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UNIVERSITY OF CALIFORNIA, IRVINE
CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT

Ethnic Influences on Stress, Energy Balance and Obesity in Adolescents

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STUDY LOCATION(S):
University of California at Irvine (UCI), Irvine, CA
Other Agencies Affiliated with UCI, CHOC & Public Places

STUDY SPONSOR(S):
National Institutes of Health

In the instance of parental permission, "You" refers to "Your child."

SUMMARY OF KEY INFORMATION:

The information provided in this box includes a brief yet complete summary of key information about the research, presented first as required by the federal regulations. Some sections that require additional information may be repeated later in this document.

Participation is Voluntary
You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. A researcher listed above will be available to answer your questions.

Study Purpose
The purpose of this research study is to identify factors that are associated with weight problems in African-American (Black), Hispanics (Latinx) and Caucasian (White) adolescent females.

Study Procedures
You and your child will participate in completing interviews and questionnaires. Your child will continue the study with a home visit where they will wear a watch-like device for 7-days to record their activity level, answer questions about their eating patterns and collect saliva samples for 2-days at home. Then, they will complete two more visits where they will participate in a 15-minute task (relaxation task or evaluation task) and saliva samples will be collected pre- and post-assessment. At one these visits, your child will provide a blood sample, hair sample and participate in a scan that measure body composition.

Expected Duration
Participation will last approximately 17-20 hours and will include four visits.
Risks of Participation

The more notable risks of participation include feeling uncomfortable reporting about personal information or any redness or soreness from the venous blood draw or completing the body composition (DEXA) scan since it emits radiation. Also, should there be a breach in confidentiality of your data, there is a slight risk that your private information could be shared with individuals who are not members of the study team.

Benefits to Participants
You will not directly benefit from participation in this study.

Benefits to Others or Society
This study will help researchers learn more about biological, behavioral and social mechanisms underlying racial/ethnic differences in obesity-related factors in adolescent females, and it is hoped that this information will help in the developing more "personalized", ethnically-sensitive programs to reduce such weight problems in youth.

Alternative Procedures or Treatments
There are no alternative treatments or procedures available. The only alternative is not to participate in this study.

WHY IS THIS RESEARCH STUDY BEING DONE?
The purpose of this research study is to identify factors that are associated with weight problems in African-American (Black), Hispanics (Latinx), and Caucasian (White) adolescent females.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 300 participants will take part in the research at UCI.

AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?
Please note this may not be a complete list of eligibility criteria. We have included a few examples of study criteria to help you better understand how your eligibility in the study will be determined; your study team will go through the study eligibility criteria with you to verify if you qualify for participation in this study.

Inclusion Requirements
You and your child can participate in this study if your child is between 13 and 17 years of age, inclusive, female, and identify as African-American, Hispanic or Caucasian.

Exclusion Requirements
You and your child cannot participate in this study if your child has a body mass index (calculated by weight and height) below the normal range, is trying to lose weight, on medications that affect appetite, or if your child is pregnant.

HOW LONG WILL THE STUDY GO ON?
This study includes four visits and takes about 17-20 over a period of 2-3 weeks.

WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY?
Before you can participate in the main part of the study...
You will need to have "screening" exams, tests or procedures. The screening process helps the researchers decide if you meet the study requirements listed below. The screening procedures include a phone screen with both parent and adolescent.

During the main part of the study...
If the screening exams, tests and/or procedures show that you can continue to be in the study, and you choose to take part, then you will have the following procedures and tests done, which will take place at UCI, UCI Medical Center, or another affiliated agency or your place of residence, if that location is more convenient for you. The main study tests and procedures include…

Assessment 1 (3-5 hours):

Interviews: During the visit, we will interview you and your child. The interview topics include questions about your family background and any health problems, and traumatic and stressful events your child might have experienced. These topics may be sensitive for you or your child. You and your child may choose to skip any questions you do not want to answer. We may audiotape the interview with a digital recorder. We will tell you and your child when we are taping. You and your child may decide at any time that you do not want your responses to be taped. Audiotapes of the interviews will not include your name or your child's name or any information that would allow someone to identify who you or your child is. These tapes will be used to assure that our research staff asks the right questions and for training new staff members. The recordings will be stored in a secure locked cabinet in the lead researcher's laboratory and only research staff will have access to them.

After this interview, based on the study criteria, you and your child may be withdrawn from the study. If you both are withdrawn from the study, we will pay you and your child for your time for this interview.

If we find that your child is experiencing physical, sexual or emotional abuse or could be in possible danger, we have to report it to the proper authorities to keep your child safe. Before we make the report, we will discuss this with you and your child.

Questionnaires: We will also ask you and your child to complete some questionnaires. You will complete information about any stressful experiences your family may be experiencing and information about your childhood and your child's experiences and any mental health problems your child may be experiencing. You will also complete information about your own stressful experiences, your relationship with your child, and your relationships with others. Your child will complete information about her puberty, mental health problems, childhood experiences, food preferences and eating patterns, stressful experiences and how she copes with these experiences, and social support. If your child says that she is thinking about or planning to hurt herself, then we will discuss this information with you and ask you and your child to speak to someone today to make sure that your child is safe. If she is unable to complete all the questionnaires during this session, she can complete them at home via email, return them by mail in a self-addressed envelope or bring them to the next visit.

Instructions: You and your child will receive detailed instructions on the assessments that will occur during Visit 2, which will take place at your home next week. Your child also will be fitted with a monitor on the wrist (watch-like) to measure daily activity levels over the next week.

Assessment 2 (3-4 hours over a one-week period):

Diet Information: One of the research staff will contact your child by telephone on three separate days and will ask her to provide information on what she ate in the previous 24 hours. Each interview should take about 30 minutes.

Physical Activity and Sleep: During the week, your child's physical activity levels and sleep will be measured by a watch-like monitor, called the Actigraph, worn on the wrist continuously. You will receive no payment of any kind until the Actigraph watch that is loaned to you is returned. The Actigraph watch is

the research property of UCI and obtained through federal funds. It has no value to outsiders but this device is very valuable to UCI because of the important research data. If you choose to discontinue your participation prior to completing the full study, you are still responsible for returning the Actigraph watch promptly. If you do not return the Actigraph watch by the specified return date, you may be held financially responsible for its replacement cost ($300). If the Actigraph is not returned, you will not be compensated for the remaining visits, and you will not pay for the replacement cost.

Saliva Samples: On two consecutive days during the same week, your child will be asked to provide five saliva samples each day. Detailed instructions will be given during Visit 1 on how to collect these saliva samples. Also, your child will be provided with a white device (MEMS cap) and tubes to collect the saliva samples. The saliva samples will be collected at the following times each of these two days: when your child first wakes up, 30 minutes after she wakes up, before lunch around 12 pm, in the afternoon around 4:00 pm, and at night around 9 pm. Collecting each saliva sample will take about 5-10 minutes. Saliva samples must be stored in provided plastic bags in a freezer until you or your child bring them to your next visit.

Questionnaire: Your child also will complete a questionnaire on stressful experiences each day of visit two.

After collecting visit two items, we may ask your child to re-do visit two assessments if we find the results are not valid.

Assessment 3 is a two-part visit (5-6 hours per visit):

Assessment 3 will consist of two separate visits and will be conducted at UCI or its affiliated centers. Directions will be provided to you and your child on how to get to the site. These two visits will be separated by 5 to 31 days in between. For each site visit, your child should not eat anything after 10 pm the night before, and she should come to the study site in a fasting state.

Blood Sample: In only one of the assessments, a blood sample (approximately 50 ml) will be collected from your child's arm. This blood sample will be used to measure liver function, metabolic markers, inflammatory mediators and hormones that relate to stress, appetite regulation, and metabolism. The blood draw will only occur once during the duration of the study.

DXA Scan: In one of the assessments, your child will have a body scan that is somewhat like an X-ray.

Your child will be asked to lie flat on a table while a machine scanner moves up and down her body, without touching, and takes pictures. These pictures provide information on the amount of muscles, bones and fat in a person's body. This test will last about 15 to 20 minutes.

Food Experiments: Your child will participate in two types of food experiments, one at each visit. In one visit, the food experiment will be conducted after she is well relaxed by watching a short nature movie. In the other visit, the food experiment will be conducted after she performs an evaluation task in front of an audience. This task is similar to what most teens experience in school, but it may cause anxiety. The order of these two food experiments (which one will occur first) is based on a random basis (like a coin toss). In both visits, she will be given breakfast and asked to relax for about 3 hours during which she may read or watch movies that have been approved. After, she will be asked to provide saliva samples for measuring stress and appetite regulating hormones and answer questions about how she is currently feeling for a total of 6 times: 15 minutes and 1 minutes before the task, 1 minute after the task, 10 minutes, 20 minutes and 30 minutes post the task. Then she will be given a buffet lunch and will be discharged from the study site.

Food Recall: A research staff member will call your child the day after both food experiment visits to ask what she ate the previous day and a half. Each interview should take about 30 minutes.

Additional Procedures (to be completed at any visit):
Blood spot: Your child will be asked to provide a few drops of blood. This sample will be used to examine biological markers for inflammation. If the first attempt is unsuccessful (i.e. your child's finger does not produce enough blood), your child will be asked if she is willing to try again.

Weight, Height and Waist Measurements: We will take your child's weight, height and waist measurements.

Hair Sample: One of the research staff will cut two separate bundles of hair from your child. A total number of ~ 60 strands of hair will be cut close to her scalp from two locations at the back of her head (most people shed between 50-100 strands per day naturally). The hair sample will be used to measure stress hormone levels. Also, she will be asked questions about hair washing frequency, hair treatment and hair color.

Visits may be combined, or assessments may be completed at the next study visit based on your preference, time constraints, and staff availability. Additionally, some interview and questionnaire measures may be completed by phone, mail or online if they are not able to be completed at a study visit.

WHAT ARE THE POSSIBLE SIDE EFFECTS OR RISKS RELATED TO THE STUDY?
There are no known harms or discomforts associate with this study beyond those encountered in normal daily life. You should talk to the research team about any side effects you experience while taking part in the study. The possible risks and/or discomforts associated with the procedures described in this study include:

Questionnaires and Interviews: Some people feel uncomfortable reporting about personal information. For example, you or your child may experience some emotional discomfort in answering questions about your family's and child's problems and past traumatic experiences. If you or your child feel(s) uncomfortable while completing the interview or any of the questionnaires, then you both are free to choose not to answer those questions. Also, if you wish to stop at any time, you can do so by telling the research staff person. However, you might not be able to continue in the study if you stop or do not answer certain questions.

Hair Sample: Collection of hair samples may cause some physical discomfort if your child's hair is pulled while cutting it. Also, it is possible that she may experience discomfort with the idea of someone cutting hair from the back of her head. We will try to make sure that the sample locations are well-hidden.
Dietary information: These have no known risks although it may be inconvenient for you or your child to provide the information at specified times.

Activity level monitoring: Wearing the watch-like device (Actigraph) can potentially cause a skin reaction so taking off the watch for a few hours is suggested.

Saliva collection: These are not associated with any known risks. However, it might be inconvenient for your child to provide the saliva samples at specified times.

Evaluation Task: The evaluation task in front of the audience might cause discomfort or anxiety. Your child can stop the procedure any time if she chooses not to continue with the task.

Psychological discomforts: Some of the procedures may cause embarrassment or anxiety, or the questions the researchers ask you may be upsetting or make you uncomfortable. If you do not wish to answer a question, you can skip it and go to the next question. If you do not wish to participate you can stop.

Fasting: Your child will have to fast overnight before the food experiments. She can stop the study if she finds this uncomfortable.

Also, she cannot request for specific foods for the food experiments. The meals will contain a wide variety of foods that she can select from. If she is allergic to certain foods, she may not participate.

Blood draw: Removing blood by a needle may cause temporary pain, bruising, bleeding, swelling, dizziness, and on rare instances fainting or infection. A numbing cream such as ELA-Max may be used so that your child will not feel the needle stick as much. The numbing cream may make your child's skin or the area have a change in skin color, but this is rare. A trained staff person will perform the blood draw.

Blood spot: Removing blood by a lancet (blade) may cause temporary pain, bruising and bleeding. In rare occasions, it may cause swelling, dizziness, fainting or infection.

DXA Scan: Having a DXA scan exposes your child to radiation. Because this scan uses radiation, your child will complete a questionnaire regarding her menstrual cycle and possibility of pregnancy to avoid possible harm to an unborn baby. If the research team suspects she is pregnant, she will be withdrawn from the study.

During this study you will have one DXA scan of your body. This scan is solely for the purpose of this research and you would not have this scan if you decide not to participate in this research study. A DXA scan uses radiation to create pictures of the structures inside the body. The total radiation dose that you will receive from once scan is about 0.7-1.5 millirem. A millirem is a unit used to quantify radiation dose. Typically persons in the U.S. receive a radiation dose of about 310 millirem per year (or 0.85 millirem per day) from natural sources of radiation, including from the sun, air, water and soils. Therefore, your child's total radiation dose will be about the same as 1-2 extra days of natural background radiation.

There is no known health effects associated with this amount of radiation exposure, and no radiation remains in the body after the scan. If you are especially concerned about radiation exposure, you should discuss this with the researcher listed at the top of this form.

Incidental finding:
There is a risk of an unexpected finding from your child's DXA scan. The results will be shared with you if there is some clinically concerning abnormality and if necessary, you will be referred to your primary care physician or other specialist for additional consultation.

Visit scheduling: If your child is in this study, it may be difficult for you to set a time when you both can take part in this study. You may stop participating in this study at any time.

Confidentiality: There is a possible risk that your or your child's confidentiality or privacy could be breached. This would mean that someone other than the research team or our collaborators may find out that your child was in the research or may see your or your child's answers or your child's medical information. However, we will take every precaution to make sure that this does not happen.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

Compensation

You will be paid up to $25 and your child will be paid up to $365 at specified time points over the course of the study. There are 4 visits. Total compensation for participation in the entire study is $390. If you or your child decide to withdraw from the study or are withdrawn by the research team, you will receive compensation for the visits and/or procedures that you have completed.

Visit/Tasks	Parent	Youth	Total
Visit 1: Questionnaire & Interviews	$25	$25	$50
Visit 2: Actigraph Activity Watch	--	$25	$25
Visit 2: Saliva Samples	--	$25	$25
Visit 2: Food Recalls (3)	--	$25	$25
Visit 2 Bonus*	--	$25	$25
Visit 3: Food Experiment	--	$50	$50
Visit 3: Post-Visit Food Recall	--	$25	$25
Visit 4: Food Experiment	--	$50	$50
Visit 4: Post-Visit Food Recall	--	$25	$25
Hair Sample	--	$25	$25
Dried Blood Spot (Finger Prick)	--	$15	$15
Blood Draw	--	$25	$25
DXA Scan	--	$25	$25
TOTAL	**$25**	**$365**	**$390**

*Note: Visit 2 bonus will only be given if all three (Actigraph watch, food recalls, and saliva samples) are completed and validated by the research team.

If your child complete all the assessments in the study, she will receive a prize (such as a toy, water bottle, t-shirt, etc.) valued at $15 or less. If you or your child withdraw from the study before completing all the assessments for any particular visit, there will be no payment. However, if the researchers decide to withdraw you or your child from the study, you will be paid for that visit even if all the assessments are not completed.

Reimbursement

Travel costs will be reimbursed to you at a rate of $0.40 (40 cents) per mile up to a maximum of $40 for a round trip visit. The payment will be rounded off to the nearest dollar. If the calculation is $0.50 and under, the payment will be rounded to the previous dollar. If the calculation is $0.51 and over, the payment will be rounded up to the next dollar. For example, if the payment is $9.50 it will be rounded to $9.00 and if the payment is $9.51 it will be rounded to $10.00. If you don't have a car, we will provide bus passes or a taxi service, if necessary. We will also serve you and your child snacks/meals when the study visits are long.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There is no cost to you or your child for participation in this study.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?
It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number listed at the top of this form.

If you are injured as a result of being in this study, UCI will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or the study sponsor National Institutes of Health, or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call UCI Human Research Protections (949) 824-8170 or by e-mail at IRB@research.uci.edu

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?
You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately**. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, the study sponsor decides to stop the study or your safety and welfare are at risk.

If you experience any of the side effects listed above, if your health worsens, or if you are injured during the research, you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare, or because the research plan does not allow people who develop certain conditions to continue to participate.

If you withdraw or are removed from the study, the researcher may ask you to return study devices.

If you elect to withdraw or are withdrawn from this research study, you may choose to terminate the continued use or disclosure of your protected health information (PHI) for research purposes. The request to end the use or disclosure of your PHI should be made in writing.

You are free to withdraw your consent to use your identifiable private information and biospecimen for future research at any time however there are some limitations. If you withdraw your consent, the researchers will not use your information or biospecimens in future research studies. However, any of your information or biospecimens already being used in a research study that began before your request to withdraw will continue to be used for that specific study. Also if information and biospecimens have already been provided to another researcher, institution, or company, it may not be possible to limit their continued and new uses.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT?
Subject Identifiable Data
Identifiable information collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data. This is to ensure that we can contact you if there is anything of concern.

Data Storage
Research data will be maintained in paper format in a secure location at UCI. Research data will also be stored electronically on a secure network in an encrypted file with password protection.

The audio/video recordings will also be stored in a secure location and transcribed. The recordings will be retained with the other research data.

Data Retention

The researchers intend to store your research data and/or de-identifiable biospecimens in a repository indefinitely. The researchers may continue to use and share your information and information obtained from analyses of your biospecimens indefinitely. Also the use and sharing of your de-identifiable biospecimens will continue until the specimens are gone.

WHO WILL HAVE ACCESS TO MY STUDY DATA?

The research team, authorized UCI personnel, the study sponsor, and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

Future Research Use

Researchers will use your specimens and information to conduct this study. Once the study is done using your specimens and information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other private identifiable information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

ClinicalTrials.gov

ClinicalTrials.gov is a Web site that provides information about clinical trials. A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, researchers cannot be forced to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Researchers will voluntarily disclose information to prevent serious harm to you or to someone else including, suspected child abuse and neglect, or concern that you and your child may hurt yourselves or others.

ARE THERE OTHER ISSUES TO CONSIDER IN DECIDING WHETHER TO PARTICIPATE IN THIS STUDY?

Use of Biospecimens

Biospecimens (such as blood, tissue, or saliva) collected from your child for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

Optional Consent for Storage of Blood Sample for Future Research

With your permission, we would like to store your child's blood sample indefinitely for use in future research. The blood sample will not contain any information that identifies your child and will be used for research purposes only. You do not have to agree to this in order to be in the study, and your decision will not affect the care you receive from study doctors or your clinical care at UCI or CHOC.

Please **initial** your preferred option:

____**Yes,** UCI researchers may store my child's blood samples indefinitely for use in future research.

____ **No,** UCI research may **not** store my child's blood samples indefinitely for use in future research.

Investigator Financial Conflict of Interest

No one on the study team has a disclosable financial interest related to this research project.

Optional Consent for Future Contact and Sharing Data

We would like to share your and your child's data with our other studies that you and your child may qualify or be eligible for and/or agree to participate. Sharing your and your child's data with other studies is entirely voluntary and optional. You and your child will still be able to participate in this study without having to agree to future contact from other studies or to share data with those studies.

If you and your child are interested, then we will share some of your and your child's identifiable information with other researchers at UC Irvine who may be performing similar research so that they may check the information against their eligibility criteria. If you and your child are a good match, then they may contact you to tell you and your child more about their research. Also, if they have same assessments, they will use the collected information so that you and your child don't have to repeat the same assessments. These researchers will follow the rules for keeping you and your child's information private, and you and your child can refuse to participate in these studies without any penalties.

The study team would like your permission to contact you for future research and share data with other studies. Please **initial** your level of permission below:

_____ **Yes**, UCI researchers may contact my child and me in the future to ask me to take part in other research studies, and share our data with other researchers.

_____ **No**, UCI researchers may **not** contact my child and me in the future to ask me to take part in other research studies, cannot share our data with other researchers

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have any comments, concerns, or questions regarding the conduct of this research, please contact the research team listed at the top of this form.

A 24-hour number is also listed on the top of this form to report any health concerns or unanticipated problems you may experience after normal hours or on weekends.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any suggestions, problems or concerns you may have about the study, please contact the UCI Institutional Review Board by phone at (949) 824-8170, by e-mail at IRB@research.uci.edu or by mail at University of California, Irvine, Office of Research, Irvine, CA 92697-7600.

What is an IRB? An Institutional Review Board (IRB) is a committee made up of scientists and non-scientists. The IRB's role is to protect the rights and welfare of human subjects involved in research. The IRB also assures that the research complies with applicable regulations, laws, and institutional policies.

HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?
You should not sign and date this consent form until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form, and the attached "Experimental Subject's Bill of Rights" to keep. **Participation in this study is voluntary.** You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center.

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

Note: If the research described in this form involves your protected health information (PHI), you will be asked to sign separate UC HIPAA Research Authorization form for the use of your PHI.

I agree to participate in the study.

_____
Printed Name of Child

_____ _____
Subject (Participating Adult) Signature **Date**

_____
Printed Name of Participating Adult Subject

_____ _____
Legally Authorized Representative/Guardian Signature ***Date***

_____ _____
Printed Name of Legally Authorized Representative/Guardian ***Relationship to Subject***

_____ _____
Signature of Person Obtaining Informed Consent **Date**

_____
Printed Name of Person Obtaining Informed Consent

This section to be completed ONLY if child participant turns 18 before completing study protocol:

_____ _____
Signature of Adult Child Participant (now over 18) **Date**

A witness signature is required on this consent form only if: (Researchers: check which one applies)

☐ Consent is obtained from the subject via the Short Form process, as approved by the IRB.
☐ The subject has decision-making capacity, but cannot read, write, talk or is blind.
☐ The subject's guardian/legally authorized representative (LAR) cannot read, write, talk or is blind.
☐ The IRB specifically mandated a witness signature for this study (e.g., high risk and/or invasive research procedures).

For the witness:
I confirm that the information in this consent form was accurately explained to and understood by the subject or legally authorized representative and that informed consent was given freely.

_____ _____
Witness Signature **Date**
Note: The witness must be impartial (i.e. not a member of the subject's family, not a member of the study team).

_____
Printed Name of Witness

UNIVERSITY OF CALIFORNIA, IRVINE
Experimental Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.

2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.

5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.

7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.

9. To receive a copy of the signed and dated written consent form and a copy of this form.

10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections unit in the Office of Research by calling (949) 824-8170 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@research.uci.edu; or by writing us by mail at University of California, Irvine, Office of Research, Irvine, CA 92697-7600.

University of California Irvine Health
Permission to Use Personal Health Information for Research

Study Title (or IRB Approval Number if study title may breach subject's privacy): Ethnic Influences on Stress, Energy Balance and Obesity in Adolescents

Principal Investigator Name: Uma Rao, MD

Sponsor/Funding Agency (if funded): NIH

A. What is the purpose of this form?

State and federal privacy laws protect the use and release of your health information. Under these laws, the University of California or your health care provider cannot release your health information for research purposes unless you give your permission. Your information will be released to the research team which includes the researchers, people hired by the University or the sponsor to do the research and people with authority to oversee the research. If you decide to give your permission and to participate in the study, you must sign this form as well as the Consent Form. This form describes the different ways that health care providers can share your information with the researcher, research team, sponsor and people with oversight responsibility. The research team will use and protect your information as described in the attached Consent Form. However, once your health information is released by UC Irvine Health it may not be protected by the privacy laws and might be shared with others. If you have questions, ask a member of the research team.

B. What Personal Health Information will be released?

If you give your permission and sign this form, you are allowing your health care provider to release the following medical records containing your Personal Health Information. Your Personal Health Information includes health information in your medical records, financial records and other information that can identify you.

☒ Entire Medical Record

☐ Ambulatory Clinic Records
☐ Progress Notes
☐ Other Test Reports
☐ Other (describe):
Type Here
(Description of Other Health Information)

☒ Lab & Pathology Reports
☐ Dental Records
☐ Operative Reports
☐ Discharge Summary
☐ Consultations

☐ Emergency Department Records
☐ Financial Records
☐ Imaging Reports
☐ History & Physical Exams
☐ Psychological Tests

C. Do I have to give my permission for certain specific uses?

Yes. The following information will only be released if you give your specific permission by putting your initials on the line(s).

_____I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment.

_____I agree to the release of HIV/AIDS testing information.

_____I agree to the release of genetic testing information.

_____I agree to the release of information pertaining to mental health diagnosis or treatment.

D. Who will disclose and/or receive my Personal Health Information?

Your Personal Health Information may be shared with these people for the following purposes:

1. To the research team for the research described in the attached Consent Form;
2. To others at UC with authority to oversee the research
3. To others who are required by law to review the quality and safety of the research, including: U.S. government agencies, such as the Food and Drug Administration or the Office of Human Research Protections, the research sponsor or the sponsor's representatives, or government agencies in other countries.

E. How will my Personal Health Information be shared for the research?

If you agree to be in this study, the research team may share your Personal Health Information in the following ways:

1. To perform the research
2. Share it with researchers in the U.S. or other countries;
3. Use it to improve the design of future studies;

4. Share it with business partners of the sponsor; or
5. File applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

F. Am I required to sign this document?

No, you are not required to sign this document. You will receive the same clinical care if you do not sign this document. However, if you do not sign the document, you will not be able to participate in this research study.

G. Optional research activity

If the research I am agreeing to participate in has additional optional research activity such as the creation of a database, a tissue repository or other activities, as explained to me in the informed consent process, I understand I can choose to agree to have my information shared for those activities or not.

☐ I agree to allow my information to be disclosed for the additional optional research activities explained in the informed consent process.

H. Does my permission expire?

This permission to release your Personal Health Information expires when the research ends and all required study monitoring is over.

I. Can I cancel my permission?

You can cancel your permission at any time. You can do this in two ways. You can write to the researcher or you can ask someone on the research team to give you a form to fill out to cancel your permission. If you cancel your permission, you may no longer be in the research study. You may want to ask someone on the research team if canceling will affect your medical treatment. If you cancel, information that was already collected and disclosed about you may continue to be used for limited purposes. Also, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

J. Signature

Subject

If you agree to the use and release of your Personal Health Information, please print your name and sign below. You will be given a signed copy of this form.

_____

Subject's Name (print)—*required*

_____ _____

Subject's Signature Date

Parent or Legally Authorized Representative

If you agree to the use and release of the above named subject's Personal Health Information, please print your name and sign below.

_____ _____

Parent or Legally Authorized Representative's Name (print) Relationship to Subject

_____ _____

Parent or Legally Authorized Representative's Signature Date

Witness

If this form is being read to the subject because s/he cannot read the form, a witness must be present and is required to print his/her name and sign here:

_____

Witness' Name (print)

_____ _____

Witness' Signature Date