Informed Consent

Title of Research Project: **Pilot of Lifestyle and Asthma Intervention**

Principal Investigator: **Anne E. Dixon, MA, BM BCh**

Sponsor: **American Lung Association-Airways Clinical Research Centers (ALA-ACRC)**

National Institutes of Health

You are being invited to take part in this research study because you have asthma, and your body mass index (BMI) is over 30 kg/m^2 (BMI is a person's weight in kilograms (kg) divided by his or her height in meters squared).

This study is being conducted by the University of Vermont at the UVM Medical Center as part of the American Lung Association's Airways Clinical Research Centers network (ALA-ACRC); participants will also be recruited at the University of Arizona, Tucson.

We plan to recruit a total of 40 patients; 20 participants will be enrolled at the University of Vermont Medical Center, and 20 patients from the University of Arizona.

We encourage you to ask questions and take the opportunity to discuss the study with anybody you think can help you make this decision.

Why is This Research Study Being Conducted?

Many people with asthma struggle to maintain a healthy weight. This research is being conducted to try and find a way to help people with asthma lose weight. Ultimately, we hope to develop a weight loss intervention that might help their overall health and theirasthma.

What Is Involved In The Study?

This study involves an online weight loss program and six visits to the clinic and one phone visit over approximately a six-month period. The weight loss portion of the study consists of an internet-based program to try and help you to lose weight. You will participate in the weight loss program weekly, throughout the six month span for the study visits. During the study visits, you will complete questionnaires about your overall health and your asthma, undergo lung function testing, and have your weight checked.

A. Weight Loss Program

After we confirm you are eligible for the weight loss intervention at visit 2, we will provide you with a laptop. You will be asked to use the laptop to access the weight loss program. If you do not have access to the internet, we will provide a data plan for this device.

You will be assigned a weight loss coach. There will also be a group of other people assigned to this coach starting the program at the same time as you.

During the weight loss program, you will be required to attend a weekly internet chat session with your group members and the weight loss coach. You will also complete a behavioral lesson during the week by accessing the study website. The weight loss lesson and chat sessions are where you will learn the principles of managing your eating and exercise behaviors. Each chat session will last about an hour.

You will be asked to keep a record of the foods you've eaten each day and you will submit this electronically each day.

Part of your treatment program is exercise. You will be asked to exercise (we recommend walking) on your own and keep track of the time you exercise to record electronically.

You will be asked to monitor your body weight and submit this information electronically to study personnel for monitoring.

All participants will be contacted via e-mail individually by their weight loss coach, who will monitor their progress and offer advice and encouragement. The coach will contact you by email weekly for the duration of the study. Your e-mail address will be displayed on the site to facilitate communication between group members. You can opt out of this feature if you would prefer that your e-mail address not be shared.

B. Description of Study Visit Procedures

Visits 1–6 and phone visit (P1) (each clinic visit estimated time 2-3 hours):

1. Weight Loss Intervention Description: We will explain the weight loss program, which will be conducted entirely over the Internet. We will show you how to access the study website and the MyFitnessPal program, which you will use for the duration of the study. After we show you how to access the programs, we will ask you to log on to enter data. To be eligible for the weight loss intervention (which starts after visit 2), you will need to have completed 3 consecutive days of the food diary in MyFitnessPal. Once enrolled in the weight loss program, after visit 2, we will ask you to complete this every day.

2. Picture: All participants will have their picture displayed on the chat page and on the biography page for their group when they use the study web site. The purpose is to help you put names with faces while participating in your group. You may opt out of this feature if you are not comfortable with displaying your picture on the website. Only study staff and other group members in your individual group (and not other study participants in other groups) will have access to your photo and all photos will be destroyed at the end of the study.

3. Medical History: We will document your medical history by asking you questions about your past and present health status, medical and surgical history, use of medications, and your family history. We will measure your height and weight, and your waist and hip circumference. We will review medical records of any prior lung function tests and allergy tests.

4. Physical Exam: If you have not been seen in our pulmonary clinic in the last 12 months, you will have a brief physical exam at visit 2.

5. Spirometry: You will be asked to perform a breathing test called spirometry. This test tells us how well your lungs work. You will be asked to take a deep breath in, and then blow out into a machine as forcefully as you can. This procedure will be repeated a number of times to get good results. At visit 2 and visit 6 we will then ask you to breathe in a bronchodilator (albuterol) to determine how well your airways respond to this medication.

6. Diary entries: You will be asked to enter an online asthma diary card form daily. On the diary card you will record your peak flow, your asthma symptoms or other symptoms you might experience, and whether you took asthma medication. The diary card will take less than 5 minutes a day to complete. The purpose of this diary is to see how well your asthma symptoms are being controlled. To be eligible to continue in the program at visit 2, you will need to have completed the same 3 consecutive days of the asthma diary, food diary and exercise diary. Once enrolled in the weight loss program, after visit 2, we will ask you to complete every day.

7. Questionnaires: You will be asked to complete questionnaires to include demographic information, and information about your asthma, activity level and eating habits.

8. Blood Draw: We will perform a fasting blood glucose and analysis of substances in your blood measuring inflammation related to your asthma, and markers of metabolism – we will need approximately 20 cc (4 teaspoons) of blood at two visits. You may have your blood drawn on another day (within one week) of the other study visit procedures if this is more convenient.

   - At visits 2 and 6, for the fasting blood draw, you will be instructed to not eat before you come to your visit. We will have snacks for you here.

   - We will share the results of your blood glucose tests with your regular doctor if you give us permission to.

   Would you like the study staff to notify your regular doctor that you are in this study, and share results of your blood glucose tests with them?

   Please initial your choice below:

   _____No, don't contact my doctor.

   _____Yes please let my doctor know.

   Name and location of your doctor:

   _____

The study visits are outlined in the table below:

Schedule of Study Visits

Visit Number	V1	V2	P1	V3	V4	V5	V6
Time (week)	-4	0	3	6	12	18	24
Informed Consent	*						
Medical History	*	*		*	*	*	*
Orientation to weight loss program	*	*					
Provision of Chromebook computer		*					
Addressing website login issues and exercise strategies/concerns at home; facilitator contact			*				
Assessment of compliance with food, asthma and weight diaries		*					
Assessment of diary entry compliance		*		*	*	*	*
Spirometry with bronchodilator		*					*
Spirometry without bronchodilator	*	*		*	*	*	
Asthma Control (ACT and ASUI) (Questionnaire)	*	*		*	*	*	*
Marks Asthma Quality of Life (Questionnaire)	*	*		*	*	*	*
Quality of Life (SF36) (Questionnaire)	*	*					*
Arizona Food Frequency Questionnaire	*						*
Stanford Brief Activity Questionnaire	*						*
Impact of Weight on Quality of Life	*						*
Motivation to lose weight (Tre-MORE)	*						
Height (V1 only), Weight, Hip and Waist Circumference	*	*		*	*	*	*
Blood draw (fasting)		*[1]					*[1]
End of Study Questionnaire							*

V# = visit number
ACT = Asthma Control Test
ASUI = Asthma symptom utility index
[1]Fasting blood draw may be performed on a separate day than other procedures for visit 2

What Are The Risks and Discomforts Of The Study?

The risks and discomforts that you may experience while participating in this research are as follows:

Weight loss intervention:
There are minimal risks for participating in behavioral weight loss control programs. It is possible that some individuals will experience initial muscle soreness from the exercise program. You will be taught warm-up and stretching techniques to use before all exercise sessions to minimize the chance of muscle soreness. We will ask you to check with your primary care physician that they do not have any concerns about you participating in this study. There is a risk that the weight loss intervention will not work for you.

Questionnaires: The questionnaires are not tests. There are no "right or wrong" answers to these questions. You may get tired or bored when we are asking you questions or you are completing questionnaires. Some people may feel uncomfortable answering some questions on the questionnaires. You do not have to answer any question that makes you feel uncomfortable or you do not want to answer. The information you provide will be kept confidential and not shared with non-research staff.

Blood draw: Having blood drawn can cause some discomfort and there is risk of bruising, infection, redness or swelling at the site where the needle is inserted.

Spirometry: The forceful breathing may cause temporary coughing or shortness of breath, and sometimes dizziness. After this testing some people may have some mild chest soreness from forceful breathing.

Bronchodilators: On rare occasions (less than 5% of the time), bronchodilators may cause nervousness, a rapid heartbeat or headache at the doses used in this study. If you develop any of these problems, we will monitor you closely until the problem goes away (typically in 30 minutes).

If you have symptoms of anxiety/depression/suicidal thoughts, we will provide you with information about mental health care resources and/or ask you to schedule an appointment with a mental health care provider. We will check in with you a week later to make sure that you have been able to get follow up care. If we can't reach you, we will discuss this with the study physician, who will contact a crisis intervention service to discuss what follow-up care you might need.

Long-term Storage of Samples

We have a number of tests planned for the blood samples and information that we collect from you during this study. We are also hoping to store any leftover blood samples and data you provide for future research on obesity and asthma. We will store your samples and data with a code number, not your name, so laboratory personnel will not be able to identify you. The list connecting your name to this code will be stored separately, in a password protected file within the Vermont Lung Center.

If you decide you no longer want your samples and data stored, you should contact Dr. Dixon to let her know and your samples will be destroyed.

Participation in this long-term storage of samples is voluntary, and if you choose not to allow it or withdraw later, your participation in the main study will not be affected.

Check the box below and initial alongside if you give permission for left-over samples and data to be stored/used/disclosed/shared for future research projects.

☐ _____ (initials)

Incidental Findings
If we find that your asthma is very poorly controlled, we will provide you with this information, and can provide it to your physician if you would like us to. If we find that your blood glucose is abnormal, we will provide you with this information, and can provide it to your physician if you agree.

What Are The Benefits of Participating In The Study?
There are no benefits to you in participating in this study, other than the opportunity to learn more about your asthma and potentially lose weight. Additionally, we may learn new information that will help patients in the future who have asthma.

What Other Options Are There?
The only option is to not participate in this study. The decision not to participate will not affect the care you receive. Other potential options to better control your asthma can be discussed with your primary care provider or pulmonologist. You may also talk to your health care provider about a weight-loss program that may help you lose weight safely.

Are There Any Costs?
The only cost to you for participating in this study is your time.

What Is the Compensation?
We will reimburse mileage at standard UVM rates, and provide you with a laptop that will have a data plan to connect to the internet. You may keep the device at the end of the study, but the data plan will only be provided for the duration of the study.

Can You Withdraw or Be Withdrawn From This Study?
Your participation in this research study is voluntary. You may decline to participate or you may withdraw at any time without prejudice, penalty or loss of benefits to which you are entitled. Should you, at any time during the study, join another weight control program (such as Weight Watchers, Jenny Craig, NutriSystems, ect.) or begin to take weight loss medications, you will be asked to withdraw from the study. Participants who become pregnant over the course of the 6-month study will be withdrawn from the study. Participants who experience other medical problems during the course of the study will be referred to their personal physician for care and withdrawn from the study if continued participation presents health risks. You can be withdrawn from this study at any time if there are concerns related to study participation.

If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Any information collected up to the point you wish to stop your participation will be used for research purposes.

What About Confidentiality of Your Health Information?

What health information will be used and disclosed for this study?
The health information we plan to collect for this study is listed below.

- Medical history and examinations
- Information that identifies you, such as your name, address, age, and sex
- Reports from hospital and clinic visits
- Laboratory and other test results
- X-ray and other images and reports
- Lists of medications you are taking
- Responses to health surveys and questionnaires

Who is disclosing your health information for this research study?

- The University of Vermont Medical Center
- Other doctors' offices and hospitals where you may receive medical care while this study is active.

Who will use your health information in this study?
Our research team will use your health information. We may also share it with those who assist with the conduct of the research or oversight of the activities for this study.

The representatives from the institutions, organizations, and agencies are listed below.

- The University of Vermont and its Committees on Human Research
- Officials from agencies and organizations that provide accreditation and oversight of research
- The University of Vermont Medical Center
- The data coordinating center for this study at Johns Hopkins University.
- The data safety monitoring board appointed by the American Lung Association
- The sponsors of this study: the National Institutes of Health and the American Lung Association, who jointly fund this research.
- Federal and state agencies that oversee or review research information, such as the U.S. Food and Drug Administration (FDA), the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities
- Your health insurer, for portions of the research and related care that are considered billable

Your health information is protected by a federal law called the Health Information Portability and Accountability Act (HIPAA). Once your health information is shared outside of the University of Vermont Medical Center, we cannot guarantee that these laws will continue to apply. As a result, your health information could be further disclosed for other purposes. In the absence of a Certificate of Confidentiality, it is also possible for a court or other government official to order the release of study data. The confidentiality of your health information cannot be guaranteed if you agree it may be used in this study.

Certificate of Confidentiality
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable disease but not for federal, state or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the NIH which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document including research data in the medical record.

Future Research
Your samples and data will be stored for future use if you have indicated that earlier in this consent form.

How long will your health information be used for research?
Your permission to use your health information will not end until the study is completed. During this study, you will not have access to study data. You may ask for your data once study activities are complete. You have a right to receive a copy of the information in your medical record at any time.

What if you decide not to give permission for research use of your health information?
If you decide not to allow the use and disclosure of your health information, you may not take part in this study. Your decision will have no effect on your current or future medical care.

If you choose to stop taking part in this study in the future, you may cancel permission for the use of your health information. You should let the research team know that you

are cancelling your permission. A member of the research team will assist you in making your decision effective. The study will continue to use the health information already collected for the study before you cancelled your permission, and you cannot get back information that was already shared with others.

Who can answer your questions about the use and disclosure of your health information?
If you have questions or concerns about the use and disclosure of your health information, you should ask a member of the study team at (802) 847-2193 or the Privacy Officer at The University of Vermont Medical Center, Inc. at (802) 847-2667.

Safeguarding Your Health Information

A record of your progress will be kept in a confidential form at the Vermont Lung Center, 792 College Pkwy, Suite 305, Colchester, VT 05446. The security of your record will be maintained by the research team. The results of this study may eventually be published and information may be exchanged between medical investigators, but patient confidentiality will be maintained.
If your record is used or disseminated for government purposes, it will be done under conditions that will protect your privacy to the fullest extent possible consistent with laws relating to public disclosure of information and the law-enforcement responsibilities of the agency.

You may be requested to provide your name, social security number, and address. This information will be disclosed one time to either the University of Vermont's Procurement Services Department or UVM Medical Center Accounts Payable Department for purposes of reimbursing you for participation in this study. If you are not a US Citizen or Permanent Resident Alien, you will be required to complete additional paperwork for payment.

Clinical Trials Registration

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.

What Happens If You Are Injured?

If you are injured or become ill as a result of being in this research, The UVM Medical Center, the hospital partner of the University of Vermont, will provide reasonable and usual medical care for that injury or illness. There will be no cost to you if the conditions listed below apply to your injury or illness. These conditions are:

1. The investigator, in consultation with the study sponsor, determines that your injury or illness results from the research and not from your underlying condition or its usual treatment.
2. You let the investigator know about the injury or illness when you first notice it; and
3. You follow medical advice about proper treatment options for the injury or illness.

The UVM Medical Center may claim payments for your medical treatment directly from the study sponsor or your insurance company when these payments are allowed.

For an injury or illness that results from being in this study, the University of Vermont and The UVM Medical Center will not offer you any other payments, such as lost wages or expenses, except for your medical care. Even though you may receive medical care at no cost to you under certain conditions if you are in this study, the UVM Medical Center and the University of Vermont do not admit to any responsibility for an injury or illness that results from being in the study.

If you agree to take part in this study and you sign this consent form, you are not giving up any of your legal rights.

Contact Information

You may contact Dr. Dixon, the Investigator in charge of this study, at (802) 847-1158 for more information about this study. If you have any questions about your rights as a participant in a research project or for more information on how to proceed should you believe that you have been injured as a result of your participation in this study you should contact the Director of the Research Protections Office at the University of Vermont at (802) 656-5040.

Statement of Consent

You have been given and have read or have had read to you a summary of this research study. Should you have any further questions about the research, you may contact the person conducting the study at the address and telephone number given below. Your participation is voluntary and you may refuse to participate or withdraw at any time without penalty or prejudice to your present and/or future care.

You agree to participate in this study and you understand that you will receive a signed copy of this form.

Signature of Subject Date

Name of Subject Printed

This form is valid only if the Committees on Human Research's current stamp of approval is shown below.

Signature of Principal Investigator or Designee Date

Name of Principal Investigator or Designee Printed

Name of Principal Investigator: Anne E. Dixon, MA, BM BCh
Address: Given D209
89 Beaumont Avenue
Burlington, VT 05405
Telephone Number: 802 847 1158

Committee on Human Research
Date Approved 11/9/17
CHRMS# 17-0314