FIU | FLORIDA INTERNATIONAL UNIVERSITY

PARENTAL CONSENT TO PARTICIPATE IN A RESEARCH STUDY
Effect of Soluble Corn Fiber supplementation for 1 year on bone metabolism in children (MetA-Bone Trial)

SUMMARY INFORMATION

Things you should know about this study:

- **Purpose:** The purpose of the study is to determine the effects of a fiber supplementation on bone mass in children
- **Procedures**: If you choose to allow your child to participate, your child will be asked to consume a fiber supplement every day for 1 year and to come to 3 visits at FIU for a bone scan, body measurements, to complete questionnaires and provide a sample of blood, urine and fecal sample.
- **Duration:** This will take about 1 year.
- **Risks**: The main risk or discomfort from this research is slight pain when collecting blood and very small radiation with bone scan.
- **Benefits:** The main benefit to your child from this research is receiving a copy of the bone scan, information on healthy eating and referrals for non-normal blood results.
- **Alternatives:** There are no known alternatives available to your child other than not taking part in this study.
- **Participation:** Taking part in this research project is voluntary.

Please carefully read the entire document before agreeing to participate.

PURPOSE OF THE STUDY

To determine the effects of Soluble Corn Fiber supplementation for 1 year on bone metabolism in children compared to controls. Studies have shown that soluble corn fiber helps to better absorb the calcium consumed in foods. With this study we will test whether consuming this supplement of fiber also improves bone mass.

NUMBER OF STUDY PARTICIPANTS

If you agree to allow your child to participate in this study, he/she will be one of 240 healthy children (aged 9-14 years) in this research study.

DURATION OF THE STUDY

Your child's participation will require 3 visits of 1 hour each at the Research Center (AHC-5) in Florida International University (at baseline, 6 months later and 12 months later) and 3 home visits of 20-30 minutes each (1-2 weeks after the first visit, at 3 months and 9 months later).

PROCEDURES

Your child will be assigned at random (like throwing a coin) to one of the four study groups:

1. Fiber supplement
2. Fiber supplement + calcium
3. Placebo (another type of fiber)
4. Placebo + calcium

The supplement of the study will be provided through a powder to mix with water or any beverage that your child usually consumes twice a day for 1 year.
During the study, we will ask you and your child to do the following things:

Pre-screening (about 30 minutes):

- Explanation of the study: we will explain in detail what the study involves, and we will answer all the questions that you may have.
- Pre-screening form: you and your child will complete a short pre-screening form to assess if you qualify.
- Sign consents: If your child qualifies and you choose to participate in the study, you will review, sign, and date the informed consent form for the parent/guardian and the assent form for the child's participation.
- Contact questionnaire: you and your child will provide your phone number (home and cell), email, address, and address in social networks (Facebook, Twitter, WhatsApp, etc.).
- Health questionnaire: you and your child will complete questions about your current health and health history, including alcohol consumption and smoking.
- Food frequency questionnaire: you and your child will complete questions on the child's frequency of consumption of foods rich in calcium, consumption of soft drinks and supplements, with the help of the researcher. If your child's calcium consumption is under the recommended amounts, we will explain how to increase calcium consumption in order to reach the recommendation.
- 24-h food recall: you and your child will complete questions about the foods and beverages consumed by your child in the last 24-hours. We will repeat this by phone on 2 different days, based on your convenience.
- Physical activity questionnaire: you and your child will complete questions about your child's physical activity, with the help of the investigator.

Screening/Baseline visit at FIU (about 1 hour)

- Clinical measurements: the study trained staff will measure the weight, height, seated height, leg length and the circumference of the waist and neck of your child, while wearing light clothes (shorts and t-shirt) and no shoes in a private room. The parent/guardian shall be present.
- Bone density test: your child will undergo a bone density test, which is a test to measure the mass of the bones using an instrument called "DXA" (Hologic). This is a test similar to X-rays but improved and with much less radiation (about 1.5 mrem, which is less than what one is exposed to when traveling on an airplane). It will not cause your child any damage or injury. For this test, your child will lie on a bed and the scanner will scan the body for approximately 7 minutes. In girls that already started menstruating, we will ask if they are pregnant. If pregnant, your child will not undergo the bone scan and will not be able to continue in the study.
- Blood test: your child will provide a blood sample of about 15 ml (1 tablespoon). We will measure various hormones related to bone metabolism. For this, your child should be fasting. With part of the sample, we will measure blood vitamin D levels in the next 3-5 days. If the result obtained is less than 20 ng/ml (meaning deficiency), your child will not be able to continue participating in the study, unless treatment is received. In this case, we will give your child vitamin D supplements (2000 international units per day for 6-8 weeks as per the

recommendation from the American Academy of Pediatrics). We will inform your pediatrician of the treatment and outcome. After 6-8 weeks, if you and your child wish to continue participating in the study, we will again measure blood vitamin D levels (1 ml or 2-4 drops of blood). If the vitamin D is 20 ng/ml or more, your child will be able to continue in the study (if less than 3 months from the initial visit). If more than 3 months from the initial visit has passed, we will repeat the DXA, anthropometry and questionnaires, as these measures change quickly at this age. If your child is too afraid or anxious with this blood collection, we will do a finger prick (similar to the one used for glucose monitoring) to collect 2-4 drops of blood. In this case, we would only measure vitamin D as it will not be enough for other analyses).

- Urine and fecal collection: your child will collect urine for 24-hours and a fecal sample at home. The study staff will explain in detail how to do this collection and will give you written instructions. In addition, we will provide collectors and bio-safety bags for the sample. We will pick these samples at home at the next visit.

Visit to deliver study supplement (1-2 weeks after the first; about 20 minutes): if the result for blood vitamin D is appropriate, we will deliver to your home (or at another convenient place for you) the supplement and we will provide written instructions on how to consume it. Also, we will pick up the samples collected.

Home visits (or at another convenient place for you) **(months 3 and 9; approximately 20-30 minutes):**

- Supplement of the study: we will collect the leftover supplements and provide you with more for the next 3 months.
- Completion of questionnaires (online or in paper): you and your child will complete again questions about taking the supplement, frequency of consumption of foods rich in calcium, foods and beverages consumed in the last 24-hours, and physical activity.
- At 9 months, we will give you containers to collect urine for 24-hours and a fecal sample. These samples shall be brought to the last study visit. We will remind you to do this.

Assessment visits at FIU (months 6 and 12; about 1 hour)

- Clinical measurements: the study trained staff will measure again the weight, length and the circumference of the waist and neck of your child, while wearing light clothes (shorts and t-shirt) and no shoes in a private room. The parent/guardian shall be present.
- Bone density test: your child will undergo a bone density test, as described in the 1st visit.
- Blood test: your child will provide a blood sample of about 15 ml (1 tablespoon) only at the 12 months visit. If your child is too afraid or anxious with this blood collection, we will only do the finger prick to collect 2-4 drops of blood.
- Urine and fecal collection: your child will bring the 24-hour urine sample and the fecal sample collected at home (12 months visit only).
- Supplement of the study: we will collect the leftover supplements and provide you with more for the next 3 months.
- Completion of questionnaires (online or in paper): you and your child will complete again questions about taking the supplement, frequency of consumption of foods rich in calcium, foods and beverages consumed in the last 24-hours, and physical activity.

☐I agree or ☐I do not agree to allow Florida International University to store my sample(s) for future research purposes.

Signature of Parent/Guardian:_____

Reminders throughout the study

We will send reminders about the study by phone, text message, email or social networks to parents/caregivers. We will send short text messages using an automated one-way service about how to consume the supplement to both parents/caregivers and children. In addition, we will send you a weekly text message or email with a link to report the number of study supplements consumed daily by your child in the past week, to which you should respond. If you prefer, you have the option of using a paper calendar to track the consumed supplements on a daily basis.

RISKS OR DISCOMFORTS

The study has the following possible risks to your child:

1. Risk of the procedure for taking the blood sample: this requires that a needle be inserted into a vein in the arm. It is very common to experience slight pain at the site of the insertion of the needle, dizziness, bruising, and in rare cases infection.

2. Risk of the bone density test: for this test using DXA, your child will be exposed to small radiation that will go through immediately (1.5 mrem). X-rays usually do not have side effects, and the amount of radiation is extremely small, which is much less than the dose of an arm x-ray (less than what one is exposed to when traveling on an airplane). The radiation does not remain in the body when the test is completed. Ask the Principal Investigator if you have questions about the risks of radiation.

3. Discomfort when taking anthropometric measurements: for this, your child will wear no shoes and light clothes (shorts and t-shirt). This may cause a little discomfort. We require the presence of the parent/guardian when performing these measurements.

4. Discomfort when responding questions about sexual development: these questions will be responded in a private room or online to reduce the discomfort.

5. Discomfort when collecting urine and feces: your child will have to urinate into a urine collector for 24-hours and collect a fecal sample at home. These collections could be a little uncomfortable.

6. Risk of consuming the fiber or calcium: the study ingredients are very safe and rarely people who eat fiber supplements experience flatulence (gas). You may feel embarrassed by this flatulence. These ingredients are not expected to have any reactions with any medication that your child may be taking.

7. Risks of disclosure of personal information.

BENEFITS

The study has the following possible benefits to your child: receive a copy of the bone density test (DXA), with referrals for non-normal results, receive copy of the vitamin D blood result and

vitamin D supplements for 6-8 weeks in case of vitamin D deficiency to continue in the study, receive information about healthy eating, receive referrals for non-normal blood results, and a certificate of completion of 5 community hours at 6 months and 12 months. The results of the study will help us to know the effects of the consumption of this fiber supplement on bone mass in children.

ALTERNATIVES

There are no known alternatives available to your child other than not taking part in this study. Any significant new findings developed during the course of the research which may relate to your child's willingness to continue participation will be provided to you.

CONFIDENTIALITY

The records of this study will be kept private and will be protected to the fullest extent provided by law. In any sort of report that we might publish, we will not include any information that will make it possible to identify your child as a subject. Research records will be stored securely and only the researcher team will have access to the records. However, your child's records may be reviewed for audit purposes by authorized University, by the Florida Department of Health or other agents who will be bound by the same provisions of confidentiality.

If we learn about serious harm to you or someone else, we will take steps to protect the person endangered even if it requires telling the authorities without your permission. If we have reason to believe that your child is being abused, we will report this to the Florida Abuse hotline. In these instances, we would only disclose information to the extent necessary to prevent harm.

The U.S. Department of Health and Human Services (DHHS) may request to review and obtain copies of your child's records.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US Law. This web site will not include information that can identify your child. At most, the web site will include a summary of the results. You can search this website at any time.

USE OF YOUR CHILD'S INFORMATION

- Identifiers about your child might be removed from the identifiable private information and identifiable biospecimens and that, after such removal, the information and biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.
- Your child's biospecimens may be used for commercial profit and you will not share in this commercial profit.
- The researcher will include genome sequencing through the fecal sample (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of the fecal sample).

COMPENSATION & COSTS

Your child will receive a payment of $25 for completing the baseline visit, $30 for the 6 months visit and $35 for the 12 months visit at FIU. Your child will also receive $20 for each of the 3 home visits (1-2 weeks after baseline, 3 and 9 months), for a total of $150 per participant for the

completion of the study. Your child will also receive small study tokens at each visit, such as a recyclable water bottle, bag, pen, notebook, and other small gifts for school. The parent will receive $40 for the baseline, $40 for the 6 months visits and $50 for the 12 months visit at FIU to cover the costs associated with these visits. Also, the parent will receive $45 every 3 months for the time related to monitor the consumption of the fiber supplement and to complete the number of supplements consumed by your child through the online short form or the paper calendar. There are no costs to participate in this study.

PARTICIPATION IN FUTURE STUDIES

___ I authorize or I do not authorize ___ (place initials) the Principal Investigator, Cristina Palacios, to keep my personal information in a database to be contacted in the future for other research studies. This information will be kept locked. If you do not authorize this, it would not affect your child's participation in this study.

MEDICAL TREATMENT

Routinely, FIU, its agents, or its employees do not compensate for or provide free care for human subjects in the event that any injury results from participation in a research project. If your child becomes ill or injured as a direct result of participating in this study, contact your regular medical provider. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be billed. Funds to compensate for pain, expenses, lost wages and other damages caused by injury are not routinely available.

RIGHT TO DECLINE OR WITHDRAW

Your child's participation in this study is voluntary. Your child is free to participate in the study or withdraw his/her consent at any time during the study. Your child will not lose any benefits if he/she decides not to participate or if your child quits the study early. The investigator reserves the right to remove your child from the study without your consent at such time that he/she feels it is in the best interest.

RESEARCHER CONTACT INFORMATION

If you have any questions about the research study, you may contact the principal investigator Cristina Palacios at (305) 348-3235 or cristina.palacios@fiu.edu.

IRB CONTACT INFORMATION

If you would like to talk with someone about your child's rights of being a subject in this research study or about ethical issues with this research study, you may contact the FIU Office of Research Integrity by phone at 305-348-2494 or by email at ori@fiu.edu.

PARTICIPANT AGREEMENT

I have read the information in this consent form and agree to allow my child to participate in this study. I have had a chance to ask any questions I have about this study, and they have been answered for me. I understand that I will be given a copy of this form for my records.

_____ _____

Signature of Parent/Guardian Date

_____

Printed Name of Parent/Guardian

_____

Printed Name of Child Participant

_____ _____

Signature of Person Obtaining Consent Date