

Informed Consent Forms (ICF) for the Feasibility Trial of Healthy Dads Healthy Kids Latino

1. Combined ICF for father and child(ren)
2. ICF for mother

NCT03532048

BCM IRB Protocol: H-38237

PI: Teresia O'Connor

Initial approval date of ICFs was 07/26/2018.

Protocol currently not enrolling, data collection complete. ICF therefore marked as not currently approved.

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Consent for Fathers and their children for the Papás Saludables, Niños Saludables study

H-38237- HEALTHY DADS, HEALTHY KIDS LATINO- ADAPTATION AND FEASIBILITY OF A LIFESTYLE INTERVENTION FOR LATINO FAMILIES

Background

You and your 5- 11 year old child or children are invited to take part in a research study. Please read this information and feel free to ask any questions before you agree to take part in the study. In this form "you" means the Father and "child" will refer to all your children between the ages of 5- 11 years old who will take part in the study.

Please indicate here the names of the children who you give permission to take part in the study:

Three horizontal lines for writing names.

You and your child are invited to take part in the Papás Saludables, Niños Saludables study. The Papás Saludables, Niños Saludables program is a group program for Hispanic fathers and their children between the ages of 5-11 years old. The program teaches fathers and their children fun, active games and sports to play together to get more active. It also teaches fathers and their children about healthy eating to help fathers lose weight and children to have a healthy weight. The program lasts for 10 weeks, and meets every weekend (Saturday or Sunday) for 90 minutes. During the program, both fathers and the children learn practical things they can do together to help each other and their family to have healthy lifestyle behaviors. Fathers are also taught how they can help their child learn basic sports skills and new ways to try to encourage healthy eating, less screen time and fun activities for their child. Both you and your child will get fun activities to try at home during the week before the next program meeting.

The Papás Saludables, Niños Saludables program will be run at your child's Clinic or another TCHP Center for Children and Women clinic.

If available, mothers are encouraged to take part by joining the Papás Saludables, Niños Saludables Facebook group to get weekly information about the program and to receive text messages about the program.

This research study is funded by National Institute of Research: National Heart, Lung and Blood Institute

Purpose

This research study will test if Hispanic families like the Papás Saludables, Niños Saludables program and if the program can help Hispanic men and their children to be physically active together and eat healthy to help them have healthy weights.

Procedures

The research will be conducted at the following location(s): Baylor College of Medicine, CNRC: Children's Nutrition Research Center, and Texas Childrens Health

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plan: Center for Children and Women.

Men and their families who agree to participate in the study will be randomly assigned to one of two groups. One of the groups will start the Papás Saludables, Niños Saludables program in September 2018 (first group); the second group will start the program in the Spring of 2019. You will have a 50/50 chance of being in the group that begins in the fall or the group that begins next spring. You wont be able to choose which group youre in because we have to do it randomly like drawing names out of a hat.

Everyone in the study will take part in two research assessments to collect information about you and your child. One research assessment will be before the first group starts Papás Saludables, Niños Saludables and the second research assessment will be after the first group has completed the Papás Saludables, Niños Saludables program. Both assessments will be the same. You and your child will find out if you are in the first or second group of Papás Saludables, Niños Saludables after you have finished the first assessment.

Research activities you will be asked to do during the assessment:

1. Have your height, weight, waist circumference, heart rate and blood pressure measured by research staff.
2. Fill out questionnaires about you and your family's demographics (age, employment, education, etc), what you eat, how much time you spend watching TV and other screens, how you interact with your child about food and physical activity, and your feelings about your family and culture.
3. Have have your index finger scanned by a light scanner. The light scanner (Veggie Meter, Longevity Link, Corp., UT) is a portable electronic device that uses a small beam of light to measure skin carotenoid levels. Carotenoids are colorful pigments found in various fruits and vegetables. The scanner works similar to a forehead thermometer. You will be asked to place your finger on the lens of the scanner, and a lever will push your finger down toward the light and allow a white light to shine on the skin for about 10 seconds. This will be repeated for a total of three measures on that finger. You may feel slight pressure on your finger during the measure.
4. Wear an accelerometer for 7 days (including two weekend days). An accelerometer is a small device you wear on an elastic belt around your waist that measures how active you are and how much you sleep. It does not measure where you are. We will give you information about how to wear the accelerometer and how to record if and when you take it off during the assessment period.

Research activities your child will be asked to do during the assessment:

1. Have his/her height and weight measured by research staff.
2. Fill out questionnaires about what he or she eats, how much time he/she spends watching TV and other screens. The child's mother or father will help the child complete these questionnaires.
3. Have his/her index finger scanned by a light scanner. The light scanner (Veggie Meter, Longevity Link, Corp., UT) is a portable electronic device that uses a small beam of light to measure skin carotenoid levels. Carotenoids are colorful pigments found in various fruits and vegetables. The scanner works similar to a forehead thermometer. He/she will be asked to place his/her finger on the lens of the scanner, and a lever will push the finger down toward the light and allow a white light to shine on the skin for about 10 seconds. This will be repeated for a total of three measures on that finger. He/she may feel slight pressure on your finger during the measure.

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4. Wear an accelerometer for 7 days (including two weekend days). An accelerometer is a small device your child wears on an elastic belt around his/her waist that measures how active he/she is and how much he/she sleep. It does not measure where you are. We will give you and your child information about how to wear the accelerometer and how to record if and when to take it off during the assessment period.

All fathers and children will be asked to complete a satisfaction survey of the program after they have completed the program, either in group one or two.

Assessments will be held at the same location that your program will be held on a weekend or weekday, at times that suits you and your child on weekends or after school hours. We will also ask you or your child's mother or other parent to help your child complete some questionnaires about what your child eats and how much TV and screens they watch.

Some Fathers and children will be asked to take part in an interview after the program has ended to tell the research team what they liked and did not like about the program. These interviews will be audio-recorded.

During the Papás Saludables, Niños Saludables assessments and program we will send you reminders about the study via text, email or phone calls, depending on your preference. By signing this consent you agree to allow us send these reminders.

In the Papás Saludables, Niños Saludables program, you will learn about tools to help you eat healthier and be active, such as MyFitness Pal. MyFitnessPal can be used as an "app" on a mobile device (such as a Smart phone) or a website on a computer to track what you eat and how active you are. It is hosted by a third-party, Under Armor Inc. Use of MyFitnessPal is voluntary in the program and is meant to be a tool to help you be successful. You will need to agree to the MyFitnessPal user agreement to use this application. If you chose to use the application, we will NOT have access or control of any of the information you enter in the program, but Under Armor Inc will.

Mothers whose kids and partner are enrolled in the Papás Saludables, Niños Saludables program will be invited to take part in a secret group on Facebook for the Papás Saludables, Niños Saludables program. This group is only for Papás Saludables, Niños Saludables participants and others cannot join the group. Papás Saludables, Niños Saludables informational videos and motivational and informational messages for moms will be shared in this group. We may also post photos and short videos of the fun things you and your child are doing in the Papás Saludables, Niños Saludables program on the Facebook group. Participation in the group is voluntary for the moms. Please let us know by initialing below, if we have your permission to post photos and/or videos of you and your child on the secret Papás Saludables, Niños Saludables Facebook group for mothers.

\_\_\_\_\_ YES, you have my permission to post photos and/or of myself and my child(ren) on the secret Papás Saludables, Niños Saludables Facebook group for mothers.

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\_\_\_\_\_ NO, please do not use my or my child(ren)'s photos or videos in any Facebook post.

If you stop coming to the Papás Saludables, Niños Saludables program, we will contact you to find out why and if we can find ways to help you start attending again.

This study is to test the feasibility of Papás Saludables, Niños Saludables. We may continue to run this program in the future. If we do, we would like to use photos or videos of families that took part in Papás Saludables, Niños Saludables in our program recruitment, training or family materials. It may also be used to describe the program in presentations about this study. Your name and your child name will not be used in the program material or presentations. Please let us know by initialing below, if we have your permission to use photos and/or videos of you and your child in future Papás Saludables, Niños Saludables program materials and presentations:

\_\_\_\_\_ YES, you have my permission to use photos and/or of me and my child(ren) in future Papás Saludables, Niños Saludables program recruitment, training or family materials and study presentations.

\_\_\_\_\_ NO, please do not use my or my child(ren)'s photos or videos in any material or presentations.

**Research related health information**

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine, CNRC: Children's Nutrition Research Center, and Texas Children's Health plan: Center for Children and Women to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Demographic information (name, D.O.B., age, gender, race, etc.)
- Photographs, videotapes, and/or audiotapes of you

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, CNRC: Children's Nutrition Research Center, Texas Children's Health plan: Center for Children and Women, and NATIONAL INSTITUTES OF HEALTH (NIH) and their representatives.

Use or Disclosure Required by Law

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Your health information will be used or disclosed when required by law .

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

Baylor College of Medicine, CNRC: Children's Nutrition Research Center, and Texas Children's Health plan: Center for Children and

Women are required by law to protect your health information . By signing this document, you authorize Baylor College of Medicine, CNRC: Children's Nutrition Research Center, and Texas Children's Health plan: Center for Children and

Women to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research does not involve treatment. Baylor College of Medicine, CNRC: Children's Nutrition Research Center, and Texas Children's Health plan: Center for Children and Women may not condition (withhold or refuse) treating you on whether you sign this Authorization.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, NATIONAL INSTITUTES OF HEALTH (NIH) and their representatives, regulatory agencies such as the U.S. Department of Health and Human Services, Baylor College of Medicine, CNRC: Children's Nutrition Research Center, and Texas Children's Health plan: Center for Children and

Women may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization .

To revoke this Authorization, you must write to: Teresia O'Connor  
 Children's Nutrition Research Center  
 Baylor College of Medicine  
 1100 Bates Street  
 Houston, TX 77025

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

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**Potential Risks and Discomforts**

Papás Saludables, Niños Saludables requires physical exertion that may be strenuous at times. You and your child may experience soreness, muscle strains, sprained ligaments, and be tired during and after the exercise. Any exercise program may cause physical injury. We will reduce these risks by delivering the program by trained leaders that will help give different levels for the exercises so you can find one that meets your abilities. The leaders have basic first aid training, but are not medical providers.

The Papás Saludables, Niños Saludables group sessions will include talking to other fathers about your experience of being a father. Some may find that uncomfortable and embarrassing. These discussions will be done with the program leader present who will enforce group rules to be respectful and keep everything that is said during the group session private.

There is also a risk that you could get embarrassed by having your weight or height measured or answering health questions about yourself. We will therefore do those measurements in a private location so others, outside of our research staff, cannot see or hear you.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

**Potential Benefits**

The benefits of participating in this study may be: learning fun, new games and exercises that help you and your child to become more physically active. You will also learn how to eat healthy with your child. Both of these may help you lose weight and lower your risk of certain diseases, such as heart disease. Papás Saludables, Niños Saludables focuses on doing fun things with your child, which may make you closer to your children and family. However, you may receive no benefit from participating.

**Alternatives**

You may choose to not participate in this study.

**Investigator Withdrawal of Subject from a Study**

The investigator or sponsor may decide to stop you from taking part in this study at any time. You could be removed from the study for reasons related only to you (for example, if you move to another city, or if you are disruptive during the program in such a way that it negatively affects other families ) or because the entire study is stopped. The sponsor, investigator, or Institutional Review Board may stop the study at any time.

**Subject Costs and Payments**

You will not be asked to pay any costs related to this research.

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If you and your child complete assessment one, you will receive \$20 for completing the survey questionnaires and \$15 each for returning your accelerometer with complete data for a total of \$50. If your accelerometer data is not complete, you and/or your child will be given the opportunity to wear the accelerometer for additional days to complete the data and receive payment.

If you and your child complete assessment two, you will be paid \$30 for finishing the surveys and \$20 each for returning your accelerometer with complete data for a total of \$70. If your accelerometer data is not complete, you and/or your child will be given the opportunity to wear the accelerometer for additional days to complete the data and receive payment.

If you and/or your child are asked to take part in an interview after the program ends, you will receive \$30 for completing the interview.

**Research Related Injury**

If you or your child are injured during the Papás Saludables, Niños Saludables program, the Papás Saludables, Niños Saludables program staff can provide first aid. If a medical emergency were to occur during the study and the injury requires more than first aid, the Papás Saludables, Niños Saludables study staff or Baylor College of Medicine may call 911 to bring emergency medical personnel to the The Center for Children and Women. You will be responsible for paying for any related costs or your medical care.

Research personnel will try to reduce, control, and treat any complications from this research. If you are injured because of this study, you will receive medical care that you or your insurance will have to pay for just like any other medical care.

**Subject's Rights**

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, TERESIA MARGARETA O'CONNOR, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: TERESIA MARGARETA O'CONNOR at 713-798-6782 during the day or page her at 832-822-2099 after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB)

**CONSENT FORM**

HIPAA Compliant

**Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals**

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can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

If your child is the one invited to take part in this study you are signing to give your permission. Each child may agree to take part in a study at his or her own level of understanding. When you sign this you also note that your child understands and agrees to take part in this study according to his or her understanding.

Please print your child's name here \_\_\_\_\_

**NOT  
CURRENTLY  
APPROVED**

**CONSENT FORM**

HIPAA Compliant

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

_____ Subject	_____ Date
_____ Legally Authorized Representative Parent or Guardian	_____ Date
_____ Legally Authorized Representative Parent or Guardian	_____ Date
_____ Investigator or Designee Obtaining Consent	_____ Date
_____ Witness (if applicable)	_____ Date
_____ Translator (if applicable)	_____ Date

**NOT CURRENTLY APPROVED**

**Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals****Consent for Mothers for the Papás Saludables, Niños Saludables study**

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**Background**

You are invited to take part in a research study with your 5- 11 year old child or children and their father. Please read this information and feel free to ask any questions before you agree to take part in the study.

Your child or children and their father are taking part in the Papás Saludables, Niños Saludables study. The Papás Saludables, Niños Saludables program is a group program for Hispanic fathers and their children between the ages of 5-11 years old. The program teaches fathers and their children fun, active games and sports to play together to get active. It also teaches fathers and their children about healthy eating to help fathers lose weight and children to have a healthy weight. The program lasts for 10 weeks, and meets every weekend (Saturday or Sunday) for 90 minutes. During the program, both fathers and the children learn practical things they can do together to help each other and their family to have healthy lifestyle behaviors. Fathers are also taught how they can help their child learn basic sports skills and new ways to try to encourage healthy eating, less screen time and fun activities for their child. Fathers and their children will get fun activities to try at home during the week before the next program meeting.

The Papás Saludables, Niños Saludables program will be run at your child's Texas Children's Health Plan (TCHP) Center for Children and Women Clinic or another TCHP clinic.

The goal of the 10 week Papás Saludables, Niños Saludables program is to get fathers more involved in their child's eating and physical activity to help them have a healthy weight. However, we know that mothers are very important in helping make this happen. While the focus of the program is on fathers, we want to make sure mothers learn the same things the fathers and children are learning and can help support and encourage their family to make healthy changes.

The program will share this information with you via short videos sent to you personally. You can choose to get these and messages of how you can help your family through a Papás Saludables, Niños Saludables Facebook closed group, by text messages, or by email. You will get a video every week and several messages and suggestions of how you can help support your family taking part in the program. You are invited to join the Papás Saludables, Niños Saludables program at your child's clinic in Week 4 of the program. You will also receive a Papás Saludables, Niños Saludables handbook for moms that has a lot of useful information and a cookbook.

This research study is funded by National Institute of Research: National Heart, Lung and Blood Institute

**Purpose**

This research study will test if Hispanic families like the Papás Saludables, Niños Saludables program and if the program can help Hispanic men and their children to be physically active together and eat healthy to help them have healthy weights.

We also want to learn what mothers think of the Papás Saludables, Niños Saludables program and if you used the Papás Saludables, Niños Saludables materials for moms.

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**Procedures**

The research will be conducted at the following location(s):

Baylor College of Medicine, CNRC: Children's Nutrition Research Center, and Texas Childrens Health plan: Center for Children and Women.

Families who agree to participate in the study will be randomly assigned to one of two groups. One of the groups will start the Papás Saludables, Niños Saludables program in September 2018 (first group); the second group will start the program in the Spring 2019. Your family will have a 50/50 chance of being in the group that begins in the fall or the group that begins next spring. You wont be able to choose which group youre in because we have to do it randomly like drawing names out of a hat.

Everyone in the study will take part in two research assessments: one before the first group starts Papás Saludables, Niños Saludables and then again after the first group has completed the Papás Saludables, Niños Saludables program. Your family will find out if you are in the first or second group of Papás Saludables, Niños Saludables after you have finished the first assessment.

During the assessments, you will be asked to complete some questionnaires. The questionnaires ask questions about your demographics, how you interact with your child about food and physical activity, how you and your child's father work together to parent your child, how you and children's father divide up household responsibilities, and your feelings about your family and culture. You will also be asked to help your child complete their questionnaires.

Assessments will be held at the same location that your program will be held on a weekend or weekday, at a time that suits you and your child after school hours.

During the 10 week program, you will receive weekly messages with information about how you can help support your family be successful. You will also get a link to a Papás Saludables, Niños Saludables informational video every week and a link to a short survey about what you thought about the video.

You will have a choice whether you would like to receive the weekly messages and videos by text , email or in a secret Papás Saludables, Niños Saludables Facebook group. The secret Facebook group will be hosted by Facebook, a third party. It is a secret group so that others cannot see what is posted and cannot join the group. If you decide to take part in the secret Facebook group, you will need to agree to Facebook's user and privacy agreements and be aware that Facebook will have access to information shared in this group. It is voluntary to join the secret Facebook group. If you prefer not to join the group, you will receive the same Papás Saludables, Niños Saludables information by text or email instead. To join the secret Facebook group, you will need to provide the Papás Saludables, Niños Saludables team with your Facebook user name.

By signing this consent you agree to allow us to send Papás Saludables, Niños Saludables messages, videos, surveys and reminders to you via text or email based on your preference. You will only be added to the secret Papás Saludables, Niños Saludables Facebook group if you initial here and provide us

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with your Facebook username.

\_\_\_\_\_ YES, you have my permission to add me to the secret Papás Saludables, Niños Saludables Facebook group.

My Facebook user name is: \_\_\_\_\_

**Participant Rules for Secret Facebook Group**

1. To join the secret group, moms have to agree to Facebooks user agreement and be aware that what is posted will be seen by others. Their Facebook username will be seen by others in the group.
2. They should not share personal information about themselves or others in the group
3. We encourage all group members to actively engage in the group , but they have to be respectful of others in the group. Disparaging names or words are not allowed.
4. All posts will be reviewed by the Papás Saludables, Niños Saludables administrator and will only be seen by others if deemed appropriate by the administrator. Information that is not in line with what is taught in Papás Saludables, Niños Saludables may not be posted.
5. The Papás Saludables, Niños Saludables team has the right to remove any post they see as not appropriate for any reason.

After your family has completed the Papás Saludables, Niños Saludables program you will be asked to complete a survey about what you thought of the program and any suggestions you have to improve it. You may be picked to take part in an interview after the program ends to give us more details about your thoughts on the Papás Saludables, Niños Saludables program. If you are asked to take part in this interview, it will be audio-recorded.

This study is to test the feasibility of Papás Saludables, Niños Saludables. We may continue to run this program in the future. If we do, we would like to use photos or videos of families that took part in Papás Saludables, Niños Saludables in our program material. Please let us know by initialing below, if we have your permission to use photos or videos of you and your child in future Papás Saludables, Niños Saludables program recruitment, training and family materials and study presentations:

\_\_\_\_\_ YES, you have my permission to use photos or videos of me in future Papás Saludables, Niños Saludables program recruitment, training and family materials and study presentations.

**Research related health information**

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine, CNRC: Children's Nutrition Research Center, and Texas Children's Health plan: Center for Children and

Women to use or disclose (release) your health information that identifies you for the research study

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described in this document.

The health information that we may use or disclose (release) for this research includes:

- Demographic information (name, D.O.B., age, gender, race, etc.)
- Photographs, videotapes, and/or audiotapes of you

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, CNRC: Children's Nutrition Research Center, Texas Children's Health plan: Center for Children and Women, and NATIONAL INSTITUTES OF HEALTH (NIH) and their representatives.

A Data and Safety Monitoring Board will have access to the research records including your health information.

**Use or Disclosure Required by Law**

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

Baylor College of Medicine, CNRC: Children's Nutrition Research Center, and Texas Children's Health plan: Center for Children and

Women are required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine, CNRC: Children's Nutrition Research Center, and Texas Children's Health plan: Center for Children and

Women to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research does not involve treatment. Baylor College of Medicine, CNRC: Children's Nutrition Research Center, and Texas Children's Health plan: Center for Children and Women may not condition (withhold or refuse) treating you on whether you sign this Authorization.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, NATIONAL INSTITUTES OF HEALTH (NIH) and their representatives, regulatory agencies such as the U.S. Department of Health and Human Services, Baylor College of Medicine, Data and Safety Monitoring Board, CNRC: Children's Nutrition Research Center, and Texas

**Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals**

**Consent for Mothers for the Papás Saludables, Niños Saludables study**

H-38237- HEALTHY DADS, HEALTHY KIDS LATINO- ADAPTATION AND FEASIBILITY OF A LIFESTYLE INTERVENTION FOR LATINO FAMILIES

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Children's Health plan: Center for Children and

Women may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization .

To revoke this Authorization, you must write to: Teresia O'Connor Children's Nutrition Research Center Baylor College of Medicine 1100 Bates Street Houston, TX 77025

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

**Potential Risks and Discomforts**

If you elect to participate in the Papás Saludables, Niños Saludables closed group Facebook page, others in the group will see anything that you post to the group. The group will be monitored on a daily basis and edited to keep the content appropriate. Participating in this group will increase the risk of loss confidentiality.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

**Potential Benefits**

The benefits of participating in this study may be: you may learn new ways that you and your family can eat healthy and be more active which may improve your weight, and thereby your health. You may also find satisfaction in helping your family have healthier lifestyle habits. However, you may receive no benefit from participating.

**Alternatives**

You may choose to not participate in this study.

**Investigator Withdrawal of Subject from a Study**

The investigator or sponsor may decide to stop you from taking part in this study at any time. You could be removed from the study for reasons related only to you (for example, if you move to another city, or if you are disruptive during the program in such a way that it negatively affects other families ) or because the entire study is stopped. The sponsor, investigator, or Institutional Review Board may stop the study at any time.

**Subject Costs and Payments**

You will not be asked to pay any costs related to this research.

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Your families payment for taking part in this study is outlined in the consent form for the father and child .

If you are asked to take part in an interview after the Papás Saludables, Niños Saludables program ends, you will receive \$30 for completing the interview.

**Subject's Rights**

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, TERESIA MARGARETA O'CONNOR, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: TERESIA MARGARETA O'CONNOR at 713-798-6782 during the day and page her at 832-824-2099 after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research , if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

**CONSENT FORM**

HIPAA Compliant

**Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals**

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

_____ Subject	_____ Date
_____ Investigator or Designee Obtaining Consent	_____ Date
_____ Witness (if applicable)	_____ Date
_____ Translator (if applicable)	_____ Date

**NOT  
CURRENTLY  
APPROVED**