UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment &position: _____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

AIM2ACT: Applying Interactive Mobile health to Asthma Care in Teens

3. Whom do you call if you have questions about this Research Study?

Principal Investigator: David Fedele, Ph.D., ABPP (352) 294-5765

4. Who is paying for this Research Study?

The sponsor of this study is the National Institutes of Health

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) In general, what is the purpose of the research, how long will you be involved?

The purpose of this study is to see whether a phone application (app) improves the health of children ages 12-15 with asthma. The study will last about 18 months.

b) What is involved with your participation, and what are the procedures to be followed in the research?

You and your child will use a phone app for 6 months. You and your child will complete 5 study visits while in the study. These visits include completing surveys and may include an interview about your family's app experience and approach to asthma care. These surveys include questions about violence in the home. We will attach a counter on your child's asthma medication for 30 days after each study visit. Finally, while at home, your child will use a spirometer to test their breathing daily for 7 days at four points during the intervention – baseline, month 2, month 4, and month 6—during the 6-month intervention.

c) What are the likely risks or discomforts to you?

You may feel uncomfortable answering survey questions about violence in the home. We will ask you these questions to better understand your family environment, which can affect your child's asthma care and management. We will protect any information we collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Questions 8-9 in this form talk about how your information will be collected, used, protected, and shared. What are the likely benefits to you or to others from the research? Benefits could include you and/or your child learning new ways to take care of asthma.

d) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

The alternative is not to participate.

Additional and more detailed information is provided within the remainder of this Informed Consent form. Please read it before deciding if you wish to participate in this study.

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

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this Research Study)?

Participating in the study will not change your child's regular clinical care or their medication.

7. What will be done only because you are in this Research Study?

You and your child are being asked to sign-up for a study that will last about 18

months. The study will include 160 children, ages 12-15 years, and their parent or legal guardian.

If you and your child agree to participate in this study, then you and your child will complete a first study visit. We will ask you and your child to complete a few questionnaires and complete an interview about your child's asthma and quality of life. You and your child will complete an interview about how you take care of asthma in your family. We will provide you with a counter to attach to your child's asthma medication. Additionally, your child will test their breathing by using a spirometer for 7 days at four points during the intervention – baseline, month 2, month 4, and month 6—during the 6-month intervention. After 30 days you will come back for your next study visit in which the medication counter will be returned, and you will meet with a team member to find out which phone app you have been randomly assigned (much like a coin flip) to.

As part of your participation in the research, you will be audio recorded. Neither your name nor personal information will be identified on this picture or recording. If you do not want your image to be recorded, please shut off your camera. Confidentiality will be strictly maintained. However, when the above is shown or heard, others may be able to identify you.
You and your child will complete the same questionnaires at each of the five study visits. The visits will occur before you are assigned to a phone app, 6 months after you and your child used the phone app, and 3, 6, and 12 months later.

Randomization

If you meet the criteria to be in the study, a computer will randomly assign you one of the two phone apps: App A or App B. Random assignment is like rolling a dice to decide which group a person is assigned to. Neither you nor the researchers will get to choose which app your family is assigned to. You will be told of your app assignment at the second study visit. Both App A and B are 6 months long.

App A – The focus of app A is goal setting and working together as a team to achieve asthma care goals. If you are assigned to App A, both you and your child will answer questions about how you take care of asthma (e.g., did you remember to take your medication this morning?) for one week on an asthma app. This app will be installed on your current smartphone, if possible. If you do not have a smartphone, you will be provided one and a data service plan to allow you to participate. After one week, you and your child will receive a report on the smartphone about how you all are doing with taking care of your asthma. You and your child will view videos on how to set asthma care goals, be asked to work together as a team to set weekly asthma care goals, and work to achieve those asthma care goals for six months. Depending on how often you and your child use this program, a member of the research team may contact you once to see if there are any difficulties.

App B – The focus of App B is learning about environmental and behavioral factors that can make asthma worse or better. If you are assigned to App B, both you and your child answer questions about how you take care of asthma (e.g., did

you remember to take your medication this morning?) for one week on an asthma app. This app will be installed on your current smartphone, if possible. If you do not have a smartphone, you will be provided one and a data service plan to allow you to participate. After one week, you and your child will be given information about asthma and ways you can work together to improve asthma care. You and your child will be asked to review the provided information and then continue to use the smartphone program for 6 months.

Once this research study is completed, any information that could identify you might be removed from any identifiable private information or identifiable biospecimens collected. After such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

If you have any questions now or at any time during this Research Study, please contact one of the researcher(s) listed in Question #3 of this form.

8. What identifiable health information will be collected about you and how will it be used?

The Research Team will collect your demographic information, medical history, and determine how you take care of asthma. This information will help us understand why people participate in our asthma app programs and how well the app programs help improve asthma management.

The Research Team may collect this information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals, or clinics). Other professionals at the University of Florida or Shands Hospital who provide study-related care, and the University of Florida Institutional Review Board (IRB), may also collect your health information.

The Research Team listed in question 3 above will use or share your health information as described below to carry out this research study.

9. With whom will this health information be shared?

This health information may be shared with:

- The study sponsor (listed in Question 4 of this form);
- United States governmental agencies, which are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections;
- Government agencies, which are responsible for overseeing public health concerns, such as the Centers for Disease Control and federal, state, and local health departments.
- The IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law.

10. How long will you be in this Research Study?

You will be in the study for about 18 months.

This Authorization to use and share your health information expires at the end of the study, unless you revoke it (take it back) sooner.

11. How many people are expected to take part in this Research Study?

We hope to sign-up 438 individuals in this study.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

12. What are the possible discomforts and risks from taking part in this Research Study?

Researchers will take steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Questions 8-9 in this form discuss what information about you will be collected, used, protected, and shared.

This Research Study may also include risks that are unknown at this time.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You have been informed that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. That is, if you give written consent for the release of information, we cannot withhold that information and we cannot hold responsibility for how that person may use your information. The Certificate of Confidentiality does not prevent the

researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. If we learn about child abuse, elder abuse, or intent to harm yourself or others, we will report that information to appropriate authorities.

Please note, participating in more than one research study or project may further increase the risks to you. If you are already enrolled in a research study, please inform one of the Research Team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

During the study, the Research Team will notify you of new information that may become available and might affect your decision to remain in the study.

The University of Florida is required by law to protect your health information. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by University policy. However, there is a slight risk that information about you could be released inappropriately or accidentally. Depending on the type of information, a release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the Research Team members listed in question 3 in this form.

13a. What are the potential benefits to you for taking part in this Research Study?

Potential benefits include learning ways to help take care of your child's asthma, or for children, improving how you take care of yourown asthma.

13b. How could others possibly benefit from this Research Study?

The information we get from this study may help us learn which apps most improve how families take care of asthma.

13c. How could the Research Team members benefit from this Research Study?

In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in question 3 of this form may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals.

13d. Will you be allowed to see the research information collected about you for this Research Study?

No information about your participation is entered in your child's medical record.

14. What other choices do you have if you do not want to be in this study?

You may also ask for information on asthma from your child's pediatrician or other

healthcare provider.

You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

15a. Can you withdraw from this study?

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in question 3 of this form to let them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in question #3.

15b. Can the Principal Investigator withdraw you from this Research Study?

You may be withdrawn from this Research Study without your consent for the following reasons:

- The study is cancelled or other administrative reasons

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

16. If you choose to take part in this Research Study, will it cost you anything?

No

17. Will you be paid for taking part in this Research Study?

All families participating in this study may be compensated up to $600 for completing all study visits, surveys/questionnaires, and spirometry measurements. Participants will be given an unloaded Visa debit card after completing informed consent. Throughout the study, the card will be loaded with the following amounts:

Baseline:

- $50 after completed informed consent, questionnaires, breathing test, and

medication counter setup and return.

During the Study:

- Adolescents may receive $30 (at month 1, month 2, month 4, and month 6—that they complete 5 out of 7 daily, at-home spirometry measurements (up to $120).

- Each dyad may receive $10 for completing both the morning and evening surveys during each 7-day EMA periods (with 3 EMA periods—month 1, month 2, and month 4—this means participants may receive up to $30).

Post Treatment:

- $50 for completing all questionnaires, spirometry device return, cell phone return from participants requiring cell phone at start of intervention, and medication counter device setup and return after 30 Days
- $50 per person ($100 total) may be offered for an additional, optional interview

Follow-up:

- $75 for 3-month follow-up: Completing all questionnaires, medication counter device setup, counter device return after 30 Days

- $75 for 6-month follow up: Completing all questionnaires, medication counter device setup, and counter device return after 30 Days

- $100 for 12-month follow up: Completing all questionnaires, medication counter device setup, and counter device return after 30 Days

Compensation will be issued once all devices have been returned. You will also only be compensated for the portions of the study that are completed.

If you are paid more than $199 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. Payments to ***nonresident aliens*** must be processed through the University of Florida Payroll and Tax Services department. If the payments total $600 or more in a calendar year, the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: http://privacy.ufl.edu/SSNPrivacy.html.

Your payment for participation in this research study is handled through the University of Florida's Research Participant Payments (RPP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (RPP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific

identification (ID) number to protect your identity.

18. If you have any problems regarding your payment contact the study coordinator. What if you are injured while in this Research Study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists, or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact one of the Research Team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this Research Study.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this Research Study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization _____ Date _____

Consenting Adults. You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

Adult Consenting for Self. By signing this form, you voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described above. By signing this form, you are not waiving any of your legal rights.

Signature of Adult Consenting & Authorizing for Self _____ Date _____

Parent/Adult Legally Representing the Subject. By signing this form, you voluntarily give your permission for the person named below to participate in this study. You hereby authorize the collection, use and sharing of protected health information for the person named below as described above. You are not waiving any legal rights for yourself or the person you are legally representing. After your signature, please print your name and your relationship to the subject.

Consent & Authorization Signature of Parent/Legal Representative _____ Date _____

Print: Name of Legal Representative _____ Print: Relationship to Participant: _____

Print: Name of Subject: _____

Participants Who Cannot Consent But Can Read and/or Understand about the Study. Although legally you cannot "consent" to be in this study, we need to know if you want to take part. If you decide to take part in this study, and your parent or the person legally responsible for you gives permission, you both need to sign. Your signing below means that you agree to take part (assent). The signature of your parent/legal representative above means he or she gives permission (consent) for you to take part.

Assent Signature of Participant	Date

CONSENT TO BE AUDIO-RECORDED