Informed Consent Forms

For

Steps to Effective Problem-solving (R01HD086211)

NCT02855008

April 8, 2021

Including:

1. Consent for STEPS arm of clinical trial for residents with intellectual and developmental disabilities
2. Consent for STEPS arm of clinical trial for residential staff
3. Consent for Food for Life arm of clinical trial for residents with intellectual and developmental disabilities
4. Consent for Food for Life arm of clinical trial for residential staff.

RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

Site Principal Investigator:	Sarah H. Ailey PhD RN
Department:	Community, Systems, and Mental Health Nursing
Address and Contact Information:	600 S. Paulina #1030B (312) 942-3383 Sarah_H_Ailey@rush.edu

Protocol Title:	Steps to Effective Problem-Solving
Sponsor(s):	National Institutes of Health – Eunice Kennedy Shriver Institute

Name of Participant:

_____

Note: *If you are the guardian or legal representative of a person with intellectual disabilities who is not able to consent for themselves, the terms "you" or "your" refer to the person being asked to participate in this research.*

Key Information:

You are being invited 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.

This consent form will give you information about the 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.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected, and services provided by your community service provider will not change or be affected.

The purpose of this study is to determine if a program called Steps to Effective Problem-solving (STEPS) works if done virtually over Webex as when done in person and whether information we collect during the STEPS Virtual program is useful in determining if your problem-solving skills improve and whether problem behaviors in group homes improve.

If you agree to participate in this study, your participation will be about 24 weeks (six months).

STEPS is a social problem-solving skills training program that assists people in improving their attitude to problems, learning how to define problems, figuring out various alternatives for solving problems, predicting what will happen when using various alternatives, and trying out chosen alternatives. The STEPS Program has six sessions covering these topics, that go about every other week for 12 weeks, and seventh "booster" session about six weeks later. Each session lasts about an hour. A research team member and an assistant will work with you, your house mates who want to participate, and your staff who want to participate in the STEPS program over Webex.

Before the program starts, a research team member will contact you to set up a time to meet over the phone or over Webex in order to ask you questions about your mood, about how you solve problems, and about what you know about nutrition. You and the other participants in the home will be asked to be in a videotape of a discussion about a problem you agree together to discuss. The video will be about 10 minutes long. The videotape will be recorded by a research staff member using the video function in Webex. A research staff member will also contact you and the other participants after you finish the STEPS program (at about 12 weeks) and about three months (at about 24 weeks) after that. The staff member will ask the same questions and make another videotape over Webex of a discussion about a problem that you and other participants all agree to discuss.

There are risks to you for participating in this study. People sometimes feel like they have a lot of problems. In this study, there is a risk that you may feel more sad or anxious about problems or may act in ways that don't help or in ways that make the problems worse while you participate in the STEPS program. It is possible that you might need to contact a doctor about these feelings of sadness and anxiety or about the ways you act. If so, you will need to contact your own insurance about paying for this. If your responses to the questions indicate that your problems are immediate, you or your guardian, if you have a guardian, will be told and asked to contact your mental health provider or given the name of a mental health provider. You will also be asked if you want to name someone close to you, like a family member or staff member, who can be told about your feelings and who can help you with treatment and appointments. There may be other risks that may happen that we cannot predict.

There may be no direct benefit to you for participating in this study**.** However, it is possible that you might learn some new ways of dealing with problems that you have. It is also possible that you and your housemates might be better able to solve problems together and that you and others will have fewer behavior incidents. Also, the study may benefit professionals to better understand how to work with people such as yourself and with the service providers who serve you on strategies for dealing with problems more effectively.

You do not have to participate in the research. If you feel like you have a lot of problems, you could see your health care provider about this.

<u>Detailed Information</u>: Please review the rest of this document for details about the above topics and additional information you should know before making a decision about whether or not you will participate in this study.

<u>Why are you being invited to participate in this study?</u>
You are being asked to participate in this study because you are someone with an intellectual disability and you are living in a group home for people with intellectual disabilities.

<u>How many participants will take part in this study?</u>
We are asking people like yourself living in 36 group homes (about 180 people) and residential staff people (about 72-108 staff) who work in the group homes to participate. Those of you in 18 group homes will participate in the STEPS program and those in the other 18 group homes will participate in the Food for Life nutrition program. The Food for Life program is a nutrition program. We want to know if participants in STEPS program are similar in learning problem-solving and having behavior incidents and in nutrition knowledge and weight and BMI as participants in the Food for Life program.

<u>Will you be contacted about participating in future research?</u>
If you agree, we may contact you after your participation in this study about participating in future research. Please initial and date one of the following options:

_____ _____ Yes, I agree to be contacted about future research.
Initials Date

_____ _____ No, I do NOT agree to be contacted about future research.
Initials Date

<u>What if there is new information that may affect your decision to participate in this study?</u>
During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent form in order to continue participating in this study.

<u>Will you receive your individual results from the study?</u>
Generally, activities performed for research purposes are not meant to provide clinical information. During our interventions, we may learn things about your mood that could be important to your health or treatment. If this happens, this information will be shared with you or someone you choose to receive the information. Along with this document, we will provide you with a document for release of information if you choose to have the research team share important information about your mood with someone you choose.

<u>Can you leave or be removed from this study?</u>
You have the right to leave a study at any time without penalty. Leaving the study does not affect any treatment or services you receive at Rush or from your community service provider. For your safety, however, you should consider the study doctor's advice about how to leave this

study. If you leave this study before the final study visit, the study doctor may ask you to complete the final steps.

The researchers and Sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You do not follow the instructions;
- The study is cancelled for any reason.

What about confidentiality of your medical information?

This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold or refuse your treatment, payment, enrollment, or eligibility for benefits if you do not sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study or receive study-related treatment.

By signing this document, you voluntarily authorize (give permission to) Dr. Sarah Ailey, her study team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information that identifies you for the study described in this document.

During the study, Dr. Sarah Ailey and her study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI that we will collect are records kept by the community service provider managing your group home. We specifically will collect information from the Inventory for Client and Agency Planning (ICAP), a form the community service provider fills out about you every year. It includes information such as: your age, ethnicity and gender; about your disability; and your behavior. We will also collect information on medications you use, your weight, and information from any behavior incident reports that involve you, and about events that may have happened in your life such as a change in job, housing and/or important events with your family.. We are not collecting PHI from your health care providers, except as also in the records at your community service provider. There may be new PHI information obtained as a result of this study This information about you will be used to complete this research.

Dr. Sarah Ailey and her study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of this study. Your health information described above may be used or disclosed to:
We may share your information with people who help with the research. Some of these people may be other researchers outside of the hospital or are in charge of the research, pay for, or work with us on the research. Some of these people make sure we do the research properly. The persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. For this study, we will share information with:

- Staff outside Rush who have assisted us with developing and evaluating STEPS
    - Dr. Tamar Heller PhD,_University of Illinois at Chicago
    - Dr. Arthur Nezu PhD,_Drexel University, Philadelphia, PA.
    - Dr. Janet Melby RN PhD, Iowa State University, Ames, IA.

- The study Sponsor, Rush University College of Nursing, and its representatives, and our Data Safety Monitoring Committee
- Monitoring agencies such as the National Institutes of Health and the Rush Institutional Review Board (IRB).

While you participate in the study, your access to your records at your health care provider and at your service provider and will not change, but Dr. Sarah Ailey is not required to release to you study information that is not part of your records. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. The results of study tests/procedures performed as part of this study may become part of your record at your service provider. Any study information in your record will be kept indefinitely. Your identity will not be revealed on any report, publication, or at scientific meetings. All audio and video recordings will be destroyed upon completion of the study or earlier if you request.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed below.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Sarah Ailey at 312 942-3383 or Sarah_H_Ailey@rush.edu. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety of this research study. It will expire upon completion of the study or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. Records of participation in this research study will be maintained at Rush College of Nursing and kept confidential as required by law. In order to conduct the study, the study nurse Dr. Sarah Ailey, will use and share personal health information about you. This includes the information that the research staff obtain during the visits before and after the STEPS program and information from your service provider. All information about you and your participation in the study will be kept in a locked cabinet and office. Digital files will be encrypted. Your identity will not be revealed on any report, publication, or at scientific meetings.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

If you disclose actual or suspected abuse, neglect, or exploitation of a disabled adult, the researcher or any member of the study staff must, and will, report this to Adult Protective Services, and/or the nearest law enforcement agency.

What are the costs to participate in this study?
No billable services are provided. All costs for the research, including conducting the intervention, interviews regarding how you solve problems and your mood, and coordination of activities will be paid by a grant from the National Institutes of Health-Eunice Kennedy Shriver Institute.

Will you be compensated or paid?
You will receive a $20 Target gift card for each time research staff visits you to ask questions. For three interview sessions, this will equal 60 dollars. You will receive your Target card within approximately one week. Your participation in this research study may contribute to the development of the *Steps to Effective Problem-solving* program as a commercial product from which Rush University or others may derive financial benefit. There are no plans to pay you for any of these developments.

What if you are injured as a result of your participation in this study?
If you get ill or injured from being in the study, Rush University Medical Center will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Sarah Ailey at telephone number 312 942-3383.

You should let any health care provider who treats you know that you are in this study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact your study doctor.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

Who can you contact for more information about this study?
Questions are encouraged. If you have further questions about this study, you may call Dr. Sarah Ailey at 312 942-3383 or email her at Sarah_H_Ailey@rush.edu.

Who can you contact if you have concerns about your rights as a study participant?
Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?

Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Sarah Ailey in writing at the address on the first page. Dr. Sarah Ailey may still use your information that was collected prior to your written notice.

SIGNATURE BY THE PARTICIPANT OR THE PARTICIPANT'S LEGAL REPRESENTATIVE:

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent/authorization form. You will be given a signed copy of this document.

Name of Participant	Signature of Participant	Date of Signature

Minor Assent	Date of Signature

Parent, Guardian or Legal Representative's Signature	Date of Signature

SIGNATURE BY THE INDIVIDUAL OBTAINING CONSENT:

I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant or the participant's legally authorized representative. I further attest that all questions asked by the participant or the participant's legal representative were answered to the best of my knowledge.

Signature of Individual Obtaining Consent	Date of Signature

SIGNATURE BY WITNESS/INTERPRETER:

I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the participant or the participant's legally authorized representative and the person signing the form has done so voluntarily.

Name of Witness/Interpreter

Signature of Witness/Interpreter	Date of Signature

SIGNATURE OF THE PRINCIPAL INVESTIGATOR:

I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

Signature of the Principal Investigator	Date of Signature

RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

Site Principal Investigator:	Sarah H. Ailey PhD RN
Department:	Community, Systems, and Mental Health Nursing
Address and Contact Information:	600 S. Paulina #1030B (312) 942-3383 Sarah_H_Ailey@rush.edu

Protocol Title:	Steps to Effective Problem-solving (STEPS)
Sponsor(s):	National Institutes of Health – Eunice Kennedy Shriver Institute

Name of Participant:

_____

Key Information:

You are being invited 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.

This consent form will give you information about the 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.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected; services provided by your community service provider will not change or be affected.

The purpose of this study is to test the benefits of a program called Steps to Effective Problem-solving (STEPS) for people with intellectual disabilities living in group homes and for people who, like you, are residential staff in group homes.

The study will last about nine months (36 weeks).

We are asking you to participate in the Steps to Effective Problem-Solving (STEPS) program STEPS is a social problem-solving skills training program that assists people with intellectual disabilities in improving their attitude to problems, learning how to define problems, figuring out various alternatives for solving problems, predicting what will happen when using various alternatives, and trying out chosen alternatives. The STEPS Program is also meant to help staff

learn more about the people with intellectual disabilities with whom they work solve problems. STEPS has six sessions covering these topics and a seventh "booster' session reviewing the six sessions. Each session lasts about one hour. A research team member and an assistant will work with you and the residents with intellectual disabilities in the home who want to participate in the STEPS program over Webex.

Before the program starts, a study staff member will contact you to set up a time to meet over the phone or over Webex to ask you some basic questions about you (age, gender, educational level), about how you solve problems and about nutrition knowledge. The residents who participate and you also will be asked to participate in a videotape of a discussion about a problem you mutually agree to discuss. The video will be about 10 minutes. A study staff member will make the videotapes using the video recording function of Webex. A study staff member will also contact you after the STEPS program (at about 12 weeks) and about three months (about 24 weeks) after that and ask the same questions over the phone or Webex and make another videotape over Webex of a discussion about a problem that the residents who participate and you agree to discuss.
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There are risks to you for participating in this study. People sometimes feel like they have a lot of problems. In this study, there is a risk that you may feel more anxious about problems in ways that make the problems worse while you participate in the STEPS program. It is possible that you might need to contact a health care provider about these feelings. If so, you will need to contact your own insurance about paying for this.

There may be no direct benefit to you for participating in this study**.** However, it is possible that you might learn some new ways of working with people with intellectual disabilities in helping them to address problems that they have, and you may learn some problem-solving skills. Also, the study may benefit professionals to better understand how to work with people such as yourself and with the agencies who serve you on strategies for dealing with problems more effectively.

You do not have to participate in the research.

<u>Detailed Information</u>: Please review the rest of this document for details about the above topics and additional information you should know before making a decision about whether or not you will participate in this study.

<u>Why are you being invited to participate in this study?</u>
You are being asked to take part in this study because you are residential staff (Direct Support Professional) in a group home for people with intellectual disabilities.

<u>How many participants will take part in this study?</u>
We are asking residents of 36 group homes (about 180 residents) and residential staff like you (72-108 staff) of the 36 group homes to participate. 18 group homes will participate in the STEPS program and the other 18 group homes will participate in the Food for Life nutrition program. The Food for Life program is a nutrition program. We want to know if participants with intellectual disabilities in the STEPS program are similar in learning problem-solving and

having behavior incidents and in nutrition knowledge and weight and BMI as participants with intellectual disabilities in the Food for Life program.

Will you be contacted about participating in future research?
If you agree, we may contact you after your participation in this study about participating in future research. Please initial and date one of the following options:

_____ _____ Yes, I agree to be contacted about future research.
Initials Date

_____ _____ No, I do NOT agree to be contacted about future research.
Initials Date

What if there is new information that may affect your decision to participate in this study?
During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent form in order to continue participating in this study.

Will you receive your individual results from the study?
Generally, activities performed for research purposes are not meant to provide clinical information. The only information we are collecting from you are demographic information of gender and ethnicity and information on how you solve problems. If you want the results of the problem-solving scale you fill out, you can ask study staff.

Can you leave or be removed from this study?
You have the right to leave a study at any time without penalty. Leaving the study does not affect any treatment or services you receive at Rush or from your community service provider. For your safety, however, you should consider the study doctor's advice about how to leave this study. If you leave this study before the final study visit, the study doctor may ask you to complete the final steps.

The researchers and Sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You do not follow the instructions;
- The study is cancelled for any reason.

What about confidentiality of your medical information?
This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold or refuse your treatment, payment, enrollment, or eligibility for benefits if you do not sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study or receive study-related treatment.

By signing this document, you voluntarily authorize (give permission to) Dr. Sarah Ailey, her study team, and other Rush personnel involved with the conduct and review of this study (which

may include off-site personnel) to use or disclose (release) information that identifies you for the study described in this document.

During the study, Dr. Sarah Ailey and her study team will collect Protected Health Information (PHI) about you for the purposes of this research, including your gender, ethnicity, where you work, and your answers to a problem-solving and a nutrition questionnaire. We are not collecting PHI from your health care providers, and we are not collecting information from your employer. except that you are an employee. This information about you will be used to complete this research.

Dr. Sarah Ailey and her study team may share your health information and the results of your study-related questionnaires with people outside of Rush. Some of these people may be other researchers outside of the hospital, or are in charge of the research, pay for, or work with us on the research. Some of these people make sure we do the research properly. The persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. For this study, we will share information with:

- Staff outside Rush who have assisted us with developing and evaluating STEPS
    - Dr. Tamar Heller PhD,_University of Illinois at Chicago
    - Dr. Arthur Nezu PhD,_Drexel University, Philadelphia, PA.
    - Dr. Janet Melby RN PhD, Iowa State University, Ames, IA.
- The study Sponsor, Rush University College of Nursing, and its representatives, and our Data Safety Monitoring Committee
- Monitoring agencies such as the National Institutes of Health and the Rush Institutional Review Board (IRB).

While you participate in the study, your access records with your health care providers will not change as we are not gathering any information and not sharing any information with your health care providers. Dr. Sarah Ailey is not required to release to you study information. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. Your identity will not be revealed on any report, publication, or at scientific meetings. All audio and video recordings will be destroyed upon completion of the study or earlier if you request.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed below.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Sarah Ailey at 312 942-3383 or Sarah_H_Ailey@rush.edu. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety of this research study. It will expire upon completion of the study or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. Records of participation in this research study will be maintained at Rush College of Nursing and kept confidential as required by law. In order to conduct the study, the study nurse Dr. Sarah Ailey, will use and share personal health information about you. This includes the information that the research staff obtain during the visits before and after the STEPS program and information from Trinity Services. All information about you and your participation in the study will be kept in a locked cabinet and office. Digital files will be encrypted. Your identity will not be revealed on any report, publication, or at scientific meetings.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

If you disclose actual or suspected abuse, neglect, or exploitation of a child, or disabled or elderly adult, the researcher or any member of the study staff must, and will, report this to Child Protective Services (such as the Department of Family and Human Services), Adult Protective Services, and/or the nearest law enforcement agency.

What are the costs to participate in this study?

No billable services are provided. All costs for the research, including conducting the intervention, interviews regarding how you solve problems and your mood, and coordination of activities will be paid by a grant from Rush College of Nursing.

Will you be compensated or paid?

You will receive a $20 Target gift card for each time research staff visits you to ask questions. For three interview sessions, this will equal 60 dollars. You will receive your Target card within approximately one week. Your participation in this research study may contribute to the development of the *Steps to Effective Problem-solving* and the *Food for Life* program as a commercial product from which Rush University or others may derive financial benefit. There are no plans to pay you for any of these developments.

What if you are injured as a result of your participation in this study?

If you get ill or injured from being in the study, Rush University Medical Center will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Sarah Ailey at telephone number 312 942-3383.

You should let any health care provider who treats you know that you are in this study. If you do seek medical treatment, please take a copy of this document with you because it may help the

doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact your study doctor.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

Who can you contact for more information about this study?
Questions are encouraged. If you have further questions about this study, you may call Dr. Sarah Ailey at 312 942-3383 or email her at Sarah_H_Ailey@rush.edu.

Who can you contact if you have concerns about your rights as a study participant?
Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?
Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Sarah Ailey in writing at the address on the first page. Dr. Sarah Ailey may still use your information that was collected prior to your written notice.

SIGNATURE BY THE PARTICIPANT
By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent/authorization form. You will be given a signed copy of this document.

Name of Participant	Signature of Participant	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

Signature of Individual Obtaining Consent	Date of Signature

SIGNATURE BY WITNESS/INTERPRETER:
I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the participant or the participant's legally authorized representative] and the person signing the form has done so voluntarily.

Name of Witness/Interpreter	
Signature of Witness/Interpreter	Date of Signature

SIGNATURE OF THE PRINCIPAL INVESTIGATOR:
I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

Signature of the Principal Investigator	Date of Signature

RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

Site Principal Investigator:	Sarah H. Ailey PhD RN
Department:	Community, Systems, and Mental Health Nursing
Address and Contact Information:	600 S. Paulina #1030B (312) 942-3383 Sarah_H_Ailey@rush.edu

Protocol Title:	Steps to Effective Problem-Solving
Sponsor(s):	National Institutes of Health – Eunice Kennedy Shriver Institute

Name of Participant:

_____

Note: *If you are the guardian or legal representative of a person with intellectual disabilities who is not able to consent for themselves, the terms "you" or "your" refer to the person being asked to participate in this research.*

Key Information:

You are being invited 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.

This consent form will give you information about the 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.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected, and services provided by your community service provider will not change or be affected.

The purpose of this study is to test the benefits of the Food for Life program compared to a program called Steps to Effective Problem-solving (STEPS) for people like you living in group homes and for your residential staff. The Food for Life program is a control group program.

If you agree to participate, the study will last about nine months (36 weeks).

We are asking you to participate in the *Food for Life program*. In the *Food for Life* program, we will cover topics such as foods you like to eat, what foods to put on your plate, the importance of water, making choices when you go out to eat, making choices at a vending machine, trying different foods and making healthy choices. We want to know if you know more about nutrition at the end of the program and what you weight and Body Mass Index are before and after the program. We also want to know if participating in a control group program helps residents and staff know more about nutrition and become better problem solvers and if residents have fewer behavior incidents. The *Food for Life* program is a control group program. A research staff member and an assistant will work with you and your staff on the *Food for Life* program over Webex. There are six sessions over twelve weeks and one more session about six weeks after that. Before the program starts, a research team member will contact you to set up a time to meet over the phone or over Webex in order to ask you questions about your mood, about how you solve problems, and about what you know about nutrition. You and the other participants in the home will be asked to be in a videotape of a discussion about a problem you agree together to discuss. This discussion will be recorded using the video function of Webex. A research staff member will also contact you and the other participants after you finish the *Food for Life* program and again about three months (12 weeks) after that. The staff member will ask the same questions and make another videotape using Webex of a discussion about a problem that you and other participants all agree to discuss.

What are the possible risks of the study?

People sometimes feel like they have a lot of problems and they may feel sad or anxious about those problems. They may act in ways that don't help or in ways that make the problems worse. There is a possibility that you may feel more sad or anxious about problems or may act in ways that don't help or in ways that make the problems worse while you answer questions your mood and how you solve problems. It is possible that you might need to contact a doctor about these feelings of sadness and anxiety or about the ways you act. If so, you will need to contact your own insurance about paying for this. If your responses to the questions indicate that your problems are immediate, you (and your guardian if you have a guardian) will be told and asked to see your psychiatrist or given the name of a psychiatrist. If you do not have a guardian, you will also be asked to name someone close to you like a family member or staff member who can be told about your feelings and who can help you with treatment and appointments.

Are there benefits to participation in the study

There may be no direct benefit to you for participating in this study. However, it is possible that you might learn some new ways of dealing with problems that you have from answering questions. Also, the study may benefit professionals to better understand how to work with people such as yourself and with the agencies who serve you on strategies for dealing with problems more effectively. It is also possible that you and your housemates might be better able to choose foods that you like and that help you with your health.

What are other options?

You do not have to participate in the research. If you feel like you have a lot of problems, you could see your health care provider about this.

Why are you being invited to participate in this study?

You are being asked to participate in this study because you are someone with an intellectual disability and you are living in a group home for people with intellectual disabilities.

How many participants will take part in this study?

We are asking people like yourself living in 36 group homes (about 180 people) and residential staff people (about 72-108 staff) who work in the group homes to participate. You and participants in 18 group homes are being asked to participate in the Food for Life program. Participants in the Food for Life nutrition program are a control group for the Steps to Effective Problem-solving (STEPS) program. Residents and staff in the other 18 group homes will participate in in the STEPS program. We want to know if you know more about nutrition at the end of the program and what you weigh and your Body Mass Index before and after the program. We also want to know if participating in a control group program helps residents like you and staff become better problem solvers and if residents have fewer behavior incidents.

Will you be contacted about participating in future research?

If you agree, we may contact you after your participation in this study about participating in future research. Please initial and date one of the following options:

_____ _____ Yes, I agree to be contacted about future research.
Initials Date

_____ _____ No, I do NOT agree to be contacted about future research.
Initials Date

What if there is new information that may affect your decision to participate in this study?

During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent form in order to continue participating in this study.

Will you receive your individual results from the study?

Generally, activities performed for research purposes are not meant to provide clinical information. During our interventions, we may learn things about your mood that could be important to your health or treatment. If this happens, this information will be shared with you or someone you choose to receive the information. Along with this document, we will provide you with a document for release of information if you choose to have the research team share important information about your mood with someone you choose.

Can you leave or be removed from this study?

You have the right to leave a study at any time without penalty. Leaving the study does not affect any treatment or services you receive at Rush or from your community service provider. For your safety, however, you should consider the study doctor's advice about how to leave this study. If you leave this study before the final study visit, the study doctor may ask you to complete the final steps.

The researchers and Sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You do not follow the instructions;
- The study is cancelled for any reason.

What about confidentiality of your medical information?

This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold or refuse your treatment, payment, enrollment, or eligibility for benefits if you do not sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study or receive study-related treatment.

By signing this document, you voluntarily authorize (give permission to) Dr. Sarah Ailey, her study team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information that identifies you for the study described in this document.

During the study, Dr. Sarah Ailey and her study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI that we will collect are records kept by the service provider for your group home. We specifically will collect information from the Inventory for Client and Agency Planning (ICAP), a form the service provider for your group home fills out about you every year. It includes information such as: your age, ethnicity and gender; about your disability; and your behavior. We will also collect information on medications you use, your weight, and information from any behavior incident reports that involve you, and about events that may have happened in your life such as a change in job, housing and/or important events with your family. We are not collecting PHI from your health care providers, except as are also in the records at your service provider. There may be new PHI information obtained as a result of this study. This information about you will be used to complete this research.

Dr. Sarah Ailey and her study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of this study. Your health information described above may be used or disclosed to:
We may share your information with people who help with the research. Some of these people may be other researchers outside of the hospital or are in charge of the research, pay for, or work with us on the research. Some of these people make sure we do the research properly. The persons who receive your health information may not be required by Federal privacy laws to

protect it and may share your information with others without your permission, but only if permitted by the laws governing them. For this study, we will share information with:

- Staff outside Rush who have assisted us with developing and evaluating STEPS
    - Dr. Tamar Heller PhD,_University of Illinois at Chicago
    - Dr. Arthur Nezu PhD,_Drexel University, Philadelphia, PA.
    - Dr. Janet Melby RN PhD, Iowa State University, Ames, IA.
- The study Sponsor, Rush University College of Nursing, and its representatives, and our Data Safety Monitoring Committee
- Monitoring agencies such as the National Institutes of Health and the Rush Institutional Review Board (IRB).

While you participate in the study, your access to your records at your health care provider and service provider will not change. Dr. Sarah Ailey is not required to release to you study information that is not part of your records. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. The results of study tests/procedures performed as part of this study may become part of your record at your service provider. Any study information in your record will be kept indefinitely. Your identity will not be revealed on any report, publication, or at scientific meetings. All audio and video recordings will be destroyed upon completion of the study or earlier if you request.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed below.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Sarah Ailey at 312 942-3383 or Sarah_H_Ailey@rush.edu. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety of this research study. It will expire upon completion of the study or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.
Records of participation in this study will be maintained and kept confidential as required by law. Records of participation in this research study will be maintained at Rush College of Nursing and kept confidential as required by law. In order to conduct the study, the study nurse Dr. Sarah Ailey, will use and share personal health information about you. This includes the information that the research staff obtain during the visits before and after the STEPS program and information from your group home service provider. All information about you and your participation in the study will be kept in a locked cabinet and office. Digital files will be encrypted. Your identity will not be revealed on any report, publication, or at scientific meetings.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

If you disclose actual or suspected abuse, neglect, or exploitation of a disabled adult, the researcher or any member of the study staff must, and will, report this to Adult Protective Services, and/or the nearest law enforcement agency.

What are the costs to participate in this study?

There are no costs to you for participating in this research. No billable services are provided. All costs for the research, including conducting the intervention, interviews regarding how you solve problems and your mood, and coordination of activities will be paid by the grant from the National Institutes of Health – Eunice Kennedy Shriver Institute.

Will you be compensated or paid?

You will receive a $20 Target gift card for each time research staff visits you to ask questions. For three interview sessions, this will equal 60 dollars. You will receive your Target card within approximately one week. Your participation in this research study may contribute to the development of the *Steps to Effective Problem-solving* and the *Food for Life* programs as commercial products from which Rush University or others may derive financial benefit. There are no plans to pay you for any of these developments.

What if you are injured as a result of your participation in this study?

If you get ill or injured from being in the study, Rush University Medical Center will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Sarah Ailey at telephone number 312 942-3383.

You should let any health care provider who treats you know that you are in this study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact your study doctor.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

Who can you contact for more information about this study?
Questions are encouraged. If you have further questions about this study, you may call Dr. Sarah Ailey at 312 942-3383 or email her] at Sarah_H_Ailey@rush.edu.

Who can you contact if you have concerns about your rights as a study participant?
Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?
Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Sarah Ailey in writing at the address on the first page. Dr. Sarah Ailey may still use your information that was collected prior to your written notice.

SIGNATURE BY THE PARTICIPANT OR THE PARTICIPANT'S LEGAL REPRESENTATIVE]:
By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent/authorization form. You will be given a signed copy of this document.

Name of Participant	Signature of Participant	Date of Signature

Minor Assent	Date of Signature

Parent, Guardian or Legal Representative's Signature	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant or the participant's legally authorized representative]. I further attest that all questions asked by the participant or the participant's legal representative] were answered to the best of my knowledge.

Signature of Individual Obtaining Consent	Date of Signature

SIGNATURE BY WITNESS/INTERPRETER:

I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the participant or the participant's legally authorized representative] and the person signing the form has done so voluntarily.

_____

Name of Witness/Interpreter

_____ _____

Signature of Witness/Interpreter Date of Signature

SIGNATURE OF THE PRINCIPAL INVESTIGATOR:
I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

_____ _____

Signature of the Principal Investigator Date of Signature

RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

Site Principal Investigator:	Sarah H. Ailey PhD RN
Department:	Community, Systems, and Mental Health Nursing
Address and Contact Information:	600 S. Paulina #1030B (312) 942-3383 Sarah_H_Ailey@rush.edu

Protocol Title:	Steps to Effective Problem-solving (STEPS)
Sponsor(s):	National Institutes of Health – Eunice Kennedy Shriver Institute

Name of Participant:

_____

Key Information:

You are being invited 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.

This consent form will give you information about the 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.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected.

The purpose of this study is to test the benefits of the Food for Life program compared to a program called Steps to Effective Problem-solving (STEPS) for individuals with intellectual disabilities living in group homes and their residential staff. The Food for Life program is a control group program.

The study will last about nine months (36 weeks).

We are asking you to participate in the *Food for Life program*. In the *Food for Life* program, we will cover topics such as foods residents like to eat, what foods to put on a plate, the importance of water, making choices when going out to eat, making choices at a vending machine, trying different foods and making healthy choices. The *Food for Life* program is a control group

program. We want to know if participating in a control group program helps residents and staff become better problem solvers and residents have fewer behavior incidents. We also want to know if the residents improve their knowledge about nutrition and what their weights and Body Mass Index are before and after the program. A research staff member and an assistant will work with the residents who want to participate and with you on the *Food for Life* program over Webex. There are six sessions over twelve weeks and one more session about six weeks after that. Before the program starts, a research staff member will contact you to set up a time to meet over the phone or over Webex and ask you some basic questions about you (age, gender, educational level), about how you solve problems and about nutrition knowledge. The residents who participate and you also will be asked to participate in a videotape of a discussion about a problem you mutually agree to discuss. This discussion will be recorded using the video function of Webex. A research staff member will also contact you after the *Food for Life* program is completed and about three months (12 weeks) after that. They will ask the same questions and make another videotape over Webex of a discussion about a problem that the residents who participate and you mutually agree to discuss.

What are the possible risks of the study?

There are risks to you for participating in this study. People sometimes feel like they have a lot of problems and they may feel sad or anxious about those problems. There is a possibility that you may feel more sad or anxious when you answer questions about how you solve problems. It is possible that you might need to contact a doctor about these feelings of sadness and anxiety or about the ways you act. If so, you will need to contact your own insurance about paying for this. If your responses to the questions indicate that your problems are immediate, you will be told and asked to seek services or given information about services.

Are there benefits to participation in the study

There may be no direct benefit to you for participating in this study**.** However, it is possible that you might learn some new ways of dealing with problems after you answer questions about this. It is also possible that you may learn information about better nutrition and how to work with residents on nutrition. Also, the study may benefit other professionals to better understand how to work with staff such as yourself who work with residents with intellectual disabilities and with the agencies who serve people with intellectual disabilities.
There are risks to you for participating in this study.

What are other options?

You do not have to participate in the research. If you feel like you have a lot of problems, you could see your doctor about this.

Why are you being invited to participate in this study?

You are being asked to take part in this study because you are residential staff (Direct Support

Professional) in a group home for people with intellectual disabilities.

How many participants will take part in this study?

We are asking residents living in 36 group homes (about 180 people) and residential staff people like you (about 72-108 staff) who work in the group homes to participate. We are asking you to participate in the Food for Life nutrition program. You and participants in 18 group homes are being asked to participate in Food for Life program. Participants in the Food for Life nutrition program are a control group for the Steps to Effective Problem-solving (STEPS) program. Residents and residential in the other 18 group homes will participate in in the STEPS program. We want to know if the programs help residents and staff know more about nutrition and we want to know residents' weights and Body Mass Index before and after the program. We also want to know if residents and staff and become better problem solvers and if residents have fewer behavior incidents.

Will you be contacted about participating in future research?

If you agree, we may contact you after your participation in this study about participating in future research. Please initial and date one of the following options:

_____ _____ Yes, I agree to be contacted about future research.
Initials Date

_____ _____ No, I do NOT agree to be contacted about future research.
Initials Date

What if there is new information that may affect your decision to participate in this study?

During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent form in order to continue participating in this study.

Will you receive your individual results from the study?

Generally, activities performed for research purposes are not meant to provide clinical information. The only information we are collecting from you are demographic information of gender and ethnicity and information on how you solve problems and what you know about nutrition. If you want the results of the problem-solving and/or the nutrition questionnaires you fill out, you can ask study staff.

Can you leave or be removed from this study?

You have the right to leave a study at any time without penalty. Leaving the study does not affect any treatment or services you receive at Rush or from your community service provider. For your safety, however, you should consider the study doctor's advice about how to leave this

study. If you leave this study before the final study visit, the study doctor may ask you to complete the final steps.

The researchers and Sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You do not follow the instructions;
- The study is cancelled for any reason.

What about confidentiality of your medical information?

This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold or refuse your treatment, payment, enrollment, or eligibility for benefits if you do not sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study or receive study-related treatment.

By signing this document, you voluntarily authorize (give permission to) Dr. Sarah Ailey, her study team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) information that identifies you for the study described in this document.

During the study, Dr. Sarah Ailey and her study team will collect Protected Health Information (PHI) about you for the purposes of this research, including your gender, ethnicity, where you work, and your answers to a problem-solving and a nutrition questionnaire. We are not collecting PHI from your health care providers, and we are not collecting information from your employer, except that you are an employee. This information about you will be used to complete this research.

Dr. Sarah Ailey and her study team may share your health information and the results of your study-related questionnaires with people outside of Rush. Some of these people may be other researchers outside of the hospital, or are in charge of the research, pay for, or work with us on the research. Some of these people make sure we do the research properly. The persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. For this study, we will share information with:

- Staff outside Rush who have assisted us with developing and evaluating STEPS
    - Dr. Tamar Heller PhD,_University of Illinois at Chicago
    - Dr. Arthur Nezu PhD,_Drexel University, Philadelphia, PA.
    - Dr. Janet Melby RN PhD, Iowa State University, Ames, IA.
- The study Sponsor, Rush University College of Nursing, and its representatives, and our Data Safety Monitoring Committee
- Monitoring agencies such as the National Institutes of Health and the Rush Institutional Review Board (IRB).

While you participate in the study, your access records with your health care providers will not change. We are not gathering any information and not sharing any information with your health care providers. Dr. Sarah Ailey is not required to release to you study information. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. Your identity will not be revealed on any report, publication, or at scientific meetings. All audio and video recordings will be destroyed upon completion of the study or earlier if you request.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed below.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Sarah Ailey at 312 942-3383 or Sarah_H_Ailey@rush.edu. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety of this research study. It will expire upon completion of the study or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. Records of participation in this research study will be maintained at Rush College of Nursing and kept confidential as required by law. In order to conduct the study, the study nurse Dr. Sarah Ailey, will use and share personal health information about you. This includes the information that the research staff obtain during the visits before and after the STEPS program. All information about you and your participation in the study will be kept in a locked cabinet and office. Digital files will be encrypted. Your identity will not be revealed on any report, publication, or at scientific meetings.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

If you disclose actual or suspected abuse, neglect, or exploitation of a child, or disabled or elderly adult, the researcher or any member of the study staff must, and will, report this to Child Protective Services (such as the Department of Family and Human Services), Adult Protective Services, and/or the nearest law enforcement agency.

What are the costs to participate in this study?

There are no costs to you for participating in this research. No billable services are provided. All costs for the research, including conducting the intervention, interviews regarding how you solve problems and your mood, and coordination of activities will be paid by a grant from the National Institutes of Health – Eunice Kennedy Shriver Institute.

Will you be compensated or paid?
You will be paid 20 dollars in the form of a gift care for each time the study staff contacts you to ask questions. For three interview sessions, this will equal 60 dollars. You will receive your gift card within approximately one week. Your participation in this research study may contribute to the development of the STEPS program and the *Food for Life* program as commercial products from which there may be economic benefit. You will have no rights to any products, patents or discoveries arising from this research, and you will receive no economic benefit.

What if you are injured as a result of your participation in this study?

If you get ill or injured from being in the study, Rush University Medical Center will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Sarah Ailey at telephone number 312 942-3383.

You should let any health care provider who treats you know that you are in this study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact your study doctor.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

Who can you contact for more information about this study?
Questions are encouraged. If you have further questions about this study, you may call Dr. Sarah Ailey at 312 942-3383 or email her] at Sarah_H_Ailey@rush.edu.

Who can you contact if you have concerns about your rights as a study participant?
Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?
Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center

will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Sarah Ailey in writing at the address on the first page. Dr. Sarah Ailey may still use your information that was collected prior to your written notice.

SIGNATURE BY THE PARTICIPANT
By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent/authorization form. You will be given a signed copy of this document.

Name of Participant	Signature of Participant	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

Signature of Individual Obtaining Consent	Date of Signature

SIGNATURE BY WITNESS/INTERPRETER:
I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the participant or the participant's legally authorized representative] and the person signing the form has done so voluntarily.

Name of Witness/Interpreter

Signature of Witness/Interpreter	Date of Signature

SIGNATURE OF THE PRINCIPAL INVESTIGATOR:
I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

Signature of the Principal Investigator	Date of Signature