CONSENT FOR RESEARCH

The Pennsylvania State University

Title of Project: *Noventa Millas:* Genomics, migration history, and health disparities within Cuban immigrants and Cuban-Americans in Miami, Florida

Principal Investigator: Margarita Hernandez

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Faculty Advisor: Dr. George Perry

Faculty Advisor Telephone Number: (814) 863-7654

Subject's Printed Name: _____

We are asking you to be in a research study. This form gives you information about the research.

Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you and there will be no penalty or loss of benefits to which you are entitled.

Please ask questions about anything that is unclear to you and take your time to make your choice.

DETAILED INFORMATION

The following is more detailed information about this study in addition to the information provided above.

1. Why is this research study being done?

This research is being done to understand how genomics, lived experiences, and narratives of migration are associated with adverse health outcomes within Cuban immigrants and Cuban-Americans living in Miami, Florida.

Approximately 120 people will take part in this research study living in Miami, Florida.

2. What will happen in this research study?

First, you will be asked to provide consent to participate in the research process. Margarita will go through the consent form with you, describing the study and the details of your participation. Margarita will also answer any questions you may have about the study prior to obtaining consent. If you choose to participate in the study, you will be asked to sign this form and will also receive a copy of this form for your records.

Once consent is obtained, you will be asked to complete the following:

- Provide a DNA sample
- Complete a survey
- Participate in a semi-structured interview

The DNA sample will be collected using a buccal (mouth) swab using a Psomagen DNA collection kit. The collection will take no more than 15 minutes to complete. Your sample will be used to generate low-coverage whole genome sequence data in order to infer ancestral population proportions.

You will be asked to complete a survey using an Apple iPad. Margarita will walk you through each question and you will answer them together to ensure accuracy of the responses. The survey will take no more than 30 minutes to complete.

Lastly, you will be asked to participate in a semi-structured interview. Margarita will be recording your conversation together. This interview may take up to an hour to complete, but no more than two hours.

The total duration of the study visit may take between one and three hours to complete.

3. What are the risks and possible discomforts from being in this research study?

There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained as required by applicable law and to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

Genetic information is unique to you, even without your name or other identifiers. For this reason, genetic information like DNA may be used to identify you and possibly your family members. We have procedures (such as labeling your samples with a password-protected code known only to select research staff) to prevent people working with your DNA from discovering if it belongs to you. However, there is the risk this can happen as new ways of tracing genetic information are being developed that may make re-identification of genetic information possible.

You will be receiving your DNA data and ancestral population proportions through this study. Although we are not testing your DNA for anything involving inherited health traits, there may be a risk in knowing the results. For example, new health information about inherited traits that might affect you or your blood relatives could be found during a research study. Such information may affect how you or your family makes health decisions. In some cases, this information could be used to make it harder for you to get or keep a job or affect your insurance. For example, life insurance companies may charge a higher rate based on this information. There are laws against the misuse of genetic information, but they may not give full protection. The chance that your information could be misused is very small. We have many protections in place to lower this risk.

You should also be aware that we may detect instances of non-paternity. For example, if a person you believe is your child is not actually your biological child, the testing may inadvertently detect this. You will not be informed of this, if it occurs.

The Genetic Information Nondiscrimination Act (GINA) may help protect you from health insurance or employment discrimination based on genetic information. The law provides that health insurance companies and group health plans:

- May not ask for genetic information from this research; and
- May not use genetic information when making decision about eligibility or premiums.

The law will not stop health insurance companies from using genetic information to decide whether to pay claims. The law does not apply to other types of insurance (such as: life, disability or long-term care).

Additionally, you may experience some distress related to answering the questions within the study. This could include recounting difficult experiences related to your life and your health. If you experience distress and are in need of mental health services, please visit https://namimiami.org/ for more information. Additionally, Margarita will provide you with a list of resources from NAMI Miami for you to use as you need.

4. What are the possible benefits from being in this research study?

4a. What are the possible benefits to you?

You will not receive any direct benefits from this research study.

4b. What are the possible benefits to others?

The results of the research may help scientists better understand the diversity of factors associated with adverse health conditions within immigrant and first-generation communities, especially as they relate to social factors that influence health. These results can help to generate better public health policy that includes individual lived experiences and contribute to understanding the social changes needed to ensure better health for all.

5. What other options are available instead of being in this research study?

You may decide not to participate in this research study.

6. How long will you take part in this research study?

If you agree to take part, it will take you about one to three hours to complete this research study. You will be visited only once.

7. How will your privacy and confidentiality be protected if you decide to take part in this research study?

7a. What happens to the information collected for the research?

Efforts will be made to limit the use and sharing of your personal research information to people who have a need to review this information. Reasonable efforts will be made to keep the personal information in your research record private. However, absolute confidentiality cannot be guaranteed.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Your extracted DNA will be sent to Psomagen for DNA sequencing and then transferred to Gencove for analytical processing. For research specimens sent to Psomagen and Gencove, you will be identified by a number that will correspond to the number of the Oragene DNA collection kit. No personal identifiable information will be shared with either Psomagen or Gencove. You will be assigned a number associated with your sample. Only Margarita Hernandez will have access to the list that links your number with your information. This list will be password-protected.

We will do our best to keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people may find out about your participation in this

research study. For example, the following people/groups may check and copy records about this research.

- The Office for Human Research Protections in the U. S. Department of Health and Human Services
- The Institutional Review Board (a committee that reviews and approves research studies) and Penn State's Office for Research Protections.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot disclose information that identifies you to anyone not connected with the research. This protection also prevents this information from being used or disclosed for legal proceedings, such as being accessed through a court order. The Certificate of Confidentiality however does not prevent disclosures required by law, such as information about child abuse or neglect and harm to yourself or others. Also, your information may be disclosed in accordance with any consent you provide, including for your medical treatment or use in other research. Additionally, the Certificate of Confidentiality does not prevent your information from being disclosed to the National Human Genome Research Institute (NHGRI) in order for it to evaluate or audit the research, or prevent disclosures required to meet FDA requirements. For additional information ask the principal investigator or a member of the study team or contact the Human Research Protection Program at (814) 865-1775.

7b. What will happen to my research information and/or samples after the study is completed?
De-identified genomic sequencing data will be deposited in the National Center for Biotechnology Information's (NCBI) Database of Genotypes and Phenotypes (dbGaP). De-identified survey and ethnographic data will be deposited on Zenodo. Both groups of data will be deposited under controlled access. This means that data will only be available for reanalysis pending the submission of a written proposal summarizing the research project, how access to the data will meet the goals of the research project, and the intended analyses to be performed on the data. Access to genomic and ethnographic data will only be made available to scientists interested in studying health within Latinx populations. Margarita Hernandez will be responsible for reading through these summaries and granting access to investigators. Projects will be restricted to only scientific, not-for-profit research, and may involve other scientists in the United States and in other parts of the world.

8. Will you be paid or receive credit to take part in this research study?
You will receive a Visa gift card for your participation in this research study at the conclusion of your visit for a total of $30.00.

9. Who is paying for this research study?
Funds from the National Science Foundation, the National Institutes of Health, and the Penn State College of Liberal Arts are being used to support this research.

10. What are your rights if you take part in this research study?
Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

11. If you have questions or concerns about this research study, whom should you call?

Please call the head of the research study (principal investigator), Margarita Hernandez at (954) 696-3502 if you:

- Have questions, complaints or concerns about the research, including questions about compensation.
- Believe you may have been harmed by being in the research study.

You may also contact the Office for Research Protections at (814) 865-1775, IRB-ORP@psu.edu if you:

- Have questions regarding your rights as a person in a research study.
- Have concerns, complaints, or general questions about the research.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

You may visit the Office for Research Protections' website at https://www.research.psu.edu/irb/participants for:

- Information about your rights when you are in a research study;
- Information about the Institutional Review Board (IRB), a group of people who review the research to protect your rights; and
- Links to the federal regulations and information about the protection of people who are in research studies. If you do not have access to the internet, copies of these federal regulations are available by calling the ORP at (814) 865-1775.

INFORMED CONSENT TO TAKE PART IN RESEARCH

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the research to the subject or subject representative, provided the subject or subject representative an opportunity to discuss and consider whether or not to participate in the research, and have answered any questions the subject or subject representative has about the research.

_____	_____	_____
Signature of person who explained this research	Date	Printed Name

(Only approved investigators for this research may explain the research and obtain informed consent.)

Signature of Person Giving Informed Consent

Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Signature of Subject

By signing this consent form, you indicate that you voluntarily choose to be in this research and agree to allow your information to be used and shared as described above.

_____	_____	_____
Signature of Subject	Date	Printed Name