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)

University of Florida
Health Center
Institutional Review Board
APPROVED FOR USE
From 3/19/2014 Through 3/18/2015

INTRODUCTION

Name of person seeking your consent: _____

Place of employment & position: _____

_____

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. 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.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

Mechanisms of Vascular Dysfunction and Effect of Aerobic Exercise Training in Adults with Type 2 Diabetes

3. Who do you call if you have questions about this research study?

The principal investigator, Dr. Demetra Christou, may be reached by phone (352)294-1715 (office) or (720)273-1553 (cell phone) or by email ddchristou@ufl.edu.

4. Who is paying for this research study?

The sponsor of this study is the University of Florida.

5. Why is this research study being done?

Individuals with type 2 diabetes are more likely to have poor blood vessel health which is a risk factor for developing heart disease. Exercise training may improve blood vessel health, and lower the risk for heart disease.

The purpose of this study is 1) to compare blood vessel function between adults with and without type 2 diabetes; and 2) to examine the effect of 2 different types of exercise training on blood vessel health in adults with type 2 diabetes.

You are being asked to be in this research study because you are between 30 and 79 years of age, and have type 2 diabetes.

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)?

This study does not involve clinical care, and it should not interfere with any clinical care you are currently receiving. All medical tests will be completed for research purposes only and do not take the place of regular physician assessments.

7. What will be done only because you are in this research study?

You will be asked to visit the Integrative Cardiovascular Physiology Laboratory at the University of Florida on 9 occasions.

Visits 1-5 will determine if you are eligible to join the study and will also establish your pre-test measures, whereas visits 6-9 will establish your post-test measures. If you are enrolled in the study, you will be randomly assigned to one of two exercise training groups (continuous or interval training) or a non-exercise control group. *Regardless of your group assignment, it is very important that you keep your dietary and physical activity habits the same throughout your study participation and to let us know if there is a change in the medications you are taking.*

You will not have a choice in which group you will be assigned. Upon completion of the study, if you would like to initiate independent home-based exercise training we will provide a walking program and a step counter.

Exercise Intervention

If you are assigned to one of the exercise training groups, the exercise training will take place at the Integrative Cardiovascular Physiology Laboratory and will be supervised by an Exercise Physiologist.

Your blood sugar will be monitored before and after the exercise sessions. You will not be allowed to exercise if your blood sugar is greater than 250 mg/dl. If your blood sugar is low you will be given a snack and the levels might be checked again in 20 minutes.

Prior to the 8-week exercise training program, you will complete a pre-conditioning exercise period until you are able to complete 45 minutes of continuous cycling. The total number of pre-conditioning sessions, the duration per session, as well as the cycling pace will depend on your initial fitness level.

Upon completion of the pre-conditioning period, you will begin the 8-week exercise intervention of 4 supervised training sessions per week. The sessions will be about 1 hour long and will include a period of warm up, aerobic training, cool down and stretching. If you are in the continuous training group the training period will consist of cycling for 47 minutes at a moderate pace. If you are in the interval training group training will consist of cycling for 40 minutes at an alternating moderate and fast pace as follows:

Interval Training

Warm up: moderate pace 10 min	Interval: fast pace 4 min	Active Recovery: moderate pace 3 min	Interval: fast pace 4 min	Active Recovery: moderate pace 3 min	Interval: fast pace 4 min	Active Recovery: moderate pace 3 min	Interval: fast pace 4 min	Cool down: moderate pace 10 min

PROCEDURES INVOLVED

The research staff will oversee all of the procedures. Every effort has been made to keep the risks and discomforts involved in this study to a minimum.

Visit 1 (1.5 hrs)

- Prior 12-hour fast. No food or liquid besides water is allowed for 12 hours prior to the beginning of this visit. Your blood sugar levels will be monitored and a snack will be available if needed.

- Return completed self-reported medical history form.

- 24hr questionnaire. We will ask if you are experiencing any health complaints (e.g., sore throat, head cold, etc.) and questions regarding your sleep, food, drink, tobacco, alcohol, caffeine and medication intake and physical activity in the last 24 hrs.

- Heart rhythm and blood pressure. We will place small electrodes on your chest to get your heart tracing. We will measure your blood pressure with a cuff on your upper arms and at your ankles.

- Habitual physical activity. We will ask you questions regarding how hard, how often and for how long you perform a variety of physical activities. We will also ask you to wear an activity monitor around your hip for 4 days.

- Food diary. To determine the make-up of your diet and the number of calories you eat, you will be asked to keep a food diary for 4 days.

Visit 2 (0.5 hr)

- Prior 4-hour fast. No food or liquid besides water is allowed for 4 hours prior to the beginning of this visit.

- 24hr questionnaire. We will ask if you are experiencing any health complaints (e.g., sore throat, head cold, etc.) and questions regarding your sleep, food, drink, tobacco, alcohol, caffeine and medication intake and physical activity in the last 24 hrs.

- Urine pregnancy test

- Height, weight, circumferences, and body composition. We will measure your body weight using an electronic scale, your height using a ruler attached to a wall, and your waist and hip circumferences using a tape measure. We will measure your body composition, i.e., body fat and lean content, as well as your bone density, using a non-invasive dual-energy x-ray absorptiometry (DXA) scan. This test requires that you lie very still on a padded table that gives off low-level X-ray radiation. The "arm" of the machine will slowly pass over your body to make the measures. This should take less than 10 minutes.

Visit 3 (1.5 hrs)

- Prior 4-hour fast. No food or liquid besides water is allowed for 4 hours prior to the beginning of this visit.

- Your blood sugar levels will be checked before and after the test and a snack will be available if needed.

  24hr questionnaire. We will ask if you are experiencing any health complaints (e.g., sore throat, head cold, etc.) and questions regarding your sleep, food, drink, tobacco, alcohol, caffeine and medication intake and physical activity in the last 24 hrs.

- Body weight. We will measure your body weight using an electronic scale.

- Physical exam. A physical examination will be performed.

- Maximal graded exercise test. This test will measure how well your heart can cope with exercise and also measure your aerobic exercise capacity (how fit you are). You will be asked to walk (or jog) on a treadmill for about 6 minutes to warm up. The speed of the treadmill may be increased until your heart rate reaches a predetermined level. During the test, the highest speed of the warm up period will be maintained while the incline (hill) will increase slightly every 2 minutes. The test will last about 10-12 minutes.

  While you walk, we will monitor the heart rhythm, your blood pressure as described above and your body's oxygen use. You will be asked to breathe in and out through a mouthpiece and wear a nose clip. If you have a problem walking on the treadmill alternatively you can perform the graded exercise test on a bicycle.

  If any abnormalities occur during the test, you will be referred to your primary care physician for further testing. To get a good heart tracing we may ask for your permission to shave small areas of your chest, if needed, before placing the electrodes.

Visit 4 (2 hrs)

- Prior 12-hour fast. No food or liquid besides water is allowed for 12 hours prior to the beginning of this visit. Your blood sugar levels will be monitored and a snack will be available if needed.

- 24hr questionnaire. We will ask if you are experiencing any health complaints (e.g., sore throat, head cold, etc.) and questions regarding your sleep, food,

drink, tobacco, alcohol, caffeine and medication intake and physical activity in the last 24 hrs.

- Body weight. We will measure your body weight using an electronic scale.

- Heart rhythm and blood pressure. We will place small electrodes on your chest to get your heart tracing. We will measure your blood pressure with a cuff on your upper arms and at your thigh.

- Blood vessel tests. We will place an ultrasound transducer (hand-held device that uses sound waves) on the surface of your skin over a blood vessel located at your neck (carotid) and another located at your thigh/groin (femoral) to measure their size and blood flow. We will also place a pencil-like piece of equipment on the surface of your skin at different sites (neck, thigh/groin, elbow, wrist, and ankle) to measure the stiffness of your vessels. A tape will be used to measure the distance between sites.

- Echocardiography. We will place an ultrasound transducer on your chest while you lie still on your side to take pictures of your heart as your heart beats. These pictures will be used to measure your heart function.

- Heart rhythm during controlled breathing. Using small electrodes placed on the surface of your skin, we will record your heart rhythm while you are prompted to breathe in and out at regular and controlled intervals over a 5-minute period.

Visit 5 (1 hr)

- Prior 12-hour fast. No food or liquid besides water is allowed for 12 hours prior to the beginning of this visit. Your blood sugar levels will be monitored and a snack will be available if needed.

- 24hr questionnaire. We will ask if you are experiencing any health complaints (e.g., sore throat, head cold, etc.) and questions regarding your sleep, food, drink, tobacco, alcohol, caffeine and medication intake and physical activity in the last 24 hrs.

- Body weight. We will measure your body weight using an electronic scale.

- Heart rhythm and blood pressure. We will place small electrodes on your chest to get your heart tracing. We will measure your blood pressure with a cuff on your upper arms and at your thigh.

- Blood collection. A small plastic catheter will be placed in a vein in your arm to draw blood (about 12 Tbsp). The blood will be used to measure factors related to blood vessel health.

- Blood vessel test. We will place an ultrasound transducer (hand-held device that uses sound waves) on the surface of your skin, a few inches higher than your right elbow to obtain pictures of your brachial artery. A small size blood pressure cuff will be inflated on your forearm for 5 minutes. The size of your artery and blood flow to your forearm will be measured before and after deflating the cuff.

  It is important to repeat this test on visit 8 over the same location on your arm. For this reason, we will ask your permission to take a photograph of the position of the equipment on your arm. The photograph will be kept in a locked cabinet, in a folder or on a password protected computer. The photograph will not be shown to any individual outside our research team and will be destroyed at the end of your participation. You have the right to refuse to have your photograph taken.

Upon completion of visit 5, if you are assigned to the non-exercise control group you will continue your normal lifestyle for about 9 to 11 weeks and return for testing for visits 6 through 9. However, if you have been assigned to one of the exercise training groups, you will begin the pre-conditioning period, followed by 8 weeks of exercise training and then return for visits 6 through 9. Exercise training will continue until all visits are completed.

During one of the pre-conditioning exercise sessions you will be asked to wear a nose clip and breathe through a mouthpiece to measure your body's oxygen use.

Visit 6 (0.5 hr)

- Prior 4-hour fast. No food or liquid besides water is allowed for 4 hours prior to the beginning of this visit.

- 24hr questionnaire. We will ask if you are experiencing any health complaints (e.g., sore throat, head cold, etc.) and questions regarding your sleep, food, drink, tobacco, alcohol, caffeine and medication intake and physical activity in the last 24 hrs.

- Urine pregnancy test

- Weight,circumferences, and body composition. We will repeat measures of your body weight, waist and hip circumferences and body composition as described under visit 2

- Habitual physical activity. We will ask you questions regarding the type of physical activity you usually do, how hard, how often and for how long you do it. We will also ask you to wear an activity monitor around your hip for 4 days.

- Food diary. To determine the make-up of your diet and the number of calories you eat, you will be asked to keep a food diary for 4 days.

Visit 7 (1 hr)
During this visit we will repeat all of the procedures performed during visit 3 except for the physical exam.

Visit 8 (2 hr)
During this visit we will repeat all of the procedures performed during visit 4.

Visit 9 (1 hrs)
During this visit we will repeat all of the procedures performed during visit 5.

If you have any questions now or at any time during the study, please contact Dr. Demetra Christou listed in question 3 of this form.

8. How long will you be in this research study?

Your total participation will be completed over about 3-4 months depending on scheduling availability. Visits 1 through 9 will require a total of ~11 hours (0.5 to 2 hours/visit; see details in question 7). If you are assigned to the exercise intervention group, you will be asked to visit our laboratory for an additional 32 to 40 training sessions lasting for about 1 hour each. The total number of sessions completed will depend on your initial fitness level and scheduling of the post-testing visits.

9. How many people are expected to take part in this research study?

A total of 246 adults are expected to take part in this study.

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

10. What are the possible discomforts and risks from taking part in this research study?

Maximal graded exercise test: Fewer than 1 in 100 people have an irregular heart beat during testing, about 4 in 10,000 people have chest pain or a heart attack, and 1 in 10,000 people die. In addition, the treadmill test can cause fatigue, dry mouth and jaw discomfort associated with the mouthpiece used to collect the air you breathe out.

Exercise training: In general, when you begin a new exercise program there is a risk that exercise may cause you to feel tired or may lead to muscle and joint soreness, or injury. As your fitness level increases and you become accustomed to the exercise, your energy levels should increase and you should not experience muscle soreness.

In individuals with diabetes, exercise is also related to the following risks:

- a drop in blood sugar levels, even several hours after exercise.

- or an increase in blood sugar levels associated with not having enough water and/or sweating a lot.

- skin blisters and open sores.

- small risk of abnormal heart rhythm, heart attack, stroke and potentially death.

Overall, the widely accepted benefits of exercising for individuals with type 2 diabetes should outweigh the risks. Risks will be minimized by having you complete health screening and pre-conditioning prior to the 8-week exercise training program. In addition, the exercise sessions will be supervised by an Exercise Physiologist. We will follow the exercise training guidelines published by the American College of Sports Medicine, the American Diabetes Association and the American Heart Association. Your blood sugar levels will be monitored and appropriate snacks (e.g., hard candy, energy drinks) will be provided as needed. Your feet will be checked before and after each exercise session for skin blisters or open sores.

Intravenous catheter and blood draw: The risks of drawing blood from a vein include discomfort at the site of puncture; possible bruising and swelling around the puncture site; rarely an infection; and, uncommonly, faintness from the procedure. The total amount of blood collected over the entire study (~3 months) is about 24 Tbsp. A snack will be provided after each the two blood draw visits.

Body composition scan: This research study involves exposure to radiation from X-rays. A Florida Department of Health licensed Basic X-Ray Machine Operator will

perform a dual-energy x-ray absorptiometry (DXA) scan. The radiation exposure from this procedure is typically an effective radiation dose equivalent (HE) of about 2.5 uSv. This is comparable to the amount of natural background radiation exposure people receive over about one day in the United States. The risk from this amount of radiation exposure is too small to be measured directly and is considered to be low when compared with other everyday risks.

Because radiation exposure might affect an unborn baby, a body composition scan will not be given to any patients who are pregnant. All women of childbearing potential must take a pregnancy test prior to completing a scan. The results of the pregnancy test will be made available to you. The use of oral contraceptives is not allowed in this study because of their potential effects on blood vessel function. You must notify Dr. Demetra Christou if you become pregnant during the course of the study.

Blood vessel tests: Inflating the blood pressure cuff on your forearm during this procedure may cause a mild to moderate intensity "pins and needles or numbing" sensation in your forearm and hand that goes away as soon as the cuff is deflated.

Researchers will take appropriate 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. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another 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.

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

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call Dr. Demetra Christou listed in question 3 in this form.

11a. What are the potential benefits to you for taking part in this research study?

You may or may not benefit from participating in this research study. Possible benefits include receiving information regarding your health at no cost. This includes general blood tests, blood pressure, body fat content, bone density, heart health, aerobic fitness and dietary analysis.

If you are assigned to one of the exercise training groups, you may receive direct health benefits by the end of the study. Exercise training has been shown to lead to the following health benefits, but individual responses may vary: better blood sugar control, lower risk for heart disease (lower lipids and blood pressure, healthier blood vessels), lower body fat, better fitness level, reduced stress, reduced depression and improved self-esteem.

If you are assigned to the non-exercise control group, at the completion of your study participation you will receive a step counter and information to help you start a home-based exercise training (walking) program should you choose to do so.

11b. How could others possibly benefit from this study?

Information collected from your participation will help expand medical knowledge and may benefit future patients with type 2 diabetes.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 of this form may benefit if the results of this study are presented at scientific meetings or in scientific journals.

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

The option to taking part in this study is doing nothing. If you do not want to take part in this study, tell the Principal Investigator (Dr. Demetra Christou) and do not sign the Informed Consent Form.

For University of Florida students: The investigators associated with this project may or may not teach in your college or be associated with courses for which you are enrolled or might be expected to register in the future. Your participation in this study is voluntary and any decision to take part or not to participate will in no way affect your grade or class standing. If you believe that your participation in this study or your decision to withdraw from or to not participate in this study has improperly affected your grade(s), you should discuss this with the dean of your college or you may contact the IRB office.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact Dr. Demetra Christou listed in question 3 of this form. She will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

Information collected prior to your withdrawal from the study may continue to be used if the researchers have relied on it to complete the research.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent if you do not follow the instructions given to you by the investigator or fail to meet pre-conditioning criterion within six weeks of training.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

The Sponsor will pay for all procedures required as part of your participation in this study. There will be no cost to you. If you receive a bill related to this study, please contact Dr. Demetra Christou at (352)294-1715.

All other medical services provided to you that are not directly related to the study will be billed to you or your insurance company. You will be responsible for paying any deductible, co-insurance, and/or co-payments for these services, and any non-covered or out-of-network services.

15. Will you be paid for taking part in this study?

No, you will not be paid for participating in this study.

16. What if you are injured because of the 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 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 Dr. Demetra Christou at (720)273-1553 if you experience an injury or have questions about any discomforts that you experience while participating in this study.

17. How will your health information be collected, used and shared?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

- *Complete past medical history to determine eligibility criteria*
- *Records of physical exam*
- *Blood pressure at rest and during maximal graded exercise test*

- *Heart tracing at rest and during maximal graded exercise test and exercise training*
- *Maximal graded exercise test results*
- *Height, weight, circumferences, and body composition results*
- *Physical activity information*
- *Food diary*
- *Blood tests related to blood vessel health*

  Blood vessel tests
- *Echocardiography*

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

To determine the effect of exercise training on blood vessel health in type 2 diabetes.

Once this information is collected, it becomes part of the research record for this study.

19. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- the study Principal Investigator (listed in question 3 of this form) and research staff associated with this project.
- other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures.
- the University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).

20. Once collected or used, who may your protected health information be shared with?

Your PHI may be shared with:

- the study sponsor (listed in Question 4 of this form).
- United States and foreign governmental agencies who 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 who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be collected until the end of the study. This information will be used and disclosed for ever since it will be stored an indefinite period of time in a secure database. If you withdraw your permission for the use and sharing of your PHI, then your information will be removed from the database.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study.

However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

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

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 questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing

Date