

Official Title: Deaf Weight Wise: Community-engaged Implementation Research to Promote Healthy Lifestyle Change With Deaf American Sign Language Users

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The Informed Consent process proposed here has 3 components and will be conducted virtually via Zoom or videophone. This study team successfully implemented this Informed Consent process in both previous Deaf Weight Wise studies (in person) and received very positive feedback from those original study participants.

1) During the enrollment virtual appointment, an informed consent video will be shown to the subject. The informed consent video will feature Deaf actors using American Sign Language dialogue scenarios (see English version of Informed Consent video script), which have been shown to be effective with health education materials¹⁶ and are considered to be the optimal learning style for many deaf people due to the dialogic nature of ASL. The consent video was scripted using information from the English version of the Study Information Sheet. This has been successfully used in both previous Deaf Weight Wise clinical trials.

The link to the final ASL consent video for this study is:

<https://www.youtube.com/watch?v=xd4235y-RfU>

This video has English captions available (click cc: button to view). 2) Upon completion of the video, the subject will be required to meet one-on-one with a sign-fluent member of the research team (on Zoom or videophone call). Research staff will engage in a one-on-one discussion with each subject privately to answer any questions, confirm that each subject makes a rational and thoughtful decision to participate without any element of coercion or undue influence, and to provide and review as needed the written English version of the Study Information Sheet (will share a pdf file through e-mail). Research team members have experience in obtaining informed consent from deaf participants; any new staff will be fully trained prior to enrollment visits.

3) Verbal/ASL consent will be obtained from all study subjects live during the Zoom/videophone call. The research staff member will document that they obtained informed consent from the subject and that the subject watched the ASL video (see Documentation of Consent). Potential subjects may review the consent video and documents as many times as they wish. Subjects will receive the Consent Video link in YouTube and the English. This consent process proposed here requires an alteration of HIPAA authorization in that we request a waiver of written authorization. This waiver of written authorization is allowable here because this study involves no more than minimal risk to the privacy of individuals and an adequate plan is in place to protect any identifiers/PHI from accidental disclosure, we are destroying identifiers at the earliest opportunity, and identifiers/PHI will not be disclosed to any other entity except as required by law or for authorized oversight of the study. We cannot practicably carry out this virtual research without this waiver of written authorization; the process proposed here is

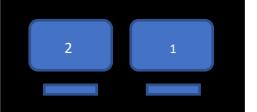
culturally and linguistically appropriate because it is happening live in sign language, the primary language of subjects. Consent/authorization will be documented by trained Deaf research staff who will be able to conduct and assess the subject's consent.

Deaf Weight Wise: Implementation Research: RSRB 5784 12.28.2020

American Sign Language (ASL) Informed Consent Video Script: English Version

Section Title/ Content Area	SCRIPT	SCENE/VISUAL CONTENT
<i>Purpose of Study</i> <i>Requirements to Join</i> <i>Study Schedule</i> <i>Data Collection</i> <i>Study Program</i> <i>Risks and Benefits</i> <i>Incentives/Payments</i> <i>Voluntary</i> <i>Participation</i> <i>What's Next?</i>	<p><i>Actors:</i></p> <p><i>(actors communicate in American Sign Language)</i></p>	<i>Scene location and/or Visual Content that will be added graphically</i>

Computer Generated Image (CGI): Welcome to DWW!

<i>Welcome:</i>	<p>Actor #1 Thank you for your interest in Deaf Weight Wise! In this video we will explain what Deaf Weight Wise program is, in-depth. At the end of this video you will have the option to consent to join Deaf Weight Wise, which can confirm your commitment to adapt to a healthier lifestyle!</p> <p>Actor #2 Hello, You will see both of us in this video, due to COVID-19, we are filming remotely. You will see both of us throughout the video.</p> <p>Actor #1 looks left at Actor #2 both actors nods.</p> <p>Both actors look straight across at the end. Hands down.</p>	 
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CGI: What is Deaf Weight Wise (DWW)?

	<p>Deaf Weight Wise (DWW) is a 16-week healthy lifestyle program for Deaf ASL users who are 18+. DWW is led by Deaf counselors with Deaf participants.</p> <p>During the 16-week program, participants will learn how to make small changes to lead a healthier lifestyle. These changes</p>	
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	may include, healthier food choices, learning new recipes, incorporating exercise and ways to move more in your everyday life, and develop tools to keep you on track with your new lifestyle for years to come.	
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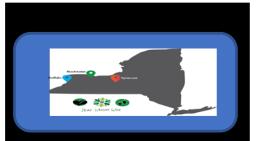
CGI: Requirements to Join DWW

<p>Requirements to Join:</p>	<p>Actor #2</p> <ol style="list-style-type: none"> 1. You are deaf 2. You sign/ASL 3. Your age is 18 or over 4. Your BMI is 18.5 or above <p>What is BMI? It is Body Mass Index. (Expand) We will accept BMI of 18.5 or above. BMI is calculated by using your height and weight (research staff will help calculate this).</p> <p>The next step is to watch this video to learn more about the research program. There may be an additional step for some people who report certain health issues: we may need to ask you to get permission from your doctor to be sure it is safe to do some of the activities in DWW.</p>	 <p>(BMI chart PIP)</p> 
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CGI: Who is leading DWW?

<p>Purpose of Study:</p>	<p>Actor #1 Who is doing this research program?</p> <p>National Center for Deaf Health Research (NCDHR) is conducting this study. NCDHR is based at University of Rochester and gets funding from the Centers for Disease Control and Prevention (CDC). This is done by a team of researchers, both deaf and hearing.</p> <p>NCDHR has partnered with agencies, programs and clubs that provide services Deaf communities in Rochester, Buffalo and Syracuse to host our DWW research program. See the team's picture(points to left corner of the screen)</p>	
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CGI: display of What is DWW? (show graphic 20-30 seconds)

	<p>Actor #1 The NCDHR has learned so much from hosting DWW in Rochester and want to continue to provide Deaf communities with the tools they need to adapt to a healthier lifestyle. This time we will be partnering with Deaf Communities in Rochester again, but also with Syracuse and Buffalo, to expand Deaf Weight Wise. (points to left corner of screen)</p>	<p>X:\Communications\Deaf Weight Wise 3.0\DWW for Riki\Deaf Weight Wise Map "NCDHR DWW MAP"</p> 
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CGI: Study Schedule/Program

<p>Study Schedule/Program:</p>	<p>Actor #2 What is DWW? The 16- week program will include DWW Group Sessions through Zoom (video calls). These group sessions will be led by a Deaf Counselor with Deaf participants. To join, you'll need to use a laptop, computer, tablet or smart phone.</p> <p>How often will I meet with the group on Zoom?</p> <p>Each DWW group will meet for two hours once a week for 16 weeks (4 months).</p> <p>Like we mentioned earlier, you will participate in the 16- week DWW program, after that -- you are not exactly done. It is now called the "maintenance phase."</p> <p>After the 16-week program is finished, you will then be in what we call the "Maintenance Phase." This phase is six months long but only has two meetings.</p> <ol style="list-style-type: none"> 1. Meeting #1 at Three months 2. Meeting #2 at Six months <p>Other than the two meetings, your counselor will continue to check in with you through videophone (VP) (1x/month) and email (every 2 weeks), just to see how you are doing and if you need additional support.</p>	<p>X:\Research\Deaf Weight Wise 3.0\Consent video "zoom or VP"</p>  <p><i>Picture of DWW calendar with a general timeline)</i></p> <ul style="list-style-type: none"> • Jenna will locate the picture from SIS 
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<p>Combining both the 16 week (4 month) program and Maintenance phase (6 months), this is a total of 10 months. In addition to the DWW group meetings, you will also have three “appointments” with NCDHR researchers for health interviews. This is to help us learn more about how the DWW program works.</p> <p>What will we do? The schedule of your health research appointments looks like</p> <ol style="list-style-type: none"> 1. Start of enrollment (today) 2. 6-month (after 16 week program) 3. 18-month (One year later after DWW program finishes) <p>Each appointment will be similar. You will meet with a NCDHR researcher over zoom or VP, they will ask you questions about your eating and exercise habits. All information shared during these appointments will be confidential. We will also ask you to complete online survey in ASL (some of the questions will change between start, 6 month and 18 months). This will only require about one hour of your time each time.</p>	
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CGI: Incentives and Payment

<p>Incentives and Payment:</p>	<p>Actor #1 Will I be paid for joining?</p> <p>It is free for you to join- Yes, you will be paid for each of the (3) appointments we just mentioned.</p> <ol style="list-style-type: none"> 1. \$30 for baseline/enrollment appointment 2. \$40 for 6month appointment 3. \$50 for 18month appointment <p>You will receive your payment (Visa Card), by mail. The Visa Card we provide you with can be re-loaded each time you complete a DWW appointment. Once you receive the card, keep it this throughout DWW. For purposes of payment, we will ask for your date of birth. Your date of birth will be shared with the gift card management company (named Forte) for purposes of verifying your personal gift card account. Your date of birth will be kept confidential and will not be used or connected with any other part of this research program.</p>	<p>(include picture of payment schedule and visa card)</p>  <ul style="list-style-type: none"> • Jenna will locate the picture from SIS
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	<p>We also have additional incentives/prizes during the 16-week program, called WiseBucks. You can earn WiseBucks each week and earn points to get prizes such as a yoga mat or kitchen gadgets.</p>	 <i>X:\Research\Deaf Weight Wise 3.0\Curriculum review\Wisebucks Planning(need to fix)</i>
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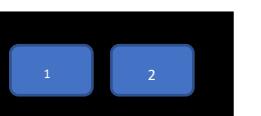
CGI: Risk and Benefits

Risks and Benefits:	<p>Actor #2</p> <p>As with any research program there are risks and benefits to joining. We want you to be aware of what may or may not happen.</p> <p>-Risk of feeling uncomfortable about some of the questions we ask in the health interview or survey. You can skip any question you don't want to answer.</p> <p>We will provide additional resources based on services in your area.</p> <p>-You may see other deaf people that you know, or learn of others that are participating in DWW.</p> <p>All counselors and researchers are trained in confidentiality and research ethics protocols.</p> <p>While you are participating in DWW, you and other group members will agree on confidentiality policy.</p> <p>This is also a benefit to community and future members of DWW since we are one of the first groups to study health issues among the Deaf community.</p> <p>- We can't guarantee 100% privacy, but will never use your name in reports, results, and presentations.</p> <p>- ClinicalTrials.gov is a website that provides information about clinical trials. A description of the DWW clinical trial will be available on http://www.clinicaltrials.gov as required by U.S. Law. This website will <u>not</u> include information that can identify you. The website will include a summary of the overall research results. You can search this website at any time.</p>	
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CGI: HIPAA: language about authorization

HIPAA: language about authorization	<p>Actor #1 Health Insurance Portability and Accountability Act (HIPAA)—you know you go to the doctor's office and they give you a paper about privacy? Same here—HIPAA is a federal law about protecting your health information and privacy. It requires us to get your authorization as part of this informed consent process today. For example, we will use your height and weight and other health information you give us, to see if DWW is effective.</p> <p>If you decide to give permission to use your health information, you can always decide to cancel your authorization. You can choose to quit this research at any time without canceling your Authorization.</p> <p>We wouldn't ask for any more health information after that in the future. But we would keep the health information you already gave us before that request to revoke.</p> <p>That HIPAA info is in the email document you will get today. Also, this consent information in this video, you will get an email copy as well. We can also mail you a copy of it on paper.</p>	PIP: Spell out HIPAA vertically 
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CGI: Use and Conditions of E-Mail

Use and Conditions of E-Mail:	<p>Actor #2 We want you to be aware that there are also risks and benefits of using E-Mail:</p> <p>For many Deaf people, E-mail sometimes can be the best way to get in touch. There are important things to keep in mind while using E mail during DWW. Actor #1 nods</p> <p>Actor #1 Some things to keep in mind:</p> <ol style="list-style-type: none"> 1. Email can mistakenly be sent to others, or forwarded and printed on paper. 2. Your email system-- like Gmail, Yahoo and others including University of Rochester-- They sometimes will inspect old emails being archived. Also, if you delete, the email may still be there. 3. Email can be stolen, changed and forwarded to other people without authorization and may include virus. 	 <p>Actor #2 freezes in pose facing camera when Actor #1 talks.</p> 
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	<p>Actor #1 We will continue to do our best to maintain confidentiality and protect all emails that are sent and receive. You and the researcher must agree to keep all emails confidential.</p> <p>Actor #2</p> <p>This also includes why email sometimes cannot be appropriate.</p> <ol style="list-style-type: none"> 1. Email is not appropriate for urgent or emergency situations. We will try our best to read and respond to any e-mail you send but we cannot guarantee to respond if you send during emergency. It is better to call. 2. Keep your email SHORT with important information. Nothing personal or sharing your information. If you want to discuss personal issues, it is best to schedule an appointment through email to discuss through Zoom or VP. 3. Any communication you send will be kept in your research record. 4. If the person you sent an email cannot answer (example: out of the office), the email may be shared with the team to respond to your question. The team will keep all emails confidential. 5. The research team will not share any email that shows your name or know it is from you to another people outside of URMC or your site without your written consent or as authorized or required by law. 6. Email is not used for communication about medical information. 	<p>Unfreeze actor #2 to nod in support of #1</p> <p>#2 Continues talking #1 looks left corner at #2</p> <p>Actor #1 talks and Actor #2 looks right at #1</p> <p>Actor #2 nods and signs to self “keep short”</p> <p>Actor #2 nods in agreement</p>
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CGI: Voluntary Participation

Voluntary participation:	<p>Actor #2 If you decide to consent to join DWW, you can decide to not participate at any time.</p> <p>Joining is up to you. You can decide not to join, or join and then later change your mind and quit at any time. No penalty or consequences if you join or quit. You will be paid for each appointment with NCDHR (interview, survey) visit you attend like we explained before. If you quit or withdraw from the program, you will not be paid for future visits.</p>	
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<h2>CGI: What's Next?</h2>		
What's Next?	<p>Actor #1 So now that you have watched our explanation, we will be happy to answer any questions you may have and one of the researchers will meet with you (1:1 on zoom/VP).</p> <p>Actor #2 The researcher will answer all of your questions and will then ask you if you are ready to give your consent/permission to join this research program. The researcher will document whether or not you give your consent. The researcher will also send an email (consent form) so that you have a copy of everything.</p> <p>Actor #1 and #2 Thank you!!</p>	 <p>No freezing of actors Actor #2 looks at Actor #1 Actor #1 looks at Actor #2</p>  <p>Add slide at the end of the video: If you wish to talk to someone other than the research staff about your rights as a research subject; Or to share concerns about the research; Or to provide input about the research process; Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441.</p>



Deaf Weight Wise: Implementation Research

Consent Documentation Form for DWW Research Staff

Participant and Research Coordinator will meet on Zoom or Videophone as part of enrollment/consent process. Participant will watch consent video in American Sign Language. Participant will be given a copy of the English Study Information Sheet.

After video is watched, ask:

Do you have any questions? Do you agree to participate in this study?

- Yes: Document consent below and continue with the health interview. Inform the participant that they will get a copy via email (and mail if requested).
- No: Thank them for their time.

Name of Subject:

Person Obtaining Consent (Research Staff)

- The person watched a video in sign language about the Deaf Weight Wise Implementation Research study.
- The person was able to ask questions and all questions were answered.
- The person understands the Deaf Weight Wise Implementation Research study.
- I will provide the person with a copy of this consent form.

Print Name and Title

Signature of Person Obtaining Consent

Date