Official Title: Evaluation of the Wits Workout Wellness Program for Older Adults

Document: Informed Consent Form

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University of Illinois at Chicago (UIC) and/or
Research Information and Consent, and Authorization for Participation in Social, Behavioral, or Educational Research
Wits Wellness Program Participant Informed Consent

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Sponsor: Midwest Roybal Center for Health Promotion and Translation

About this research study
You are being asked to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

Taking part in this study is voluntary
Your participation in this research study is voluntary. You may choose to not take part in this study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with the University of Illinois at Chicago (UIC), the University of Illinois at Urbana Champaign (UIUC), or the University of Illinois Extension Office.

This consent form will give you information about the research study to help you decide whether you want to participate. Please read this form and ask any questions you have before agreeing to be in the study.

You are being asked to participate in this research study because you are an adult over age 50, live in Illinois, and have expressed interest in participating in the Wellness Workshop. A total of 300 participants will be enrolled in this research study.

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

WHY IS THIS STUDY BEING DONE?	We want to evaluate the effects of a 12-week wellness program for adults age 50 and older.

WHAT WILL I BE ASKED TO DO DURING THE STUDY?	You will be invited to participate in the 12-week wellness program immediately or you will be in a waitlist group for the next session. Regardless of what group you are in you will be asked to complete an online questionnaire prior to the start of the 12-week program or waitlist, which asks questions about you and your health, including your physical activity, sleep, stress, cognitive and social health. If you are unable to complete the online survey, we will offer you the opportunity to take the survey via phone, or provide you a paper copy via mail. You will then participate in the 12-week program one time a week for 60 minutes or you will be on a waitlist and complete the program later. The program will be offered in-person unless state requirements change and then we will offer it online using Zoom. At the end of the 12-week program or waitlist period, all participants in both groups (workshop and waitlist) will complete the same online survey described above, as well as a phone call to ask some additional questions about your health. Again, three months after the end of the program or waitlist period all participants in both groups will be asked to complete the same online survey and phone call. If you participated in the first 12-week wellness program, you will be invited to come to a focus group meeting with the workshop participants and researchers where we will ask you questions about your experience and participation in the program. We will audiotape the focus group so that we can transcribe your responses. All participants will be compensated $20 for completing the study survey and phone calls at each time. You could earn up to $60 for completing all three surveys and phone calls. Participant safety is our top priority. Local and state guidelines and regulations for COVID-19 will be followed for all in-person study procedures. In the event that the research cannot be conducted in-person, the research team will transition to using a video conferencing platform such as Zoom. None of the workshops will be video or audio taped. If we conduct the focus group by Zoom we will audio and video tape the focus group so that we can transcribe it. We will delete the video tape immediately and use the audio to create a transcription. The audiotape will be deleted immediately

	after it is transcribed.
HOW MUCH TIME WILL I SPEND ON THE STUDY?	The survey (either online, via phone, or via mail) will take approximately 30 minutes each time. The additional phone call questions will take about 15 minutes each time. The total time estimated to complete all surveys and phone calls over the course of the project will be 2.5 hours. The wellness workshop is 60 minutes one time a week for 12 weeks for a total of 12 hours. The focus group interview will last 60 minutes. The total amount of time for the entire study will be approximately 15.5 hours.
ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?	You may find that participating in the program benefits some aspects of your health or well-being. Your participation may also benefit others in the future by helping us learn more about how the program affects others.
WHAT ARE THE MAIN RISKS OF THE STUDY?	The primary risks presented by this research study are breaches of privacy (others outside of the study may find out you are a subject) and/or confidentiality (others outside of the study may find out what you did, said, or information that was collected about you during the study). Data collected via the electronic/paper survey and/or phone call will be stored in a secure electronic database only accessible to the research team members. However, security of electronic data collection depends on the technology used and cannot be 100% guaranteed. While researchers will ask others in the focus group to respect each other's privacy, and not repeat what is said to others outside of the group, this confidentiality cannot be guaranteed.
DO I HAVE OTHER OPTIONS BESIDES TAKING PART IN THE STUDY?	This research study is not designed to provide treatment or therapy, and you have the option to decide not to take part at all or you may stop your participation at any time without any consequences.
QUESTIONS ABOUT THE STUDY?	For questions, concerns, or complaints about the study, please contact Julie Bobitt at 312.355.0247or email at jbobitt@uic.edu.

	If you have questions about your rights as a study subject; including questions, concerns, complaints, or if you feel you have not been treated according to the description in this form; or to offer input you may call the UIC Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research. Please also feel free to ask the researchers questions at any time.

What procedures are involved?

This research will be performed at a University of Illinois Extension office or partner facility.

The study procedures are:

→ *After an initial screening phone call, if you qualify for the study, you will be sent a consent form and a survey. The survey asks questions about you and your health, including your physical activity, sleep, stress, cognitive and social health. If you are unable to complete the online survey, we will offer you the opportunity to take the survey via phone, or provide you a paper copy via mail. This survey should take approximately 30 minutes. You will be provided a gift card (Visa or Amazon) in the amount of $20 for completing the survey.*

→ *When you return the first survey you will be 'randomized' into one of the two study groups. Randomization means that you are put into a group by chance, it is like flipping a coin or pulling numbers from a hat. Neither the investigators nor the study participants can choose the group into which you are assigned, it will be done by a computer. You will be either invited to participate in a health and wellness workshop immediately (Group 1) or you will be assigned to a waitlist group for the next workshop session (Group 2).*

→ *If you are assigned to Group 1, you will participate in the 12-week health and wellness program one time a week for 60 minutes.*

→ *If you are in Group 2, you will continue go about your everyday life until you are assigned to the next workshop series in approximately 6 months.*

→ *All participants in both groups (workshop and waitlist) will be asked to complete the same survey and a phone call with some additional question at 3 months (**the end of the 12-week program or waitlist period**) regardless of which group you are in. You will be provided $20 for completing the second survey and telephone call questions.*

→ *If you are in Group 1 you will be asked to complete a brief satisfaction questionnaire on the last day of the 12-week workshop about the health and wellness program. You will be asked questions about the program components and the facilitator. This will be provided on paper*

at the end of the workshop program. If the program is offered online, this will be provided electronically via a secure survey link.

→ *Both groups (workshop and waitlist) will be asked to complete the same survey and phone call **at 6 months after the baseline survey** (3 months after you filled out the second survey). You will be provided $20 for completing the follow-up survey and telephone call.*

→ *If you are in Group 1, after you complete the six-month survey (three months after the end of the 12-week program), you will be invited to come to a focus group meeting with your fellow workshop participants. We will serve refreshments and will ask you questions about your participation in the program. For example, we may ask you how you feel about the program, if you have any suggestions for changing program components, etc. This focus group meeting will be audio recorded so that we can transcribe it.*

→ *All COVID precautions will be implemented and followed for in-person workshop program sessions and focus group meetings. If either the workshop sessions or the focus group meeting cannot be conducted in-person due to local and state regulations pertaining to COVID-19, they will be conducted electronically using a video conferencing platform such as Zoom. If we use Zoom the workshop series will NOT be recorded. The only aspect of the study that will be recorded is the focus group. Should we need to conduct the focus group online via Zoom we will audio/videotape the session so that we can transcribe it. The videotape will be immediately destroyed and the audiotape will be deleted as soon as we have transcribed it.*

During this study, Dr. Julie Bobitt and members of the research team will collect information about you for the purposes of this research. We will collect your name, address, email and phone number. We will collect demographic information about you such as your birth year and any chronic health conditions you may have. We will ask you about your quality of life, physical activity, sleep, stress, cognitive and social health.

What will happen with my information used in this study?

Your identifiable private information collected for this research study will not be used for future research studies or shared with other researchers for future research.

What about privacy and confidentiality?

Efforts will be made to keep your personal information confidential; however, we cannot guarantee absolute confidentiality. In general, information about you, or provided by you, during the research study, will not be disclosed to others without your written permission. However, laws and state university rules might require us to tell certain people about you. For example, study information which identifies you and the consent form signed by you may be looked at and/or copied for quality assurance and data analysis by:

- Representatives of the university committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for the Protection of Research Subjects.

- Other representatives of the State and University responsible for ethical, regulatory, or financial oversight of research.
- Government Regulatory Agencies, such as the Office for Human Research Protections (OHRP).
- The sponsor of the research study, Midwest Roybal Center for Health Promotion and Translation.

A possible risk of the study is that your participation in the study or information about you might become known to individuals outside the study. Your personal information, survey and focus group data will be kept on a password protected server. Survey data that is returned via mail will be stored in a locked cabinet in a locked office to prevent access by unauthorized personnel. All participants are assigned an alphanumeric ID so your name or any other identifiable information will never be associated with your responses on the surveys or focus group data. When the study is finished and the data analysis is complete, all names will be deleted from the study data. Your contact information will not be retained or kept for future research studies.

During the focus groups, the researchers will ask all members of the group to respect each other's privacy and confidentiality, and not identify anyone in the group or repeat what was said during the group discussion, but other members of the group may accidentally disclose this information.

When the results of the study are published or discussed in conferences, no one will know that you were in the study. The data we present is averaged across all participants in the study groups. During the focus group part of the study audio recordings will be collected. Your identity will be protected or disguised by removing any identifying information when the tape is transcribed and by destroying the audio-tape once it has been transcribed.

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

What are the costs for participating in this research?
There are no costs to you for participating in this research.

Will I be reimbursed for any of my expenses or paid for my participation in this research?
You will receive up to $60 for your participation in the study. You will receive a gift card in the amount of $20 per survey/phone call you complete (there are three survey/phone questionnaires). If you do not finish the study, you will be compensated for the surveys you have completed. If you complete the study, you will receive a total of $ 60. Your contact information will be shared with e-gift card issuers for compensation purposes only. You will receive your payment within 30 days by email or mail depending on your preference. You will have the opportunity to enter your name each week that you attend a workshop session for a monthly giveaway of a prize such as a mug, t-shirt, drink coupon, or book. If you complete all 12 sessions you will have your name entered into an additional drawing to receive a similar prize. Your name will be put in a

drawing and your chances of winning depend on how many complete the program but are estimated to be 1 out of 15.

Can I withdraw or be removed from the study?
If you decide to participate, you have the right to withdraw your consent and leave the study at any time without penalty. You may do so simply by emailing or calling the primary researcher, Julie Bobitt at 312.355.0247or jbobitt@uic.edu. The researchers also have the right to stop your participation in this study without your consent if they believe it is in your best interests, you were to object to any future changes that may be made in the study plan.

Remember:
Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

[if virtual or verbal consent is obtained]
Documentation of Subject Consent
I have read the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I will be given a copy of this form.

Do you provide your consent to participate in this research study and authorization for the researcher to use and share your de-identified health information for this research?

☐ Yes, I DO consent to participate in this research
☐ No, I DO NOT consent to participate in this research

PLEASE SAVE A COPY OF THIS DOCUMENT FOR YOUR RECORDS.