UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

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

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study (this "Research Study")?

Adaptability and Resilience in Aging Adults (ARIAA)–2

3. Whom do you call if you have questions about this Research Study (the "Study Team")?

Principal Investigator: Emily Bartley, Ph.D., Assistant Professor, (352) 273-8934
Co-Investigator: Kimberly Sibille, Ph.D., Associate Professor, (352) 294-5864
Clinical Research Coordinator: Kasey Page, B.S., (352) 273-8798

4. Who is paying for this Research Study?

The sponsor of this study is the National Institute on Aging.

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

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

A 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.

a) **In general, what is the purpose of the research, how long will you be involved?** The purpose of this research study is to test a new self-management treatment for low back pain. You are being asked to be in this research study because you are at least 50 years of age and meet criteria for low back pain. Your participation will require eight weekly visits to our research clinic at the University of Florida. These sessions will last approximately 1.5 to 2 hours.

b) **What is involved with your participation, and what are the procedures to be followed in the research?** If you qualify for this study, your participation will last approximately 8 weeks. Each study visit will be scheduled approximately one week apart. We will ask you about your recent health experiences and obtain a list of your current medications. Based on your responses, it may not be appropriate for you to participate in the study. If you decide to participate, you will be assigned to a group-based pain management intervention focused on increasing resilience. You are free to withdraw your participation at any time.

c) **What are the likely risks or discomforts to you?** During the study, you will be asked to complete a series of activity tests and questionnaires. The activity tests may produce discomfort and you can stop these procedures at any time. You may be uncomfortable answering some of the questions on the surveys. You are free not to answer those questions.

d) **What are the likely benefits to you or to others from the research?** You may or may not benefit from taking part in this research study. The potential benefit is that you may experience improvement in your symptoms of low back pain.

e) **What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?** There are no additional procedures or courses of treatment offered during this study.

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

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)?

Your normal clinical care will not be affected by your participation in this study. Tests and procedures done only for research purposes will not be evaluated or used to diagnose or treat any of your medical conditions.

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

You have already completed a brief telephone screening to determine your eligibility and interest in participation. You will also be asked to complete the following procedures during the eight study visits.

Procedures for Visit 1:

- The Informed Consent will be reviewed with you to make certain that you understand everything that is involved in the study.
- A health assessment will be completed which includes obtaining information on your health and current medications. We will also measure your blood pressure and record your height and weight.
- We will conduct a short test of your thinking and memory having you remember things, follow some commands, and write and draw items.
- You will be asked to complete several questionnaires about your physical and emotional health, pain symptoms, how you cope with pain and stress, mood (e.g., whether you feel down or nervous), and how you feel and think about things (including pain). Some of the questionnaires will ask how you are feeling right now or in the recent past, while others ask how you generally feel. You do not have to answer any questions that you do not want to.
- A physical performance test will be conducted which will involve you performing brief movements using your back (e.g., bending down, picking up objects from the floor).

Procedures for Visits 2-8:

- **Pain Management Intervention.** If you decide to take part in this study, you will be assigned to a 7-session intervention whereby you will learn ways in which to manage pain through the development of resilience. Due to COVID-19, visits 2-8 may be delivered online via PHI Zoom video calls. This program will build skills that center on enhancing positive emotions, setting goals, focusing on values, and boosting self-confidence in managing pain. Each session will occur weekly in a group of 6 to 8 people and someone with training in pain management would lead the group. As part of the intervention, we will ask you to complete home activities related to the content of the sessions. These activities will be discussed during each group visit. Examples of self-administered activities include the identification of personal strengths, pleasant activity scheduling, expressing gratitude, values clarification, mindfulness practice, goal setting, and noting positive events.
- During Visit 8, we will ask you to complete several questionnaires about your physical and emotional health, pain symptoms, how you cope with pain and stress, and feedback on the intervention (e.g., satisfaction with the intervention content).
- We will also ask you to complete a series of questionnaires at home about 3 months after the group sessions conclude. These questionnaires will be completed online and will ask about your pain symptoms and mood (e.g., whether you feel down or nervous), and assess how often you are using the skills presented during the intervention sessions.

Session	Content	Home Practice
WK 1: Introduction	Symptoms and causes of back pain. Rationale for resilience in managing pain.	Complete a character strengths survey; Record personal strengths.
WK 2: Pleasant Activities	Benefits of gratitude, pleasant activities, and pacing in the context of pain.	Complete a log of gratitude practice; Engage in weekly pleasant activities.
WK 3: Values-Based Living	Values-based activity and mindfulness practice for pain.	Complete a values assessment; Practice mindfulness exercises.
WK 4: Hopeful Thinking	Setting and achieving attainable goals. Using personal strengths to reach goals.	Select a goal to achieve; Identify areas in life that inspire hope.
WK 5: Positive Reappraisal	Interpreting stressful events and learning ways to reframe negative situations.	Log positive events and situations where reframing was helpful.
WK 6: Self-Efficacy	Discuss achievements made during group; Education on relaxation for stress and pain.	Record group successes; Practice stress management exercises.
WK 7: Review	Review of skills learned during group; Open feedback on group activities and skills.	Continue to practice resilience skills after the end of group.

We would like your permission to audio-record these intervention sessions. We will also be video-recording these sessions via PHI Zoom, however, only the audio will be used and the video file will be promptly deleted after each session. The purpose of these recordings will be to evaluate the study personnel and make certain that they are delivering the intervention appropriately. This review process is a necessary part of the research study as it will ensure that you receive the same intervention that other study participants are receiving. There is a separate form for this that we will ask you to sign.

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

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in question 3 of this form.

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

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 research team will collect:

- Your name, contact information, and tests related to your participation

- Medical history as self-reported
- Current medications
- Responses to questionnaires and home activities
- Your social security number for compensation purposes

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.

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

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

9. With whom will this health information be shared?

This health information may be shared with:

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

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

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

Your participation in this study will require eight visits. The sessions will last approximately 1.5 to 2 hours. There will also be questionnaires and home-activities for you to fill out at home which could take up to 1 hour to complete.

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

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

If you decide to take part in this study, you will be one of approximately 130 people in this research from the University of Florida.

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

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

- The activity tests during Visit 1 may produce discomfort and you can stop these procedures at any time.
- You may experience some distress from completing the questionnaires due to the sensitive nature of the items. You do not have to answer any questions if you do not wish to. We will take all necessary steps to minimize discomfort and you can omit any questions that you do not wish to answer. If your answers to any of the questions suggest that you are feeling down or nervous, we may recommend you seek treatment to help with your mood and give you information about where you can get this type of treatment.

Other possible risks to you may include:

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

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

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in

the research project under the following circumstances. If we learn about child abuse, elder abuse, or intent to harm yourself or others, we will report that information to appropriate authorities.

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

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

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

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

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

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

You may or may not benefit from taking part in this research study. The potential benefit is that you may experience improvement in your symptoms of low back pain.

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

The results of this study may provide information leading to the identification of new self-management treatments for low back pain and may increase our knowledge about the factors that increase positive treatment response.

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

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

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

The other option to taking part in this study is not participating. If you do not want to take part in this study, tell the Principal Investigator and do not sign this Informed Consent Form.

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

15a. Can you withdraw from this study?

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in question 3 of this form. They will tell you how to safely stop your participation.

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

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

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

- You have had an unexpected negative reaction to the study, have failed to follow instructions, you do not have a working camera/microphone or are not willing to turn them on during the Zoom intervention sessions, you are found not to meet eligibility criteria, or because the entire study has been stopped. In addition, if the investigator believes that your continuing in the study could cause problems for you or for the study, you can be withdrawn.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

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

No. There will be no extra cost to you for participating in this Research Study.

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

You will be paid for your participation in this study. We will pay you $60 for Visit 1, $20 each for Visits 2-7, $60 for Visit 8, and an additional $15 for completing the 3-month follow-up online assessments, for a total maximum payment of $255. Payments will be made after each study visit. In addition, for participants traveling more than 25

miles each way to complete study visits, we will reimburse some travel expenses at up to the federal mileage rate. You will receive partial payment if you do not complete the entire study.

If you are paid more than $75 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. Payments to ***nonresident aliens*** must be processed through the University of Florida Payroll and Tax Services department. If the payments total $600 or more in a calendar year, the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: http://privacy.ufl.edu/SSNPrivacy.html.

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

If you have any problems regarding your payment contact the principal investigator.

18. What if you are injured while in this Research Study?

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

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

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

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

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

SIGNATURES

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

Signature of Person Obtaining Consent and Authorization Date

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 above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing Date

Consent to be Photographed, Video and/or Audio Recorded

With your permission, you will have the following done during this research (check all that apply):

☐ photographed ☐ video recorded ☐ audio recorded

Your name or personal information will not be identified on the photograph(s), video or audio recordings, and confidentiality will be strictly maintained. However, when these photograph(s), video and/ or audio recordings are shown or heard, others may be able to identify you.
The Principal Investigator (PI) of this study, _____, or *[his/her]* successor, will keep the photograph(s), video and/or audio recordings in a locked cabinet, in a folder on a password protected computer server drive, or as an encrypted electronic file. These photograph(s), video and/or audio recordings will be shown under *[his/her]* direction to students, researchers, doctors, or other professionals and persons. Please indicate under what conditions Dr. _____ has your permission to use the photograph(s), video and/or audio recordings, and sign and date below.

☐ The following will be **destroyed once the study is closed** (initial next to all that apply):
____ photograph(s) _____ video recording(s) _____ audio recording(s)

☐ As described in the Informed Consent Form, and for the purposes of **education at the University of Florida Health Science Center**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):
____ photograph(s) _____ video recording(s) _____ audio recording(s)

☐ As described in the Informed Consent Form; for the purposes of **education at the University of Florida Health Science Center; and for presentations at scientific meetings outside the University**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):
____ photograph(s) _____ video recording(s) _____ audio recording(s)

_____ _____
Signature Date