Title: Family Connections: Cultural Adaptation and Feasibility Testing for Rural Latino Communities

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**CONSENT FORM**
**Consent Form - ENGLISH**

**Title of this Research Study**
Family Connections

**Invitation and Summary**

You are invited to be in this research study. Taking part in this research is voluntary. You do not have to take part. For the purposes of this document: "You" can refer to:

- Yourself
- The person for whom you are the Legally Authorized Representative (LAR)
- Your child under the age of 19.

"Organization" can refer to: University of Nebraska Medical Center (UNMC), Nebraska Medicine (NM), University of Nebraska at Omaha (UNO) or Children's Hospital & Medical Center (CH&MC).

Here is a summary of the purpose, methods, risks, benefits, and alternatives, to help you decide whether or not to take part in the research.

What is Family Connections program?

- Family Connections is a health study that is being done by University of Nebraska Medical Center (UNMC) in partnership with Central District Health Department - CDHD, Community Action Partnership of Western Nebraska - CAPWN, Two Rivers Public Health department - TRHD, and East Central District Health Department - ECDHD. The study started in April 2021.
- In this study we have a health program to help families develop healthy eating habits and increase physical activity.
- People in this study will be put in one of two groups. You have an equal chance of getting in any of the 2 groups.

What will I be asked to do?
If you agree to be a part of this study you will be asked to:

- Complete with your child in 3 visits (at the beginning of the program, at 6 months and 12 months post-program) with you Community Health Worker in the place you choose (home or local clinic).
- Use a workbook
- Complete 2 classes with our health coach and 10 automated telephone calls over a 6-month period

What are the programs?

- Program A: People in this program will come for their first study visit with their child, complete 2 visits with your community health worker. This usual care offers an option for being in a waitlist to participate in the program B after the study is completed.

- Program B: People in this program come for their first study visit with their child, and get a family lifestyle workbook to take home. The workbook offers tools to help families eat better, be more active, and control weight. To help your family stay on track you will get 1 call from our health coach and 10 automated support calls over the next 6 months.

What will I have to do at each study visit?
We measure a lot of things at each study visit. We will measure your blood pressure, waist, weight, and height. We will also ask you and your child to complete a survey. We will also measure the height and weight of your child. You and your child will each receive a $25.00 gift card, a total of $50.00 for each study assessments visit (a total of $150.00 if you both complete all 3 visits).

How will the Family Connections study help me?
You may get a free program to help your family improve healthy living habits.

What are the risks to being in the Family Connections study?
The risks for being in the study are small. They involve the normal risks you would have from being more active.

**Why are you being asked to be in this research study?**
You and your child are being asked to be part of this research study because you are identity yourself as a Latino or Hispanic, you are living in a rural area, you are 19 years or older, and you have a child ages 6-12 overweight or obese living in your home. If you are pregnant, nursing an infant, or plan to become pregnant during this study, you may not be in this study.

**What is the reason for doing this research study?**
This study is designed to adapt and test a health program to help families develop healthy eating habits and increase physical activity. Both you and your child have been invited to participate in this study. The main goal of this program is to improve you and your child's weight and health by providing helpful tips to improve you and your child's eating and physical activity behaviors. The main goal of this program is to

improve you and your child's weight and health by providing helpful tips to improve you and your child's eating and physical activity behaviors.

**What will be done during this research study?**
If you agree to be a part of this study you and your child will be put in one of two groups. You have an equal chance of getting in any of the 2 groups.

What are the programs?

- Program A: People in this program will come for their first study visit with their child, complete 2 visits with your community health worker. This usual care offers an option for being in a waitlist to participate in the program B after the study is completed.

- Program B: People in this program come for their first study visit with their child, and get a family lifestyle workbook to take home. The workbook offers tools to help families eat better, be more active, and control weight. To help your family stay on track you will get 2 classes from our health coach and 10 automated support calls over the next 6 months.

This study will include a health assessment and an education program for both you and your child.

## Health Assessment

As a part of enrollment in this study, you and your child will need to attend three visits: one study visit at the beginning and one study visit at 6 months and one 12 months after your initial visit. The study visits can be scheduled at your local health department or at your home for your convenience. The health assessment information for you and your child will be collected in-person and includes:

- Surveys about eating and physical activity habits, health status, home, and quality of life
- Height, weight, and waist measurements
- Blood pressure

It will take approximately 30 minutes for the health assessment for you and your child, and both you and your child can do your health assessments at the same time. If you or your child do not want to do parts of the health assessment or answer some of the questions, you or your child do not have to. At the health screening at the 6-month visit, we will ask you and your child a few questions about what you liked and did not like about the program. You may also be invited to participate in a focus group to share about what you liked and did not like about the program.

## Family Connections Health Education Program

As we explained before you and your child will have equal chance of being assigned to either group A or B. You and your child may or may not be asked to participate in the Family Connections Health Education Program (program A). If you and your child do not take part in the Family Connections Health Education Program, both you and your child will receive the Health assessment (outlined above) at initial visit, at 6 months when you complete the program, and after 12 months of the program completion. If you and your child are asked to participate in the Family Connections Health Education Program, this program will start after you complete your initial visit and continue for 6 months.

During this time you will be asked to:

Complete one live phone call and complete 10 automated telephone calls to provide support and to help you and your child reach your eating and physical activity goals. The live phone call will take approximately 30 minutes and each automated call will take about 5-10 minutes. You will be asked to complete approximately at the beginning of the program one weekly call. That will be gradually reduce to 2 per month, and one monthly calls towards the end.

Protected Health Information
As part of this study, we will collect protected health information from you and your child. Information collected from you and your child will include: age, race and ethnic origin, body weight and height, and medications. As part of this study, information (including protected health information about you and your child) collected during phone calls that are part of this study will initially be stored in a HIPPA-compliant database before being transferred to UNMC Research staff. The staff who will have access to your and your child's information are listed at the end of this form.

**What are the possible risks of being in this research study?**
There are minimal risks for being involved in this study. They involve the normal risks you would have from being more active. It is possible that the health screening could cause stress or anxiety for you or your child. You and your child have the right to refuse to participate or to answer any questions in the health screening. If you or your child become too tired during the health screening, you can take a break or finish on another day. There is also a possible risk of loss of confidentiality.

**What are the possible benefits to you?**
You and your child may not get any benefit from being in this research study. If you

and your child decide to take part in this study, there is no guarantee that you and/or your child will have any changes in your health. However, you and/or your child may receive the following benefits: weight loss, learning how to improve eating and physical activity behaviors, and/or other improvements in your health.

**What are the possible benefits to other people?**
It is possible that information obtained from this study may help develop programs that can be used to encourage Latino and Hispanic families to have a more active and healthier lifestyle.

**What are the alternatives to being in this research study?**
Instead of being in this research study, you can choose not to participate and continue with the standard care in your community clinic and/or local health department.

**What will being in this research study cost you?**
There is no cost to you to be in this research study.

**Will you be paid for being in this research study?**
You and your child will receive compensation for your participationin this research study. You and your child will receive your study compensation at the completion of each required study visit.
You will receive $25 and your child will receive $25 at each visit (a total of $50 for each visit). This adds to a total of $150 if you both complete all 3 visits.

**Who is paying for this research?**
The National Institutes of Health (NIH) gives us money to do research like this study.

**What should you do if you are injured or have a medical problem during this research study?**
The well-being of you and your child is the primary concern of all members of the research team. If you or your child have a problem as a direct result of being in this study, you should immediately contact one of the people listed at the end of this consent form.

**How will information about you be protected?**
You and your child have rights regarding the protection and privacy of medical information collected before and during this research. This medical information is called Protected Health Information (PHI).
The PHI used in this study may include the address, date of birth, medical history, the

results of physical examinations, as well as the results of other research procedures for you and your child. Only the minimum amount of PHI will be collected for this research. Your child's medical and research records will be kept in a secure manner. In the future, we may take the identifiers off the information. It is possible that this information without identifiers could then be used for other research by us, or by another researcher, without asking you for your permission.

**Who can see information about you?**
By signing this consent form, you are letting us (the researchers listed on this consent form and other people involved in this research at the Organization) to have access to your research data. Your research data will be used only for the purpose(s) described in the section "What is the reason for doing this research study?".

You can change your mind and tell us to stop collecting further research data for use in this research at any time by contacting the principal investigator or any of the study personnel listed at the end of the consent form. However, the information which is included in the research data obtained to date may still be used. If you cancel this authorization, you will no longer be able to take part in this research.

We may share your research data with other groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- The HHS Office for Human Research Protections (OHRP)
- National Institutes of Health (NIH)
- Above Ground Development (a HIPPA compliant company contracted to conduct the automated phone calls)

You are letting us use and share yours and your child research data for as long as the research is going on.

**How will results of the research be made available to you during and after the study is finished?**
Information obtained in the course of the research that will not be shared with you is the overall or partial results of the program you will be participating. Yours and your child's individual results will be share with you. By signing this authorization, you are temporarily giving up your right to see this research-related information while the research is going on. You will be able to see this information if you wish after the research is completed.

In most cases, the results of the research can be made available to you when the

study is completed, and all the results are reviewed by the researcher. The information from this study may be published in scientific journals or presented at scientific meetings, but you and your child's identity will be kept strictly confidential.

If you would like the results of the study, please contact the Principal Investigator at the phone number given at the end of this form or by writing to the Principal Investigator at the following address:

Dr. Fabiana Brito Silva
984365 Nebraska Medical Center
Omaha, NE 68198-4365

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

**What will happen if you decide not to be in this research study?**
You can decide not to be in this research study. Deciding not to be in this research will not affect your relationship with the investigator or the organization. You will not lose any benefits to which you are entitled.

**What will happen if you decide to stop participating once you start?**
You can stop being in this research (withdraw) at any time. Just call the researcher or any research staff

Deciding to withdraw will otherwise not affect your care or your relationship with the investigator or this institution. You will not lose any benefits to which you are entitled.

You can decide not to give permission for your child to be in this research study, or you can stop his/her participation in this research study ("withdraw") at any time before, during, or after the research begins. Deciding not to be in this research study or deciding to withdraw will not affect your child's relationship with the investigator or the Institution. Your child will not lose any benefits to which he/she is entitled.

You and your child may be taken off the study if you do not follow instructions of the investigator or the research team.

You and your child may also be taken off the study if:

- You and your child do not attend the required study visits

- You do not complete the required study phone calls

**Will you be given any important information during the study?**
We will tell you right away if we get any new information that might make you change your mind about you and your child being in the study.

**What should you do if you have any questions about the study?**
You have been given a copy of the handout*"What Do I Need to Know Before Being in a Research Study?"*

If you ever have any questions about this study, you should contact the Principal Investigatoror any of the study staff members listed on this consent form, or any other document provided to you.

**What are your rights as a research participant?**
You and your child have rights as a research subject. These rights have been explained in this consent form and in The Rights of Research Subjects material provided to you. If you have any questions about these rights or complaints about the investigation, you may contact any of the following people:

- The investigator or other study personnel, or the Institutional Review Board (IRB)
    - Telephone: (402) 559-6463.
    - Email: IRBORA@unmc.edu
    - Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830
- Research Subject Advocate
    - Telephone: (402) 559-6941
    - Email: unmcrsa@unmc.edu

**Documentation of informed consent**
It is your free choice to give permission for your child to participate in this research study. Signing means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects
- You received answers to your questions.
- You have decided to participate and allow your child to participate in the research study.

- You have been told that you can talk to one of the researchers listed below on this consent form if you have any questions during the study.
- You will be given a signed and dated copy of this consent form to keep.

**Child consent clause.**

If your child is invited to participate in this study, you are signing up to give permission. Each child can agree to participate in a study at his or her own level of understanding. When you sign this form, you also indicate that your child understands and agrees to participate in this study based on your understanding.

Signature of Subject_____Date_____

Signature of Parent/Guardian_____Date_____

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the subject possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate

Signature of Person Obtaining Consent_____Date_____

**Authorized Study Personnel**

**Principal**

* Silva, Fabiana (Fabiana)
alt #: 402-552-6363
degree: PhD

**Secondary**

* Almeida, Fabio
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* Eisenhauer, Christine
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**Participating Personnel**

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* Santos, Natalia
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# What Do I Need To Know Before Being In A Research Study?

You have been invited to be in a **research study**. Research studies are also called "clinical trials" or "protocols." **Research** is an organized plan designed to get new knowledge about a disease or the normal function of the body. The people who are in the research are called **research subjects**. The **investigator** is the person who is running the research study. You will get information from the investigator and the research team, and then you will be asked to give your **consent** to be in the research.

**This sheet will help you think of questions to ask the investigator or his/her staff. You should know all these answers before you decide about being in the research.**

What is the **purpose** of the research? Why is the investigator doing the research?

What are the **risks** of the research? What bad things could happen?

What are the possible **benefits** of the research? How might this help me?

**How is this research different** than the care or treatment I would get if I wasn t in the research? Are there other treatments I could get?

Does **everyone** in this research study get the same treatment?

Will being in the research **cost** me anything extra?

Do I have to be in this research study? Will the doctor still take care of me if I say **no**?

Can I **stop** being in the research once I ve started? How?

Who will look at my **records**?

How do I reach the investigator if I have more **questions**?

Who do I call if I have questions about being a **research subject**?

**Make sure all your questions are answered before you decide whether or not to be in this research.**

# THE RIGHTS OF RESEARCH SUBJECTS
# AS A RESEARCH SUBJECT YOU HAVE THE RIGHT

**to be told everything you need to know about the research before you are asked to decide whether or not to take part in the research study.** The research will be explained to you in a way that assures you understand enough to decide whether or not to take part.

**to freely decide whether or not to take part in the research.**

**to decide not to be in the research, or to stop participating in the research at any time.** This will not affect your medical care or your relationship with the investigator or the Nebraska Medical Center. Your doctor will still take care of you.

**to ask questions about the research at any time.** The investigator will answer your questions honestly and completely.

**to know that your safety and welfare will always come first.** The investigator will display the highest possible degree of skill and care throughout this research. Any risks or discomforts will be minimized as much as possible.

**to privacy and confidentiality.** The investigator will treat information about you carefully, and will respect your privacy.

**... to keep all the legal rights you have now.** You are not giving up any of your legal rights by taking part in this research study.

**to be treated with dignity and respect at all times**

**The Institutional Review Board is responsible for assuring that your rights and welfare are protected. If you have any questions about your rights, contact the Institutional Review Board at (402) 559-6463.**