Study ID #: IF# 1688246, PD# 14-04987 **Form Versior**
Date: 12/01/2014

TITLE OF RESEARCH STUDY:

Title: Asthma Mobile Health Application

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

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 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 four weeks.
The number of people expected to take part in this research study is 100 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 right on your mobile phone. 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 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 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 than that, you may choose to not answer any question that makes you uncomfortable

- **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.

  You will 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. Your will be asked about daytime and nighttime asthma symptoms in the last 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

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 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.

You may have the choice to use the AMHA to receive information about pollen and air quality in your area. If you choose to do so, 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.

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. You can also choose not to do this and still participate in the study.

The app will track your use of the app and features in the app. This way the study investigators 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.

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 the end of the study we will ask you to repeat the surveys 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).

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 data that identifies you (including name, birthdate, mobile phone number, etc.) will be removed before the data is transferred for researchers to 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 research data.

● **Use in research:** We will combine your study data including survey response and tasks 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 without 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

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.

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 investigators will have access to any personally identifying 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 a low risk because we separate your personal information (information that can directly identify you, such as your name or phone number) from the research data 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.

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.

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.

If you stop being in the research study, already collected information may not be removed from the research study database and will continue to be used to complete the research analysis. You may be asked whether the investigator can collect information from your routine medical care. If you agree, this data will be handled the same as research data.

You may also 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 the information that was already collected if that information is necessary to complete the research 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 participating in the research study.
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 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 include if the Study Director believes it is in your or the study's best interest or if the study is cancelled.

You are free to remove the research study 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 or phone number 212-659-8541.

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.

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.

DISCLOSURE OF FINANCIAL INTERESTS:

The study is funded by the Icahn School of Medicine at Mount Sinai, with technology support from Apple, Sage Bionetworks, and LifeMap Solutions.

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.

The Principal Investigator's Department has a financial interest that could be affected by the outcome of this research study or receives significant support from the research study sponsor.

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.

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.

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

The protected health information will not be shared outside of the study team.

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 research team and other authorized members of The Mount Sinai Hospital and Icahn School of Medicine at Mount Sinai (together, "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 your records. Even if those records are identifiable when inspected, the information leaving the institution 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 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.

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 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.

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.

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.