The Personalized Nutrition Study (POINTS): Evaluation of a genetically-informed weight loss approach

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CONSENT TO PARTICIPATE IN A RESEARCH STUDY FOR AN ADULT
INFORMED CONSENT - PART I

Title of Study: The Personalized Nutrition Study (POINTS): Evaluation of a genetically-informed weight loss approach

Study Sponsor: WW International Inc.

Key Information:

- **Why am I being asked to review this form?**
  - You are being asked to take part in a research study. This form is provided so that you may read and understand the reasons why you might or might not want to participate in the research. Your participation is voluntary.

- **What is the purpose, duration, and procedures of this study?**
  - The purpose of this research study is to determine if a person's genetics affects how much weight they lose on diets that differ in macronutrients. Two diets will be tested. One diet is high in carbohydrates and low in dietary fat. The other diet is high in dietary fat and low in carbohydrates. Both diets have the same amount of protein. People will be selected for this study whose genetics suggests that they will lose more weight on one diet vs. the other.
  - Your expected time in this study will be approximately 16 weeks. You will complete two clinic visits, one at week 0 (about 1.5 hours) and one at week 12 (about 1.5 hours). You will also attend 12 in person or virtual weekly intervention visits (about 1.5 hours each).
  - The procedures involved in this study include:
    - Completion of genealogy testing if not completed before and willingness to share the genetic code with the research team
    - Height/weight measurement
    - Measurement of waist/hip circumference
    - Measurement of body composition
    - Measurement of blood pressure and heart rate
    - Blood draw to measure fasting glucose and insulin levels
    - Completion of questionnaires assessing:
      - medical history
      - current medication and supplement use
      - demographics
      - food cravings and food preference
      - different factors of eating behavior
      - intervention satisfaction

- **What are the possible risks and discomforts?**
  - Genetic Information: Genetic information is unique to you and your family, even without your name or other identifiers. As part of this study, Pennington Biomedical Research Center will analyze the results from your genealogy test and work with your genetic information to determine if you are a carbohydrate or fat responder. All attempts will be made to maintain a subject's privacy. Safeguards such as password-protected computer and networks have been put in place in order to limit access to subject data.
  - Diet Risk: There are no anticipated risks associated with the expected amount of weight loss during this study. The high carbohydrate diet is higher in carbohydrate and the high-fat diet is higher in fat than typical recommendations during weight maintenance. In the high-fat diet, expected dietary fat intake is about 11% percentage points higher than the typical American diet, but the proposed diet keeps saturated fat intake to less than 10%, which is consistent with guidelines. The high carbohydrate diet is about 22% higher than the typical American diet. There are limited anticipated risks of following such a high fat or high carbohydrate diet for 12 weeks, particularly when body weight is being reduced. The changes in dietary intake may lead to minor abdominal and bowel issues.
  - A more comprehensive and detailed description of reasonably foreseeable risks to subjects is included later in Section 6 of this document.

- **What are the possible benefits?**
  - It is expected that you will lose weight, which can improve your health. You will learn if you are a fat or carbohydrate responder. If you take part in this study, you may help others in the future. We cannot promise any further benefits from your being in the study.

- **If you choose not to participate in the study, are there other choices?**
  - You have the choice at any time not to participate in this research study.
  - If you decide not to participate in this study, no additional data will be collected.

Detailed Information:

1- Who is doing the study?

Investigator Information:

Principal Investigator:	Corby Martin, Ph.D. (225) 763-2585
Medical Investigator:	Frank Greenway, M.D. (225) 763-2578 24-hr. Emergency Phone Number: (225) 765-4644
Sub Investigators:	Christoph Höchsmann. Ph.D. John Apolzan, Ph.D. James Dorling, Ph.D.

Dr. Martin directs this study, which is under the medical supervision of Dr. Greenway. We expect about 154 people will be enrolled in this study. The study will take place at Pennington Biomedical Research Center over a period of one year. Your expected time in this study will be approximately 16 weeks. Dr. Martin invented and developed the SmartIntake app that will be used sporadically as needed to monitor diet adherence during the intervention. The SmartIntake app is the intellectual property of Pennington Biomedical Research Center.

2- Where is the study being conducted?

This study takes place at the Pennington Biomedical Research Center in Baton Rouge, Louisiana.

3- What is the purpose of this study?

A person's genotype is believed to affect how much weight he/she will lose during diets that vary in carbohydrate and dietary fat content. 'Carbohydrate responders' are hypothesized to lose more weight on diets that are high in carbohydrates, as compared to high in fats. 'Fat responders' are hypothesized to lose more weight on diets that are high in dietary fat, as compared to high in carbohydrates. The purpose of the proposed randomized study is to test if these two types of people lose weight differently on high-carbohydrate and high-fat diets.

4- Who is eligible to participate in the study?

Inclusion criteria:

- Males or females aged 18-75 years
- BMI ≥ 27.0 kg/m^2 to ≤ 47.5 kg/m^2

- Completed genealogy test that can provide raw data of the combined genotype being researched in this study and willingness to share this genetic information. If you do not have this test, it can be provided to you free of charge.
- Willingness to allow further use of study-related data in future research projects

Exclusion criteria:

- Current smoker or has smoked in the previous year
- For females, pregnant or planned pregnancy during the study duration, or breast-feeding, based on self-report
- Conditions, diseases, or medications that affect body weight or metabolism (e.g., certain antipsychotic medications; type 2 diabetes mellitus; heart failure; cancer, excluding certain melanomas; etc.)
- Has gained or lost more than 10 pounds in the last 3 months
- Currently diagnosed with an eating disorder, major depression, or other condition that, in the judgment of the investigators, could affect the risk to the participant or study completion

You may not qualify for this study based on other eligibility criteria not listed. The study coordinator will go over this information in detail.

5- What will happen to you if you take part in the study?

The study consists of an orientation visit, and if you are eligible and wish to participate, two clinic visits (one before and one after the intervention), and 12-weekly in person or virtual intervention visits.

Orientation Visit: About 1 hour.
The orientation visit will take place at Pennington Biomedical Research Center and it will include the following procedures:

- Informed consent
- Questionnaires assessing medical history, current medication and supplement use, and demographics
- Measurement of height and weight
- If you have completed a genealogy test before the study, we will review the data to verify your eligibility to participate in the study
- If you have NOT completed a genealogy test before the study, we will provide you with a genealogy test kit and we will review the data as soon as they are available to us to determine your eligibility to participate in the study

Baseline Clinic Visit: About 1.5 hours.
If you are eligible and wish to participate in the study, we will schedule the first clinic visit. Both clinic visits will take place in the Outpatient Clinic at Pennington Biomedical Research Center. *This is a fasting visit (nothing to eat or drink before the visit, following a 12-hour fast).* The clinic visit will include the following procedures:

- Measurement of waist/hip circumference
- Bioelectrical impedance analysis (weight and body fat percent)
- Measurement of blood pressure and heart rate
- Completion of the following self-report instruments: Food Craving Inventory, Food Preference Questionnaire, Eating Inventory
- Blood draw to measure fasting serum glucose and insulin levels (2 mL of blood, equal to 0.4 teaspoons).

Weekly Intervention Visits (approximately 1.5 hours per visit)
The 12 weekly intervention visits will take place virtually or in person at Pennington Biomedical Research Center. Your weight will be recorded by study staff at each of these 12 intervention visits. Additionally, you will regularly weigh yourself at home (approximately once per day) and you will turn in a record of your self-measured weights to each weekly intervention visit. The first intervention visit will be a virtual or in person one-on-one meeting with your interventionist, following the baseline visit. The next 11 intervention visits will be virtual or in person group meetings with other participants and a facilitator. The facilitator is a Pennington Biomedical Research Center staff member. You will receive a meal plan that you will follow precisely throughout the intervention period. The meal plans will be tailored to your specific calorie and macronutrient target and they will include precise portion sizes of daily meals and snacks, a shopping list, and restaurant options. Two snacks per day (e.g., granola bar) will be provided by the sponsor, WW. The sponsor will further provide a food scale to facilitate adherence to the prescribed portion sizes. At your first intervention visit and week 6 intervention visit, you will complete the Diet Personalization Survey. As needed, you may be asked to use the SmartIntake app to take pictures of your foods for 3-4 days to monitor your adherence to your prescribed diet. If you are participating in a virtual (online) visit, we ask you to *not* share the participation link with anyone else.

Week 12 Clinic Visit: About 1.5 hours.
This is a non-fasting visit. The clinic visit will include the following procedures:

- Measurement of weight and waist/hip circumference
- Bioelectrical impedance analysis (weight and body fat percent)
- Measurement of blood pressure and heart rate
- Completion of the following self-report instruments: Food Craving Inventory, Food Preference Questionnaire, Eating Inventory, Intervention Satisfaction Survey, Diet Personalization Survey

6- What are the possible risks and discomforts?

- Bioelectrical Impedance Analysis (BIA): You will be asked to change into a gown and to remove all footwear and socks/stockings. Once changed and barefoot, you will be asked to stand on a scale (similar to a large gym scale), and you may be asked to hold on to hand electrodes on each side of the scale. You will be

asked to step off the scale once the measurement is complete (less than one minute). There is no known risk associated with the BIA measurement.

- *Blood Pressure Testing:* Temporary discomfort may be experienced during blood pressure recordings due to the pressure of the cuff inflating on their arm. No other known risks are associated with blood pressure testing.
- *Self-reported Questionnaires:* There are no anticipated risks from completing self-report questionnaires. Due to the sensitive nature of the questionnaires, participants may skip any questions that they do not wish to answer.
- *Blood collection:* The risks of taking blood include pain, a bruise at the point where the blood is taken, redness and swelling of the vein and infection, and a rare risk of fainting. Aseptic (sterile) technique and trained personnel minimize these risks.
- *Genetic Information:* Genetic information is unique to you and your family, even without your name or other identifiers. As part of this study, Pennington Biomedical Research Center will analyze the results from your genealogy test and work with your genetic information to determine if you are a carbohydrate or fat responder. All attempts will be made to maintain a subject's privacy. Safeguards such as password-protected computer and networks have been put in place in order to limit access to subject data.
- *Diet Risk:* There are no anticipated risks associated with the expected amount of weight loss during this study. The high carbohydrate diet is higher in carbohydrate and the high-fat diet is higher in fat than typical recommendations during weight maintenance. In the high-fat diet, expected dietary fat intake is about 11% percentage points higher than the typical American diet, but the proposed diet keeps saturated fat intake to less than 10%, which is consistent with guidelines. The high carbohydrate diet is about 22% higher than the typical American diet. There are limited anticipated risks of following such a high fat or high carbohydrate diet for 12 weeks, particularly when body weight is being reduced. The changes in dietary intake may lead to minor abdominal and bowel issues.
- *What you need to know about 23andMe, Ancestry.com and GeneticDirection if you have NOT completed a genealogy test before the study:*
    - Pennington Biomedical Research Center will create an online account for you, using a newly created email address (POINTS_01@gmail.com, POINTS_02@gmail.com, etc.) and your date of birth. If a name and phone number are required for creating the online account, we will use POINTS_01, POINTS_02 etc. for the name and a Pennington phone number. Pennington Biomedical Research Center will have access to the login information during the study to retrieve the raw data once they are available. After completion of the study, the login information will be provided to you, which will give you access to your genealogy data.
    - With access to your data you have the option to provide additional information about yourself through surveys, forms, features, and applications. Unless you consent to sample storage ("Biobanking") and additional analyses, your saliva sample and DNA are destroyed after the

23andMe, Ancestry.com or GeneticDirection or affiliated laboratories completes its work, subject to the laboratory's legal and regulatory requirements.

- 23andMe, Ancestry.com, and GeneticDirection may give you the ability to share information, including Personal Information, through their services related to health and ancestry. You have the option to share directly with individuals with these companies' accounts through (i) their Forums, (ii) relative finding features (e.g., "DNA Relatives"), (iii) other sharing features and tools.
- To understand how 23andMe, Ancestry.com and GeneticDirection will use your information, please read the respective Privacy Statement, accessible via the following links:
  - https://www.23andme.com/about/privacy/
  - https://www.ancestry.com/cs/legal/privacystatement
  - https://geneticdirection.com/privacy-policy/For the purpose of this study, the collaborating institutions identified in this informed consent form, but no one else, needs to receive your genetic information. Should you decide to share additional information with 23andMe, Ancestry.com or GeneticDirection, we encourage you to become familiar with the companies' policies, procedures, and privacy statement. Should you choose to provide additional information to these companies, have your samples stored by them, or share your genetic information with others, you do so at your own risk.

Will I be notified if my data or samples result(s) in an incidental finding?
During a research study, a researcher may notice something that he or she was not looking for. This is called an "incidental" or "unexpected" finding. These incidental findings are not directly related to the research. However, they may show important information about the health of a research volunteer.
Researchers may share some or all of their findings with you. However, you may not learn about any findings for a very long time. If such findings occur, you will be notified by the medical investigator or trained study personnel and referred to a treatment facility for further testing and/or treatment.

Risks: It can be very upsetting to learn unexpected information about your health. This is especially true if you learn that you have or will develop a condition that has no treatment or cure. There is a chance that unexpected findings could affect your family or social relationships, change your family planning decisions, or affect you financially. You might need more tests and procedures to find out what the information really means. It is also possible that the information will be incorrect, so you would worry without cause.

7- What are the possible benefits?

You will receive weight-loss treatment and it is expected that you will lose weight, which can improve your health. If you take part in this study, you may help others in the future. We cannot promise any further benefits from your being in the study.

8- If you do not want to take part in the study, are there other choices?

You have the choice at any time not to participate in this research study. If you choose not to participate, any health benefits to which you are entitled will not be affected in any way. You have the right to take part now and change your mind later on.

9- If you have any questions or problems, whom can you call?

If you have any questions about your rights as a research volunteer, you should call the Institutional Review Board Office at 225-763-2693 or the Executive Director of Pennington Biomedical at 225-763-2513. If you have any questions about the research study, contact Dr. Corby Martin at (225) 763-2585. If you think you have a research-related injury or medical illness, you should call Dr. Frank Greenway at (225) 763-2578 during regular working hours. After working hours and on weekends you should call the answering service at 225-765-4644. The on-call physician will respond to your call.

10- What information will be kept private?

Every effort will be made to maintain the confidentiality of your study records. However, someone from the Pennington Biomedical Research Center or WW Inc. (the sponsor) may inspect and/or copy the medical records related to the study. Results of the study may be published; however, we will keep your name and other identifying information private. During the group-based intervention sessions, your identity will be known to other people in the study. You can choose what to share during those sessions. Other than as set forth above, your identity will remain confidential unless disclosure is required by law.

De-identified Information for Future Research

Any personal information that could identify you will be removed from your data. Your data may be used for future research studies or given to another investigator for future research without asking for your additional permission.

Genetic Information

The Genetic Information Nondiscrimination Act (GINA) may help protect you from health insurance or health-related 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 a 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).

Despite the GINA protections and the best efforts of the research team to protect your information, you may still be at risk if information about you were to become known to people outside of this study.

11- Can your taking part in the study end early?

Dr. Corby Martin, Dr. Frank Greenway, or the study sponsor can withdraw you from the study for any reason or for no reason. Possible reasons for withdrawal include missing clinic or intervention visits. The sponsor of the study may also end the study early.

You may withdraw from the study at any time without penalty; however, all data Pennington Biomedical has previously collected cannot be removed from the study. If you withdraw, no additional data will be collected. If your participation in the research ends early because of the investigator or by your choice, termination procedures may need to be completed or follow-up data may need to be obtained to ensure your safety. The study staff will go over the details with you.

12- What if information becomes available that might affect your decision to stay in the study?

Significant New Findings

During the course of this study, there may be new findings from this or other research, which may affect your willingness to continue participation. Information concerning any such new findings will be provided to you.

Clinically Relevant Research Results

In this study, you will be informed of any clinically relevant research results, including your individual results that may be discovered. However, this study does little testing. Therefore, clinically relevant results would most likely be related to your risk for diseases such as diabetes.

13- What charges will you have to pay?

None.

14- What payment will you receive?

If you agree to take part, we will compensate you $150 for completion of the study ($60 for completion of the baseline visit, and $90 for completion of the Week 12 visit). Your

check will be requested from the LSU payroll department when you complete the appropriate milestones. It usually takes about 3-4 weeks for it to arrive at Pennington Biomedical Research Center.

U.S. citizens, legal resident aliens, and those who have a work eligible visa will need to provide their social security number to receive payment.

You are subject to a 1099 for receiving compensation. Payments in excess of $600 per calendar year are considered taxable income. If you will be paid more than $600, Pennington Biomedical/LSU will report this income to the IRS.

Non-US citizens are subject to having taxes withheld from payment and will need a passport, visa, and 1-94 for payment to be processed.

I authorize that all information provided on this Informed Consent form and HIPAA Authorization form, including any and all personal and financial data, may be shared with the Internal Revenue Service (IRS) for tax reporting. This data will be securely retained indefinitely.

15- Will you be compensated for a study-related injury or medical illness?

No form of compensation for medical treatment or for other damages (i.e., lost wages, time lost from work, etc.) is available from the Pennington Biomedical Research Center.

In the event of injury or medical illness resulting from the research procedures in which you participate, you will be referred to a treatment facility. Medical treatment may be provided at your expense or at the expense of your health care insurer (e.g., Medicare, Medicaid, Blue Cross-Blue Shield, Dental Insurer, etc.) which may or may not provide coverage. The Pennington Biomedical Research Center is a research facility and provides medical treatment only as part of research protocols. Should you require ongoing medical treatments, they must be provided by community physicians and hospitals.

16- Signatures

By signing this consent form, I agree to participate in the study as it is described. The study has been discussed with me and all my questions have been answered. I understand that additional questions regarding the study should be directed to the study investigators. I agree with the terms above and acknowledge that I will be given a copy of this signed consent form. With my signature, I also acknowledge that I have been given either today or in the past a copy of the Notice of Privacy Practices for Protected Health Information and have received the links to 23andMe, Ancestry.com or GeneticDirection's Full Privacy Statement within this consent form.

_____
Printed Name of Volunteer

_____ _____
Signature of Volunteer Date

_____
Printed Name of Person Administering Informed Consent

_____ _____
Signature of Person Administering Informed Consent Date

Dr. Corby Martin
Principal Investigator

Dr. Frank Greenway
Medical Investigator

17- What you need to know about future research with your data.

Your stored data may be used and reviewed at Pennington Biomedical Research Center or sent to researchers outside of the Pennington Biomedical Research Center and used in future research. Any personal information that could identify you will be removed before the data are shared.

Withdrawal of Consent

If you decide you would like to withdraw your consent to use your information, you must provide a written request to have your samples destroyed. In the event you withdraw your consent, it will not be possible to destroy the information or samples that have already been given to researchers. To withdraw your consent of your information, you can send a request to the Principal Investigator at:

Dr. Corby Martin
Pennington Biomedical Research Center
6400 Perkins Road
Baton Rouge, LA 70808