questions, concerns, or complaints at any time about this research, or if you think the research has hurt you, please contact the office of the research team and/or the Principal Investigator at [asthmamobilehealth@mssm.edu](mailto:asthmamobilehealth@mssm.edu) or phone number 212-659-8541. If contacting the research team by phone, please be sure to include the country code (+1).

If you experience a medical emergency during your participation in this research, call 911 or go to the emergency room, or call your primary physician as needed. In the United Kingdom, the emergency number to call is 999 and in the Republic of Ireland the number to call is 999 or 112.

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 following reasons:

- 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.

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**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.

Dr. Eric Schadt (a Co-Investigator in this study and Chair of the Department of Genetics and Genomics Sciences, and Director of the Icahn Institute for Genomics and Multiscale Biology) and Dr. Joel Dudley (a Co-Investigator in this study and the Director of Biomedical Informatics at the Icahn School of Medicine at Mount Sinai (ISMMS) both hold equity in the form of stock options in LifeMap Solutions, a privately held company. In addition Dr. Schadt serves as an uncompensated advisory board member and is administratively responsible for the medical school's collaboration with LifeMap Solutions.

Apple Inc has provided technological support for this project. The technological support from Apple, Inc. has included hiring a third party vendor – Y Media Labs (a digital business focused on building user-friendly mobile experiences) to assist in the development of this asthma mobile health applications (apps).

**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?

As part of this research project, the researchers may collect your name, location, telephone numbers, birth date, or e-mail/internet protocol (IP) addresses, genetic data, finger print, device ID. This will be stored separately from the other data you provide using the app.

During the study the researchers will gather information by: taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, allergies, etc.) and reviewing the questionnaires explained in the description section of this consent, and reviewing genetic tests.

What protected health information might be disclosed (shared) with others?

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Your personal contact information will only be accessed by the study team if necessary and will not be shared outside the study team. Your de-identified study data, such as survey results, which does not include any identifying personal information, may be shared with other researchers who Mount Sinai has approved to receive the study data.

Why is your protected health information being used?

Your health information 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 research team and other authorized members of the 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 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 Food and Drug Administration
- The United States Department of Health and Human Services and the Office of Human Research Protection

In all disclosures outside of Mount Sinai, you will not be identified by any 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, or a contract research organization will come to inspect records to review our compliance with the study terms. Even if those records are identifiable when inspected, all information leaving Mount Sinai will be stripped of direct identifiers. Additionally, **the monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records for verification of the**

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Form Approval Date: **3/1/2016**

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**12/1/2016**

Rev. 4/1/15

IRB Form HRP-502a

**THE MOUNT SINAI HEALTH SYSTEM  
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY  
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**  
Icahn School of Medicine at Mount Sinai,



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**research procedures and data. 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?

While you are participating in the study, you will be able to view the answers you have given through the "asthma app." Once you have finished participating in the study, you will no longer be able to view your study data because it will become disassociated with you and therefore cannot be traced back to you.

This will be done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to your own medical record and any study information that is part of that record when the study is over or earlier, if possible. The researcher is not required to release to you research information that is not part of your medical record and no information regarding other participants will be released to you.

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.

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

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to continue to protect your confidentiality. In the case of this study, details linking the information you provide to you personally are separated within Mount Sinai, and your confidentiality is further protected in this way.

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.

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**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.

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**MAINTAINING CONFIDENTIALITY/DATA PROTECTION INFORMATION – PARTICIPANTS IN THE REPUBLIC OF IRELAND AND THE UNITED KINGDOM:**

Participants from the Republic of Ireland and the United Kingdom should read the entirety of this Consent Form, and in particular the section above titled "MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION".

That section explains how the sensitive personal data that you provide concerning your health will be used in the research project. For purposes of your review of this consent form, and in particular, the above section concerning HIPAA, what is called "sensitive personal data" for purposes of legislation in both the Republic of Ireland and the United Kingdom is called "protected health information". The above sections in the Consent Form also explains your rights to withdraw from the research study and also explains that the researchers, under the direction of the Principal Investigator, may withdraw you from the study, and in both cases what happens to the data you have supplied in these circumstances. It also explains how your data may be shared by Mount Sinai with other researchers.

The "data controller" for purposes of data protection legislation in the Republic of Ireland and the United Kingdom responsible for data protection matters is Mount Sinai. The data controller can be contacted through the Principal Investigator named above.

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The above section "MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION" also describes the measures that Mount Sinai will implement to protect your personal data, including your protected health information. It is important that you understand that the data you submit when you use the App will be transferred from within the European Union to the United States of America and that it will be used and processed in the United States. The federal laws of the United States and the laws of each state in the United States relating to the protection of personal data are not the same as those of the Republic of Ireland or of the United Kingdom. The laws and procedures that will be applied to your data are as described in the section "MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION", and this is the reason it is very important that you read this section carefully. By signing this consent form, you are confirming your consent to the transfer of the data you submit to the United States in accordance with the terms of this Consent Form, and in particular the section titled "MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION."

If you have any questions concerning the use of your personal data, including your protected health information, or you wish to exercise any of the statutory rights you have concerning the use of the data you submit to the research study, including the rights of erasure and rectification, you should contact the Principal Investigator at the address set out at the front of this form.

Permission for study team to contact you

By participating in this study, you agree that the study team may contact you if needed to get feedback about the asthma app or to further develop mobile health apps. If you do not want the study team to contact you, use the "asthma app" to opt out of giving permission to be contacted.

**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.

**DO NOT SIGN THIS FORM AFTER THIS DATE →**

**12/1/2016**

\_\_\_\_\_  
Signature of subject

\_\_\_\_\_  
Date

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\_\_\_\_\_  
Printed name of subject

\_\_\_\_\_  
Time  
[required if used for FDA  
documentation purposes]

**Person Explaining Study and Obtaining Consent**

\_\_\_\_\_  
Signature of person obtaining consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of person obtaining consent

\_\_\_\_\_  
Time

**Witness Section: For use when a witness is required to observe the consent process,, document below (for example, subject is illiterate or visually impaired, or this accompanies a short form consent):**

*My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.*

\_\_\_\_\_  
*Signature of witness to consent process*

\_\_\_\_\_  
*Date*

\_\_\_\_\_  
*Printed name of person witnessing consent process*

\_\_\_\_\_  
*Time*

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