**********DO NOT DELETE OR ALTER THIS PAGE**********

CAUTION: IF YOU HAVE PRINTED THIS CONSENT FOR USE WITH PARTICIPANTS, IT IS NOT THE IRBMED APPROVED VERSION. Access the approved/watermarked consent from the Documents Tab in the main study workspace. The approved/watermarked document *will not* contain this cover page and *will* have the approval watermark present in the header.

****

INSTRUCTIONS FOR EDITING THIS DOCUMENT

1. Turn on Track Changes.
2. Make necessary changes in consent, and update the footer intended for study team version control.
3. Upload the revised consent into Section 10-1, maintaining the IRBMED standard naming convention as follows:
   - **Consent - Tracked**
   - **Consent -** *Concise Subtitle* **– Tracked** (provide a subtitle when there are multiple consents associated with the study)
   - **Assent - Tracked**
   - **Parental Permission/Assent - Tracked**
   - **Parental Permission – Tracked**

NOTES:
Words identified above in bold must not be changed; words identified in italics may be modified by the study team. Informed consent subtitles should be a one or two word descriptor, such as**:** **Consent – *Genetic* – Tracked** or **Consent – *Blood Draw* - Tracked**.

Each subsequent track changes version should be stacked on the previously uploaded track changes version.

DO NOT delete any documents or stacks of documents from eResearch; these are retained for historical and regulatory reference purposes.

DO NOT upload a clean version of the consent**.**

---------- IRB OFFICE USE ONLY ----------

Study ID: HUM00119545 / Amendment ID: Ame00108294

Approval Date: 11/19/2020

Document Finalized: 1/19/2021 4:10 PM

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title: Active for Life: COPD

1.2 Company or agency sponsoring the study: National Institutes of Health

1.3 Names, degrees, and affiliations of the researchers conducting the study:

Janet L. Larson, PhD, RN, School of Nursing, University of Michigan
MeiLan Han, MD, Pulmonary & Critical Care Medicine, University of Michigan

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

Many people with chronic obstructive pulmonary disease (COPD) are very inactive and do not get enough physical activity. This lack of physical activity makes their health even worse.

In this study, we want to compare two different approaches to helping people with COPD become more physically active:

1. Active for Life: This approach is relatively new, and researchers are still testing its effectiveness.
2. Chair Exercises and Health Education: This is an older approach recommended for older adults with chronic disease to help them get more exercise.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

You may be able to take part in this study if:

1. you are at least 50 years old
2. moderate or severe COPD is your primary health problem
3. for at least eight weeks, your COPD has been stable and has not required treatment in the form of:
    1. newly prescribed steroids
    2. a change in steroids that you were already receiving
    3. antibiotics
4. your primary doctor provides written permission for you take part

You *cannot* take part in this study if:

1. your primary lung problem is a condition other than COPD
2. you have recently had a heart attack or experienced chest pains
3. you have physical problems besides COPD that limit your physical activity
4. in the past 8 weeks, you have been hospitalized for any major illnesses that might limit your physical activity or ability to move
5. you require an assistive device to walk (such as a cane or walker)
6. you have difficulty with balance or walking
7. you are physically active (perform at least 30 minutes of moderate physical activity a day, five days a week)
8. you are already receiving pulmonary rehabilitation (Subjects in maintenance rehabilitation will be able to participate as long as they report activity levels that meet criteria for a sedentary lifestyle.)

3.2 How many people (subjects) are expected to take part in this study?

At three sites (Ann Arbor, Flint, Grand Blanc) throughout the Michigan, a total of up to 250 subjects will be enrolled in this study.

The University of Michigan Ann Arbor site hopes to enroll up to 210 subjects. Twenty subjects will be recruited at each of the two remaining sites (Flint, Grand Blanc)

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you decide to take part in the study, we'll first ask you to visit our laboratory so that we can make sure you qualify. This will involve a brief test of your lung function (spirometry) and some questions about your health history.

If you qualify for the study and wish to continue, we will use a random method (similar to flipping a coin) to assign you to one of two study groups:

1. **Active for Life**. This program focuses on circuit training and walking with a behavioral component and the goal of increasing daily physical activity.
2. **Chair Exercises and Health Education**. This program focuses on stretching and toning exercises with a health education component and the goal of establishing a healthy lifestyle.

Both programs include a combination of exercises in our study laboratory and exercises in your home.

1. All laboratory exercise will be supervised by an exercise specialist. There will be a total of 18 laboratory exercise sessions, approximately 1½ – 2 hours per session.
2. All home exercise sessions will be about 1 hour in length. Home exercises will be the same as those performed in the laboratory.

Exercise program descriptions

<u>Active for Life</u>

If you're assigned to this group, research staff will guide you in all exercises and activities and you will receive a booklet to guide you in the exercises. Each session will include:

1. 20 minutes of hall walking
2. Circuit training that will involve performing 13 exercises that are somewhat hard. The room will be set up with one station for each exercise and you will move through the stations at your own pace with the guidance of a staff member. The level of each exercise will be adjusted to your ability. The circuit training will use minimal equipment: elastic bands, a small ball and a chair. The circuit training will last approximately 45

minutes.

3. Behavioral activities that will include goal setting, and reviewing strategies to help you engage in regular physical activity and to build your confidence in your ability to be physically active
4. Educational activities that will include learning about the importance of exercise and physical activity
5. 5 minutes of stretching and relaxation at the end of the session.

Chair Exercises and Health Education

If you're assigned to this group, you will receive a DVD called *Armchair Fitness: Gentle Exercise* to guide you in the exercises. Each session will include:

6. Chair exercises that will include stretching of all major joints with an emphasis on arms and shoulders, and massage of muscles that can be reached from the chair and the use of light hand weights. Each session includes 5-10 minutes of slow stretching, 20-30 minutes of faster paced exercises, 5 minutes of slower paced stretches, followed by 5-10 minutes of relaxation.
7. Health education that will include topics such as basic lung physiology, pathophysiology of COPD, commonly used medications, breathing techniques, healthy eating and PA, relaxation, travel considerations, and energy conservation. This portion will take 20-30 minutes.

Once you have completed your assigned program (after 1 year 3 months), you may, if you wish, take part in the other program for 10 weeks.

Study schedule

Visit 1 (screening). At visit 1, you'll come to our laboratory and we will perform a lung function test (spirometry) and interview you to make sure that you qualify for this study.

Visit 2 (testing). At visit 2, you'll come to our laboratory for a testing visit. At this visit, we will:

1. measure the following:
    1. how far you can walk in six minutes
    2. your balance
    3. your walking speed
    4. how fast you can stand up from a chair five times
    5. your knee strength
2. fit you with two small activity monitors; one is a lightweight box that is clipped to your waist and the other is a small rectangular device taped to the front of your thigh. We'll give you instructions on wearing both of these devices for 7 days in a row; you will also fill out a daily activity log during these 7 days.
3. ask you to complete paper and pencil questionnaires about your health, physical activity and breathing symptoms

Weeks 1 – 8

You will attend exercise classes in our laboratory twice a week and perform exercises in your home once a week. At week two, you will be asked to complete a self-efficacy survey identical to the one you completed during your initial testing.

Weeks 9 – 10

You will attend exercise classes in our laboratory once a week and perform exercises in your home twice a week.

Week 11

At week 11, you will come to our laboratory for a testing visit. This will be just like the testing visit 2 (above). You will be asked to complete a program evaluation survey.

Weeks 12 – 62

You will perform the exercises in your home three times a week for the next year. We will contact you by phone (5 minute calls) weekly for two weeks, and then every other week for the next 2 ½ months and monthly for the next 3 months (11 calls total). During these calls, we will coach you as you move from exercise in the laboratory to exercise at home.

At weeks 22 and 34, you will return to our laboratory for testing and booster sessions. These visits will take longer than previous testing visits because the testing and booster sessions are combined in one visit. These will be just like the testing visits at visit 2 and week 11 (above), except that you will also receive a booster session where you perform exercises just like the ones you performed in our laboratory during your first ten weeks. The booster sessions are to help strengthen your skills for being physically active.

At week 62, you will return to our laboratory for a fifth and final testing visit. The procedures at this visit will be exactly like the testing visits at visit 2 and week 11, except that we will also measure your lung function (spirometry), just as we did at your very first visit. This will also include an exit program evaluation survey.

Summary of Activities								
Study Visits	Visit 1	Visit 2	Week 1-10	Week 11	Week 12-21	Week 22	Week 34	Week 62
Screening	X							
Testing visit		X		X		X	X	X
Activity monitoring (wear for 7 days)		X		X		X	X	X
Structured program elements			**Week 1- 10**	**Week 11-21**		**Week 22**	**Week 34**	
Lab-based exercises, with behavioral/ educational program			two visits a week for 8 weeks, then one visit/week for 2 weeks.					
Coaching phone calls (5 minutes)					Total of 11 phone calls during the first 6 months of follow-up.			
Booster session (one full lab-based session)						X	X	

Optional sub-study

We would also like your permission to keep some of your study data and medical information, so that we may study it in future research. The future research may be similar to this study or may be completely different.

This sub-study is totally optional. You can take part in the main study even if you decide not to let us keep your study data and medical information for future research.

Even if you give us permission now to keep your study data and medical information, you can change your mind later and ask us to destroy it. Keep in mind, however, that once we have analyzed your data, we may not be able to take the information out of our research.

We may share your data and medical information with other researchers, so that they can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your data and medical information with other researchers, we will not be able to get it back.

There is the risk that people outside this study may find out that study data or medical information is about you. To minimize this risk, we will remove identifying details (such as your name) from your data. We will store hard copies of your data in secure locked cabinets and we will store digital data on secure encrypted computers.

Allowing us to do future research on your data and medical information will not benefit you directly.

You will not find out the results of any future research on your data.

Please indicate below whether we have your permission to keep your information.

____ Yes, I permit the researchers to keep my study data and medical information for use in future research.

____ No, I do not want the researchers to keep my study data and medical information for use in future research.

4.2 How much of my time will be needed to take part in this study?
The testing visits will take 2 hours and the final testing visit will take approximately 2.5 hours. Each laboratory-based exercise class will take approximately 2 hours, booster sessions will take approximately 2 hours and the home-based exercises and physical activity will take approximately 1 hour a day.

4.3 When will my participation in the study be over?
The study will last for one year and 3 months. You may also leave the study before it's complete if you wish.

4.4 What will happen with my information and/or biospecimens used in this study?

With appropriate permissions, your samples and collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
The known or expected risks are: muscle soreness (common, but not severe), joint injury (uncommon), falling (rare), decrease in oxygen level during exercise, severe shortness of breath, abnormal heart rhythm (rare), heart attack (very rare) and death (very rare).

Muscle soreness is common when people begin a new exercise program because the muscles involved in the training are not used to working hard. The muscle soreness is usually mild and goes away as your muscles become trained.
Joint injury can occur if the training load is too heavy or the exercises are not performed correctly.
Falling can occur while exercising if you are too rushed or if you lose your balance.
Respiratory problems can occur when you exercise. Most people will become very breathless during exercise tests and for some this will occur during exercise training. In addition your oxygen level could decrease and this can occur in as many as 20 percent of people though the actual expected percentage is not known.
Heart problems including heart attack and death can occur but are very rare. When you exercise your heart must work harder, so there is some risk of heart problems including a heart attack, abnormal heartbeat, blood pressure changes and death. The risk of serious heart problems, heart attack or death during or after a strenuous exercise test is reported to be less than or equal to 1 in 2,500. The reported risk is associated with strenuous exercise testing and the tests performed in this study are less strenuous. The actual expected risk is unknown in people with your degree of pulmonary function.

The researchers will try to minimize these risks by the following.
Muscle soreness. The intensity of exercises will be increased gradually to reduce the risk of muscle soreness.
Joint injury or falling. You will be directly supervised by an exercise trainer during laboratory-based training to reduce the risk of joint injury or falling. The exercise trainer will teach you the right way to exercise and will set the training intensity at a level that you can manage, and you will be required to warm-up before exercises to lessen the chance of injury. During the training, you will be instructed to stop the exercise if you experience muscle or joint pain. We want you to work during the training program, but we do not want you to feel pain in your muscles or joints. We will observe your gait and balance during the exercise training to detect early evidence of fatigue that might put you at risk for falling. In addition we will teach you about the clothes to wear and how to do the exercises safely to reduce the risk of stumbling and/or falling.
Respiratory problems. You will be encouraged to slow down and/or rest if you become extremely breathless. We will monitor your oxygen levels during each exercise test and we will measure it at the beginning of each exercise class to make sure that it is safe for you to exercise. We will measure your oxygen level during the class if you experience severe breathlessness and we will ask you to slow down or stop exercising if your oxygen level drops below safe levels.
Heart problems. We will observe you during each of the exercise tests and stop the test if you respond negatively or if you request that we stop the test. An experienced exercise trainer will supervise exercise classes. We will take your heart rate, blood pressure and oxygen saturation before and after each exercise session to make sure that values are within an appropriate range. You will have frequent rest periods during the training sessions. If you have a serious cardiac event we will call 911 and administer appropriate emergency assistance until they arrive.

A potential risk involves accidental disclosure of protected Health Information (PHI). We will minimize this risk by keeping all PHI information separate from our study documents. Your study documents will be assigned a unique identifier and will not contain any PHI. The PHI collected (name, phone number, address, etc.) will be collected as part of this study however, that information will be stored separately in a locked file cabinet and office. Only research staff will have access to this information.

Unknown risks. As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.** There will be trained nurses on site when you are exercising in our laboratory.

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However possible benefits for some subjects may include an increase in fitness, day-to-day physical activity and healthy living. The knowledge gained from this research could lead to improved exercise programs for people with COPD and this could be beneficial to others in the future.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?
You could perform exercises on your own or enroll in a pulmonary rehabilitation program.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information" (below).

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
You will not experience harm by leaving the study before it is finished.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

1. The researcher believes that it is not in your best interest to stay in the study.
2. You have an abnormal response to exercise such as a high blood pressure or chest pain.
3. You become ineligible to participate.
4. Your condition changes and you need treatment that is not allowed while you are taking part in the study.
5. You do not follow instructions from the researchers.
6. The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researchers' number listed in section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

1. Health care given during the study as part of your regular care
2. Items or services needed to give you study drugs or devices
3. Monitoring for side effects or other problems
4. Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

If you are injured or in the event of a medical emergency, dial 911 or visit your nearest Emergency Room. If you believe the study has made you sick or caused you injury, contact one of the people listed in section 10 of this document. If taking part in the study makes you sick or causes you injury, you will have to arrange for treatment on your own, as the study will not provide medical treatment or provide any compensation to you. You or your insurance provider will be billed for all costs of treatment for sickness or injury caused by the study. It is possible that your insurance will not cover these costs.

There is no compensation for research-related injury. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
Participants will be paid for inconveniences associated with this research. This includes $25 a day for each of five visits required to test walking, balance, gait and standing up from a chair and $50 for each full week (7 days) of activity monitoring. Seven days of activity monitoring will be schedule five times during the study. Payment will be prorated if you wear the activity monitor for less than 7 days, $6/day for the first 5 days and $10/day for the 6th and 7th day for a maximum of $50 for each week of monitoring. The maximum compensation is $375 for the entire study. Payment will be made either by Gift Card or cashier voucher at the end of the each 7-day monitoring based upon the preference of the subject. Subjects who quit the study early will be paid for the number of testing visits and the days of activity monitoring that they complete.

8.3 Who could profit or financially benefit from the study results?
The researchers conducting the study and the University of Michigan will not benefit financially from the results of this research.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?

The data will be stored in Dr. Larson's research office and the office is kept locked at all times. Specifically hard copies of the data will be stored in locked file cabinets and electronic copies will be stored on a password protected computer.

After all data are collected for this study your identifying information will be removed from the data that you provided and if you agree to the optional sub-study (retention of de-identified data for future use) your de-identified data will be kept indefinitely. At this point it will not be possible for the researchers to identify your information from that of others, but the data could be used to answer new research questions.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

1. Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
1. All records relating to your condition, the treatment you have received, and your response to the treatment
1. Demographic information
2. Personal information
3. Other information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

4. The researchers may need the information to make sure you can take part in the study.
5. The researchers may need the information to check your test results or look for side effects.
6. University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.
1. Study sponsors or funders, or safety monitors or committees, may need the information to:
    1. Make sure the study is done safely and properly
    2. Learn more about side effects
    3. Analyze the results of the study
2. Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
3. The researchers may need to use the information to create a databank of information about your condition or its treatment.
1. Information about your study participation may be included in your regular UMHS medical record.
2. If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
3. Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

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 Website will include a summary of the results. You can search this Website at any time.

9.3 What happens to information about me after the study is over or if I cancel my permission?
As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:
1. To avoid losing study results that have already included your information
2. To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
3. To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission expire?
Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?
Please contact the researchers listed below to:
1. Obtain more information about the study
2. Ask a question about the study procedures or treatments
3. Talk about study-related costs to you or your health plan
4. Report an illness, injury, or other problem (you may also need to tell your regular doctors)
5. Leave the study before it is finished
6. Express a concern about the study

Principal Investigator: Janet L. Larson, PhD, RN
Mailing Address:400 N Ingalls
Telephone:734 647-0126
Study Coordinator: She'Lon Tucker, BS, CPT
Mailing Address:400 N Ingalls
Telephone: 734 936-3283

You may also express a concern about a study by contacting the Institutional Review Board listed below.

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies: US Country Code: 001)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

1. This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*
2. Other (specify):_____

12. SIGNATURES

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Witness

I observed the above subject (or his/her legally authorized representative, if applicable) sign this consent document.

Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____