Cover Page for Consent

Official study title:	Preventing excessive weight gain and maternal and infant fat accretion by increasing fiber intake and changing the maternal microbiome during pregnancy
NCT number:	NCT04868110
Document date:	1/12/2022

RESEARCH CONSENT FORM

Preventing excessive weight gain and maternal and infant fat accretion by increasing fiber intake and changing the maternal microbiome during pregnancy

Principle Investigator: Dr. Holly Hull

University of Kansas Medical Center
Department of Dietetics and Nutrition
3901 Rainbow Blvd, Kansas City, KS, 66160
Phone: 913-588-5358
Version 10

- We are asking you to be in a research study.
- Research is done to answer a scientific question. Research studies may or may not help the people who participate.
- Joining this study is completely voluntary. If you say yes, you can quit the study at any time.
- You can still get medical care and other services from the University of Kansas Medical Center even if you are not in the study.
- The research team will explain what happens if you decide to join the study. This conversation is called "informed consent."
- Informed consent includes a chance to get your questions answered before you make your decision. Please ask as many questions as you need to.
- This consent form explains the study. Take as much time as you need to decide.
- If you decide to be in the study, you will be asked to sign this form.

Dr. Holly Hull is doing the study at the University of Kansas Medical Center (KUMC). About 56 pregnant women will be in the study.

Why is this study being done?

We are doing the study to learn more about if a high fiber diet (≥30 g/day) will reduce excessive weight gain during pregnancy and will change body fat composition of pregnant women and their babies.

How long will I be in this study?

The study will last about 20 months during and after your pregnancy, which involves 6 visits to Dr. Hull's laboratory at KUMC.

What will I be asked to do?
If you decide to join the study, you will be asked to track your body weight weekly.

You will continue to have your routine prenatal care with your regular doctor.

You will be randomly assigned (like rolling the dice) to one of 2 groups:

- Group 1: You will be asked to participate in group-based video counseling weekly to instruct you to consume a high fiber diet (≥30 g/day).
- Group 2: You will continue with your usual activity. You will not be advised on your diet but will report your body weight weekly.

You will have a 1 in 2 (50%) chance of being assigned to Group 1, and a 1 in 2 (50%) chance of being assigned to Group 2, the usual care control group.

You will be recruited between 9 to 19 weeks and enrolled in the study between 12 and 20 weeks of pregnancy. If you are assigned to Group 1, you will start the intervention after you are enrolled. You will be asked to read and sign this consent form before any tests or procedures can be completed.
Below is a table that lists all the procedures that will happen at each study visit. After the table, you will find more details about the study procedures.

Time	During Pregnancy		Postpartum			
	12 -20 weeks	30 - 38 weeks	2 weeks	2 months	6 months	12 months
Study procedure	**Visit 1**	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**
Questionnaires	X	X	X	X	X	X
Maternal body weight, height, heart rate, & blood pressure	X	X	X	X	X	X
Maternal body composition (BIA, Bod Pod®)	X	X		X	X	X
Maternal DXA scan				X	X	X
Maternal diet recalls	X	X		X	X	X
Maternal Veggie Meter®	X	X		X	X	X
Maternal smell test	X	X		X		X
Maternal cognitive testing	X	X		X	X	X
Maternal urine	X	X	X	X	X	X
Maternal stool	X	X		X	X	X
Maternal blood tests	X	X		X	X	X
Maternal physical activity/sleep monitor	X	X		X	X	X
Infant body weight and length			X	X	X	X
Infant skinfolds			X	X	X	X
Infant stool			X	X	X	X
Infant body composition (Pea Pod®)			X	X	X	
Infant DXA scan			X			X
Infant diet recalls			X	X	X	X
Breast milk*				X	X	

*Breast milk collection will occur monthly for 6 months after the birth of your baby. You will be asked to return the breast milk samples at the 2-month and 6-month visits.

Questionnaires: You will be asked to complete questionnaires about your diet, nutrition, health, income, education, household information, supplement use, alcohol consumption, hunger, gut health and symptoms, emotional health, etc. These can happen at the visits, on the phone, or through an internet survey throughout the study. One of the questionnaires asks you to rate likes and dislikes of items you eat, drink, and do and will be completed through the University of Connecticut.

Maternal body weight and height: Your body weight will be measured using an electronic scale, and height measured using a ruler and headpiece on the wall. You will be given a body weight scale and asked to report your body weight weekly.

Maternal blood pressure & heart rate: Your blood pressure & heart rate will be taken using an automated machine. You will be told to contact your healthcare provider if your blood pressure is out of normal range.

Maternal body composition (BIA, Bod Pod®): Your body fat will be measured using BIA and Bod Pod®. Total body water will be measured using a platform bioelectrical impedance scale that you stand on. It sends a very low frequency signal from one foot to the other that you cannot feel and is not harmful. The Bod Pod® is a computerized, egg-shaped chamber and it measures a person's mass and volume, from which their body density is determined. Using these data, body fat and lean muscle mass can then be calculated. The procedure will take about 5 minutes and you will need to change into a tight-fitting garment like a swimsuit or spandex shorts before the test. You will have a private place to change clothes and enter the chamber.

Bod Pod®

Maternal DXA scan: Your body fat will be measured using by DXA scan as well. You will lie down on a table on your back. A small arm will slowly pass over your body from head to toe. It emits low-dose x-ray beams through the body into the table. The entire scan will take less than 10 minutes and exercise clothing without any metal will be worn.

DXA scan

Maternal diet recalls: Three 24-hour diet recalls will be collected (1 in person, 2 via phone at each visit). You will be asked everything you had to eat and drink in the past 24 hours. Starting in week four of the intervention for group 1, one 24-hour dietary recall will be collected every four weeks (4 recalls total) to determine fiber intake.

Maternal Veggie Meter®: Your fruit and vegetable consumption will be analyzed using a non-invasive machine that measures skin carotenoid levels in your fingertip called the VEGGIE METER. This measurement involves shining a light on the skin of your finger and will take 45 seconds to complete.

Maternal smell test: You will be asked to identify 14 different scents on sticks up to 2 times each.

Maternal cognitive testing: You will be asked to take a cognition test. The entire test will take place on an iPad. This test will measure different areas of cognition including executive function, language, episodic memory, processing speed, and attention.

Maternal urine: You will be asked to collect urine in a cup at each visit. This will be used to measure levels of chemicals present in your urine. The urine will also be used for pregnancy tests at postpartum DXA scan visits. If we find out you are pregnant, we will not perform a DXA scan.

Maternal stool: You will be provided instructions on how to collect and return a stool sample. We will examine if there are differences between group 1 and group 2 for bacteria found in the stool.

Maternal blood tests: About 2.6 tablespoons of blood will be collected at 5 time points throughout the study by inserting a needle in a vein in your arm for laboratory tests. Your blood sample will be used for the following:

- Serum lipids
- Glucose metabolism
- Inflammation
- Gut health (hunger/satiety) biomarkers
- Neuronal health biomarkers (including ApoE genetic test)

Maternal physical activity/sleep monitor: You will receive a wearable wrist band by mail to measure maternal physical activity and sleep will be monitored using the actigraphy. The device will be worn at the wrist for 7 days around each of the study visits (baseline, end of pregnancy, 2 months, 6 months, and 12 months postpartum). You will not be able to read the data. You will be asked to download an application to your phone that you will use to sync your device daily. You will be asked to keep a log of your sleep and activity during this time. Following the 7-day monitoring period, you will be asked to return the wrist band back to the study team.

Infant body weight and length: Your baby's body weight will be measured using an electronic pediatric scale and length measured on an infant length board. Two or more measurements will be taken.

Infant body composition (Pea Pod®): Your baby's body fat will be measured using the Pea Pod®. The amount of mass (weight) and volume (space) occupied by your infant will be measured, from which their body density is determined. Using these data, body fat and lean muscle mass can then be calculated. Your child will lie on their back on a flat tray that slides into a transparent plastic chamber. This measurement takes 2 minutes. The baby will be undressed during this procedure, except for a standard hat. The temperature of the Pea Pod® chamber is about 88°F, which is comfortable for an undressed newborn. You will be able to monitor your child during the test through the transparent top.

Pea Pod®

Infant DXA scan: Your baby's body fat will be measured using by DXA scan as well. Your baby will need to lie down on a table on the back. A small arm will slowly pass over your baby's body from head to toe. It emits low-dose x-ray beams through the body into the table. The entire scan will take less than 10 minutes. Your child will be wearing only a diaper and swaddled with our immobilization device to help them remain still. We will attempt to complete the scan while your child is sleeping. If your baby moves during the scan, the DXA scan may need to be re-done on the same day or a later day but no more than 6 total scans will be given during the entire study.

Infant Immobilizer

Infant skinfolds: Your child's skinfold measurements will be taken by compressing the skin and measuring the thickness with an instrument called calipers. Measurements will be taken on the arm, back, hip, thigh, side, and abdomen. This is what a skin fold test looks like:

Infant stool: You will be provided instructions on how to collect and ship a stool sample. We will examine if there are differences between group 1 and group 2 for bacteria found in the infant's stool.

Infant diet recalls: One 24-hour diet recall will be collected at Visit 3, 4, 5 and 6. You or another caregiver will be asked everything your baby had to eat or drink during the past 24 hours.

Medical records: Medical records will be requested for both you and your baby. We will obtain medical records from 1 year prior to becoming pregnant to 1 year after giving birth for you and birth to 1 year of age or 12-month medical check-up for your baby. We will record the illnesses you or your child had, how long they lasted and how they were treated.

Breastmilk collection: If you breastfeed your infant, you will be asked to collect 4 teaspoons of breastmilk once a month for the first 6 months after giving birth. This process will involve emptying one entire breast, mixing, collecting and returning 4 teaspoons to the study team. The remainder of the breastmilk may be kept and fed to your baby.

Satisfaction survey (group 1 only): You will be asked three questions measured at the completion of the study: "How confident are you that you will stick to the study diet?"; "I am always hungry on this diet"; and "This diet is a benefit to my health". Responses for the confidence question will be: not at all, not very, somewhat, very and extremely confident. Responses for the hunger and benefit to health questions will be: strongly agree, agree, neutral, disagree and strongly disagree.

Process evaluation (group 1 only): We will call you and ask you questions about what you thought of the intervention including both positive and negative feedback, challenges that you had, and overall satisfaction with the intervention. These calls will be recorded so the researchers can use your feedback to refine and develop future studies.

Group 1 Activities: You will be asked to attend weekly 60-minute lessons (18 in total) through group-based Zoom video calls.

- Lessons will focus on how to increase fiber intake with education on foods that contain fiber, high fiber recipes, and how to update current recipes to contain more fiber, both during and after your pregnancy. You will be provided sample weekly menu plans with grocery and shopping guides. If you are not meeting the daily fiber goal, a dietitian will call you to discuss barriers, troubleshoot any challenges associated with diet adherence and develop a plan to increase fiber intake.
- The lesson session will start with a review of the prior week's goals, with support and encouragement from study participants and the Dietitian (5-10 minutes). A group discussion will occur with 5-10 study participants relating and/or providing personal insight and support. The Dietitian will lead discussion and engage study participants by asking opened ended questions. Each week there will be a structured lesson with an assignment to be completed after the session (20-30 minutes). The last 10-20 minutes of the session will be devoted to goal setting, discussion, questions, and wrap-up. Mid-way through the week, the Dietitian will contact you by email to follow-up to see how you are doing in meeting your goal. The Dietitian will provide feedback based on your comment such as encouragement for doing a great job or how to troubleshoot if you are not meeting your goal.
- We will use the Zoom Video Conferencing System through KUMC for this lesson sections. Your will be given a link with a password and instructed to join 5 minutes prior to the start. This allows you to enter the group session each week. All conference calls will be recorded for quality assurance and to serve as

additional training for the group leader. A log will be generated to track your attendance.

- You will be asked to complete a daily log electronically through REDCap (Research (Research Electronic Data Capture) to report number of servings of high fiber food groups (e.g., fruits, vegetables, whole grains, legumes, nuts and seeds). We will contact you if you miss the daily logs or report a body weight change ± 5 pounds over two weeks.

If you are assigned in Group 1, you will also receive a box of high fiber snacks at enrollment. These daily snacks include multiple flavors of Kind bars, chickpeas and snap peas. The snacks will be pre-portioned for one serving with recommendations to consume 2 snacks per day.

Group 2 Activities: If you are assigned to Group 2, you will attend regularly scheduled visits. The standard visit schedule is once monthly until 32 weeks gestation, bi-weekly for 32-37 weeks gestation, weekly until delivery, and at 6 weeks post-partum. At the first prenatal visit, you will receive the standard nutrition and physical activity counseling provided by the obstetrics team. You will be asked to report body weight weekly via internet.

What are the risks of being in the study?
There are no physical risks involved in collecting information about you. There is a small risk of breach of confidentiality. For that reason, your information will be protected as described in the Privacy section below.

You may have problems because of the procedures that will be performed during the study. It is important that you tell the study team immediately about any problems you have.

Radiation Risks:
As part of this study, you and your baby will receive DXA scans. These scans are not needed for your medical care. You are exposed to radiation every day. This radiation comes from the sun and the earth. It is called background radiation. For you, the amount of radiation in one year from this study could be up to the amount you are exposed to in one day from background radiation. For your baby, the amount of radiation in one year from this study could be up to twice the amount one is exposed to in one day from background radiation. Children are more likely than adults to be harmed from the exposure because a large amount of their tissues are still growing and changing. Radiation exposure at these levels may be associated with a low increased risk of cancer. Most cancers caused by radiation develop 20 or more years after the exposure to radiation. There are many factors that contribute to an individual's personal risk, and your increased risk may be higher or lower than the average person. You may wish to discuss radiation risk further with your Study Doctor or radiologist.

Bluetooth Risks:
The device in this study uses unencrypted Bluetooth to send and receive data. Private

information sent by unencrypted Bluetooth could be intercepted by others. There are weaknesses in Bluetooth that people can take advantage of to view information. These weaknesses can also make it possible to control devices that use Bluetooth. Bluetooth connections can be made with devices that are 160 feet away or less.

Blood Draw Risks:
During the study you will have blood drawn for laboratory tests. The risks of drawing blood from a vein may include bruising, soreness, pain, and rarely, infection, fainting or bleeding at the site that is used for the blood draw. This will be minimized by careful and clean techniques.

Questionnaire Risks:
There is a risk of feeling uncomfortable while answering some of the questions in the questionnaire. If you feel uncomfortable at any time you may skip a question or stop the questionnaire all together. Your participation in the study may be affected if you are not able to complete these questionnaires.

Genetic Risks:
There may be risks to giving your samples for genetic research. A federal law called the Genetic Information Non-Discrimination Act, or GINA is in effect. This law does not allow insurers or employers to use genetic information to discriminate against you. The law does not cover other types of misuse by life insurance, disability, or long-term care insurance. To learn more about the GINA Law, go to https://www.eeoc.gov/laws/statutes/gina.cfmj.

Are there benefits to being in this study?
You will not get personal benefit from being in this study. Researchers hope this study may be helpful in controlling body weight in pregnant women.

Will I have any costs or payments for being in the study?
You will not be charged for being in the study. The cost of the intervention program will be covered by the study.

Will I get paid for participation?
You will be compensated $100 for each of the 6 study visits: baseline, 18 weeks, 2 weeks postpartum, 2 months postpartum, 6 months postpartum, and 12 months postpartum. This is a total of up to $600 for participation in this study. Please note that the 18 weekly lessons are not considered as study visits. If you leave the study early or miss study visits, you will be paid only for the visits you completed. If needed, you may be asked to return for a repeat DXA scan for your infant. You will be compensated an additional $50 at the completion of this additional visit.

Compensation will be given to you through a ClinCard, which works like a debit card. After a study visit, payment will be added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at an ATM or at a store.

No one at KUMC will know where you spent the money. You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600 or more in a calendar year.

Your personal information will be kept on a secure computer. It will be removed from the computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. It will be kept completely confidential.

Will the researchers get paid for doing the study?
The institution (KUMC Research Institute, Inc.) will receive payments from the sponsor, Department of Dietetics and Nutrition for conducting this study. Payments will be used for research purposes only.

What other choices do I have if I don't want to be in the study?
You can choose not to be in the study. You can decide to leave the study at any time. Leaving will not affect the treatment or services you get at KUMC. You will continue to have your routine prenatal care with your regular doctor.

How will my confidentiality and privacy be protected?
The researchers will keep your identity confidential, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

Your health information is protected by a federal privacy law called HIPAA. If you sign this consent form, you give permission for KUMC to use and share your health information. If you gain or lose too much weight in a short period of time, we will notify your doctor. You can decide not to sign this form and not be part of the study.

Dr. Holly Hull and members of the research team will only use and share information that is needed for the study. They will collect health information from the study activities and from your medical record. Your medical records may contain information such as name, address, phone, date of birth, social security number, or other identifiers. Others at KUMC might need to look at your research records. They include KUMC Research Institute, the Institutional Review Board or other committees and offices that review and monitor research studies.

All study information that is sent outside KU Medical Center will have information that could easily identify you (such as name and address) removed. By limiting the

information that is released, we are lowering the risk that your identity could be discovered and used for unauthorized purposes.

Your study information will be labeled with your research ID number. The KUMC study team will keep a separate list that matches your name to the research ID number. By taking these steps, there is less risk that your personal identity and information will be seen by others who shouldn't have it.

Researchers plan to use your information indefinitely unless you cancel your permission. Any research information that is put in your medical record will be kept indefinitely. You have the right to see and copy any study information that is included in your medical record.

The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

What if I decide to leave the study?
You can choose to cancel your permission for researchers to use your health information. If you want to cancel your permission, please write to Dr. Holly Hull using the contact information on the first page of this document. If you cancel permission to use your health information, you will be withdrawn from the study. The researchers will stop collecting any additional information about you about you unless they need information about a side effect of the study intervention. They are permitted to use and share information that was gathered before they received your cancellation.

Will I be told about research results?
You will not be told about any lab results, including the genetic test. At the end of the study, we will send you a letter with a summary of the study results. Your lab results will not be added to your medical record.

How will my research information and specimens be used in the future?
In the future, researchers at KUMC and at other locations might re-use the information and specimens from this study for other research. If that happens, information that could identify you will be removed first. You will not be asked if you agree to the future research that has identifiers removed.

Who can I talk to about the study?
Dr. Holly Hull or other members of the study team should answer all your questions before you sign this form. They will also tell you if they learn anything new that might affect your decision to stay in the study. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints. If you have questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may contact the KUMC Institutional Review Board at (913) 588-1240 or humansubjects@kumc.edu.

CONSENT

Dr. Holly Hull or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered.
You will be given a signed copy of the consent form to keep for your records.

_____
Print Participant's Name

_____ _____ _____
Signature of Participant Time Date

_____
Print Additional Parent's Name

_____ _____ _____
Signature of Additional Parent Time Date

_____
Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

In the future, the researchers may conduct additional studies about body composition, infant growth, nutrition, or maternal and infant health. If you agree, the researchers will contact you to see if you want to join future studies. You would receive a separate consent form describing the future studies.

☐ Yes, I would like to be contacted if I qualify for future studies. _____
Signature

☐ No. Please do not contact me about future studies. _____

Signature