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Study PI: Dr. Patria Rojas, Ph.D.

Study Title: Hispanic Men Building Respect Education and Safety (Family Men) - Substudy Under Center for Latino Research Opportunities (CLaRO)

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Center for Latino Health Research Opportunities
UNIVERSITY OF MIAMI | FLORIDA INTERNATIONAL UNIVERSITY

ADULT CONSENT TO PARTICIPATE IN A RESEARCH STUDY

**HoMBRES de Familia (Hispanic Men Building Respect, Education, and Safety within Families) sponsored by the National Institute of Health
Intervention Phase**

PURPOSE OF THE STUDY

You are being asked to consent to take part in this study now that you are a legal adult.

You are asked to be in a research study. The purpose of this study is to see if the HoMBRES program can help Latino fathers in the urban or semi-rural communities of Miami-Dade talk to their sons about drugs, alcohol and Human Immunodeficiency Virus (HIV)/Sexual Transmitted Infections (STIs).

NUMBER OF PARTICIPANTS

We are asking 320 father-sons to be in the study (160 fathers and 160 sons).

DURATION OF THE STUDY

You are asked to be in the study for about 6 months.

PROCEDURES

If you agree, you will first be asked to do some questionnaires. You will be asked about cultural beliefs, use of alcohol/drugs, and sexual practices. The questionnaire will take around 1-2 hours. The answers from the questionnaire are confidential. Fathers cannot see their sons' answers and sons will not see their fathers' answers.

All fathers and their sons will be asked to complete the questionnaires again 6 months after the first. The questionnaire will take around 1 to 1.5 hours.

If you or another adult refer another father-son dyad, who sign up for the study, you will get \$20 cash.

RISKS AND/OR UNEASINESS

You may become uneasy and/or stressed with the questions. You can say no to take part in the study or not answer questions. Study staff can help you in any way you need.

BENEFITS

No direct benefits are promised to you. We hope the study will help fathers learn about these sensitive topics and better talk to their sons about them.

CONFIDENTIALITY

Every attempt will be made to keep your information private. Study ID numbers will be used in place of your names. The list containing these numbers and names will be saved in locked cabinets or password-protected devices at Florida International University (FIU) and only available to the study team.

This research is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health (NIH). The researchers, with this CoC, may not give out or use information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding. Your information may not be used as evidence if there is a court subpoena, unless you consent to this use. Information and documents protected by this CoC cannot be disclosed to anyone else who is not connected with the research except as described below, and

- If you consent to the disclosure;
- If it is used for other scientific research as allowed by federal regulations protection research subjects.

A CoC does not prevent you from saying you are in this study. If you want your research information given to anyone not part of this research, you must give consent to allow the study team to release it.

The CoC cannot be used to prevent reporting information that is required by law. If we find that you are at risk to harm yourself or others, abuse or neglect a child or elderly person, or other forms of abuse, we are required by law to report this immediately to the proper authorities.

Your information may be looked at and/or copied for research or regulatory purposes by:

- The sponsor;
- Department of Health and Human Services (DHHS);
- other government agencies;
- other University of Miami employees for audit and/or monitoring purposes; and
- other organizations collaborating in the research.

At the end of this study, the researchers may publish their findings. Information will be presented in summary format. You will not be identified in any publications or presentations.

COMPENSATION AND EXPENSES

You will get:

- \$25 cash for the first questionnaires and \$40 cash for the 6 months follow up questionnaires.

RIGHT TO DECLINE OR TO LEAVE

Your time in this study is voluntary. You are free to say no or leave at any time. The investigator can remove you without your consent if they feel it is best for the study and you.

CONTACT INFORMATION OF THE INVESTIGATOR

If you or your son have a question about the research study, you can contact:

- FIU Principal Investigator: Dr. Patria Rojas, Assistant Professor at the Robert Stempel College of Public Health and Social Work, 11200 SW 8TH Street, Miami, FL, 33199; at 305-348-7352 or email to patria.rojas@fiu.edu.

-UM Principal Investigator: Dr. Victoria Behar-Zusman, Professor and Dean for Research at the School of Nursing and Health Studies, 5030 Brunson Drive, Coral Gables, FL 33126; at 305-284-9139 or email to vmitrani@miami.edu

IRB CONTACT INFORMATION

This research has been reviewed and approved by an Institutional Review Board ("IRB"). The Human Subject Research Office (HSRO) provides administrative support to the University of Miami's IRBs. Please call the HSRO at 305-243-3195 if you are a participant in any research being conducted by UM.

PARTICIPANT'S STATEMENT/SIGNATURE

- *I have read this form and the research study has been explained to me.*
- *I have been given the chance to ask questions, and my questions have been answered. If I have more questions, I have been told who to call.*
- *I agree to be in the research study described above.*
- *I will receive a copy of this consent form after I sign it.*

Verbal Assenting:

☐ Adult provided verbal assent for his participation in the study (Adult's **signature is not required**; witness signature is required).

Printed Name of Adult

Printed Name of Person Obtaining Consent

Signature of Person Obtaining
Consent

Date

Face to Face Assenting:

☐ Adult provides written consent for his participation in the study (Adult's **signature is required**; witness signature is not required).

Printed Name of Adult

Signature of Adult

Date

Printed Name of Person Obtaining Consent

Signature of Person Obtaining
Consent

Date



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LAR CONSENT TO PARTICIPATE IN A RESEARCH STUDY

**HoMBRES de Familia (Hispanic Men Building Respect, Education, and Safety within Families) sponsored by the National Institute of Health
Intervention Phase**

PURPOSE OF THE STUDY

Your minor, between 11 and 17 years of age, is being asked to be in a research study. The purpose of this study is to see if the HoMBRES program can help Latino fathers who live or work in the farm industry, construction, sales, services, self-employed, or any other work industry in the urban or semi-rural areas of Miami-Dade talk to their sons about drugs, alcohol and Human Immunodeficiency Virus (HIV)/Sexual Transmitted Infections (STIs).

You are being asked to give consent for your minor to take part in the study. The consent describes what your minor is being asked to do.

NUMBER OF PARTICIPANTS

We are asking 320 father-sons to be in the study (160 fathers and 160 sons).

DURATION OF THE STUDY

Your minor is asked to be in the study for about 6 months.

PROCEDURES

If you agree, your minor will first be asked to do some questionnaires. He will be asked about cultural beliefs, use of alcohol/drugs, and sexual practices. The questionnaire will take around 1 to 1.5 hours. The answers from the questionnaire are confidential. We will not share his results with you.

He will be asked to complete the questionnaires again 6 months after the first. The questionnaire will take around 1-2 hours.

RISKS AND/OR UNEASINESS

Your minor may become uneasy and/or stressed with the questions. He (and you) can say no to taking part in the study and he does not have to answer questions that make him uneasy. Study staff can help him in any way he needs.

BENEFITS

No direct benefits are promised your minor. Fathers may learn about ways to talk to their sons about HIV/ STI, alcohol, drugs and violence.

CONFIDENTIALITY

Every attempt will be made to keep your minor's information private. Study ID numbers will be used in place of your names. The list containing these numbers and names will be saved in locked cabinets or password-protected devices at Florida International University (FIU) and only available to the study team.

This research is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health (NIH). The researchers, with this CoC, may not give out or use information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding. Your information may not be used as evidence if there is a court subpoena, unless you consent to this use. Information and documents protected by this CoC cannot be disclosed to anyone else who is not connected with the research except as described below, and

- If you consent to the disclosure;
- If it is used for other scientific research as allowed by federal regulations protection research subjects.

A COC does not prevent you from saying you are in this study. If you want your research information given to anyone not part of this research, you must give consent to allow the study team to release it.

The COC cannot be used to prevent reporting information that is required by law. If we find that you are at risk to harm yourself or others, abuse or neglect a child or elderly person, or other forms of abuse, we are required by law to report this immediately to the proper authorities.

Your minor's information may be looked at and/or copied for research or regulatory purposes by:

- The sponsor;
- Department of Health and Human Services (DHHS);
- other government agencies;
- other University of Miami employees for audit and/or monitoring purposes; and
- other organizations collaborating in the research.

At the end of this study, the researchers may publish their findings. Information will be presented in summary format. Your minor will not be identified in any publications or presentations.

COMPENSATION AND EXPENSES

Minors will get:

- \$25 cash for the first questionnaires and \$40 cash for the 6 months follow up questionnaires.

RIGHT TO DECLINE OR TO LEAVE

Your minor's time in this study is voluntary. You are both free to say no or he may leave at any time. The investigator can remove your minor without your consent if they feel it is best for the study, you and/or of your minor.

CONTACT INFORMATION OF THE INVESTIGATOR

If you or your minor have a question about the research study, you can contact:

- FIU Principal Investigator: Dr. Patria Rojas, Assistant Professor at the Robert Stempel College of Public Health and Social Work, 11200 SW 8TH Street, Miami, FL, 33199; at 305-348-7352 or email to patria.rojas@fiu.edu.

-UM Principal Investigator: Dr. Victoria Behar-Zusman, Professor and Dean for Research at the School of Nursing and Health Studies, 5030 Brunson Drive, Coral Gables, FL 33126; at 305-284-9139 or email to vmitrani@miami.edu

IRB CONTACT INFORMATION

This research has been reviewed and approved by an Institutional Review Board ("IRB"). The Human Subject Research Office (HSRO) provides administrative support to the University of Miami's IRBs. Please call the HSRO at 305-243-3195 if you are a participant in any research being conducted by UM.

PARTICIPANT'S STATEMENT/SIGNATURE

- *I have read this form and the research study has been explained to me.*
- *I have been given the chance to ask questions, and my questions have been answered. If I have more questions, I have been told who to call.*
- *I agree to be in the research study described above.*
- *I will receive a copy of this consent form after I sign it.*

Verbal Consenting:

☐ Legal representative provided verbal consent for youth's participation in the study (**legal representative's signature is not required**; witness signature is required).

Printed Name of Legal Representative

Printed Name of Youth

Printed Name of Person Obtaining Consent

Signature of Person Obtaining
Consent

Date

Face to Face Consenting:

☐ Legal representative provides verbal consent for youth's participation to the study HoMBRES de Familia (**legal representative's signature is required**; witness signature is not required).

Printed Name of Legal Representative

Signature of Legal Representative

Printed Name of Youth

Date

Printed Name of Person Obtaining Consent

Signature of Person Obtaining
Consent

Date



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ASSENT OF THE MINOR TO PARTICIPATE IN A RESEARCH STUDY

HoMBRES de Familia (Hispanic Men Building Respect, Education, and Safety within Families /Hombres Manteniendo Respeto, Educacion y Seguridad de Familia (HoMBRES) Intervention

PURPOSE OF THE STUDY

We are asking you to be in a research study. We want to study education sessions to help fathers learn about Human Immunodeficiency Virus (HIV) and Sexually Transmitted Infections (STIs). This is to help fathers talk to their teen sons about not using drugs or alcohol, violence and HIV/STIs in the urban or semi-rural communities of Miami-Dade.

NUMBER OF STUDY PARTICIPANTS

You will be one of 320 (160 adults and 160 teens) in this study.

WHAT WILL HAPPEN IN THIS STUDY?

We will ask you to answer some questions that you will receive via a link that you can open on your phone, computer, tablet or iPad. You will be asked to answered these questions at the beginning of the study and again 6 months later. The questionnaires will take about 1 to 1.5 hours each time.

MAYBE SOMETHING BAD MAY HAPPEN?

We do not think that anything bad will happen to you. Some of questions are personal and may make you uncomfortable. Study staff can help you in any way you need. You do not have to answer any question or you can leave the study at any time.

MAYBE SOMETHING GOOD MAY HAPPEN?

No direct benefit is promised to you. We hope the study will help fathers learn about these sensitive topics and better talk to their sons about them.

Will SOMEONE KNOW THAT I AM PARTICIPATING IN THE STUDY?

Your records will be kept private. Study ID numbers will be used in place of you name. The list that has these numbers and names will be saved in locked cabinets or password-protected devices at Florida International University (FIU). Your information will only available to the study team.

To protect your privacy, we have a Certificate of Confidentiality from the National Institutes of Health (NIH). With this certificate, we cannot be forced to share information that could identify you in any civil, criminal, administrative, or any legal procedure.

There are some cases that the certificate does not protect your personal information. Research staff need to share records:

- When the government is auditing or evaluating a study that has received federal funds.
- If your father gives allows someone to get information on your participation in the study.
- If you report wanting to harm yourself or another person.
- In case of abuse and/or neglect of any minor and/or elderly.

In any report that we publish, we will not include your identity. We will not share your questionnaire results with your parents.

WILL I GET ME SOMETHING FOR PARTICIPATING?

You will get \$25 cash for the first questionnaire and then \$40 cash for the 6 months follow up.

WHAT HAPPENS IF I DON'T WANT TO DO THIS?

Your participation in this study is voluntary. No one will get mad if you decide that you do not want to do this.

WHO CAN I TALK TO ABOUT THE STUDY?

If you have any questions about the research study, you may contact Dr. Patria Rojas at 305-348-7352 or by email to patria.rojas@fiu.edu. If you want to talk to someone about your rights as a research participant, you may contact the University of Miami Human Subjects Research Office by phone at 305-243-3195.

Verbal Assenting:

☐ Youth provided verbal assent for his participation in the study (**youth's signature is not required**; witness signature is required).

Printed Name of Youth

Printed Name of Person Obtaining Consent

Signature of Person Obtaining
Consent

Date

Face to Face Assenting:

☐ Youth provides written consent for his participation in the study (**youth's signature is required**; witness signature is not required).

Printed Name of Youth

Signature of Youth

Date

Printed Name of Person Obtaining Consent

Signature of Person Obtaining
Consent

Date