# Use of a weight loss aid in a population exposed to Polybrominated Biphenyl (PBB)

## Informed Consent Form Dated: March 23, 2018

## NCT Number: NCT03582722

# You Are Being Asked to Be in a Research Study

## What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though you might benefit from participating in this research study.

## Do I Have to Do This?

No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

## What Is This Document?

This form is an informed consent document. It will describe the study risks and procedures.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

## What Should I Do Next?

1. Read this form, or have it read to you.
2. Make sure the study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. Take time to consider this; you may want to talk about it with your family and friends before deciding if you will participate.

**Title**: Use of a weight loss aid in a population exposed to Polybrominated Biphenyl (PBB)

**Principal Investigator:** Michele Marcus, PhD, MPH

**Study-Supporter:** *National Institutes of Health*

**Introduction**

You are being asked to be in a PBB research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.**

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study staff explain the study to you
- Please ask questions about anything that is not clear

You can have a copy of this consent form to keep. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

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

**What is the purpose of this study?**

The purpose of this study is to determine if use of a weight loss medication, along with diet and exercise, will result in weight loss and a reduction of Polybrominated Biphenyl (PBB) blood levels and blood levels of other chemicals that are stored in body fat. PBB is stored in body fat and leaves the body very slowly. The weight loss medication can limit the absorption of fat from the food you eat and increase the fat your body gets rid of. This can help with weight loss and possibly help get rid of PBBs faster. Approximately 120 individuals will be enrolled for this purpose. Sixty people will receive capsules containing 60mg of Orlistat, an FDA-approved medication for weight loss, and sixty people will receive a placebo. The placebo capsule is designed to look similar to the Orlistat capsule but does not contain any active ingredients. You will not know which medication you receive. Participants will be assigned at random – like the flip of a coin – to either the active drug or placebo.

**What will I be asked to do?**

Before enrolling in the study, we want to be sure you are healthy. You will be asked about your health and have a blood test. Participation in the study will last 6 months. During those 6 months you will participate in blood collections, physical measurements, health questions, daily medication use, telephone calls, and follow diet and exercise recommendations as per the participation schedule below.

**Participation Schedule**

| | Screening | Month: | | | | | |
|---|---|---|---|---|---|---|---|
| | | 1 | 2 | 3 | 4 | 5 | 6 |
| **Activity:** | | | | | | | |
| A: Blood Collection & Physical Measurements | **X** | | | **X** | | | **X** |
| B: Health Questions | **X** | | | | | | |
| C: Daily Medication | | **X** | **X** | **X** | **X** | **X** | **X** |
| D: Telephone Calls | | **X** | **X** | **X** | **X** | **X** | **X** |
| E. Follow Diet and Exercise Recommendations | | **X** | **X** | **X** | **X** | **X** | **X** |

**A: Blood Collection and Physical Measurements**
In order to determine eligibility for the study, you will be asked for a blood sample that will be tested for kidney, liver, thyroid, cholesterol and triglycerides and glucose. Some of the blood collected will also be used to measure PBB and other chemicals. Any remaining sample may also be used to assess your genes or hormone levels or other tests in future research. You will be asked to give a sample of blood (four tubes, which is about 2.5 tablespoons) collected from a vein in your arm by a trained medical technician. The blood draw should take approximately 10 minutes. In addition, your height, weight, and waist circumference will be recorded. Your body fat may also be measured. The results of this screening process will help inform us of your eligibility to continue in the rest of the study procedures.

**B: Health Questions**
You will be asked questions about your health to determine if you are eligible for the trial. You will also be asked to complete a confidential comprehensive health questionnaire online.

**C: Daily Medication**
After enrollment, you will be sent a six-month supply of a daily multivitamin to your home. You will be asked to take the multivitamin, once-a-day, at bedtime because the study medication may reduce the absorption of certain vitamins from the food you eat. You will be asked to take the prescribed medication three times-a-day with meals containing fat. You will not know whether you are taking the weight loss medication or the inactive medication. You will be asked to take the prescribed medications for 6 months.

**D: Telephone Calls**
You will be called and asked brief questions about your study participation.

**E: Follow Diet and Exercise Recommendations**
As part of the study, you will be asked to follow a recommended diet and exercise plan.

**What happens to my study information and samples?**
If you join this study, you will be donating your samples and study information to Dr. Michele Marcus at Emory University. Once collected, the samples and data will be stored for research purposes. If you withdraw from the study, data and samples that were already collected may still be used for this study or future studies.

**What are the possible risks and discomforts?**

There may be side effects from taking the weight loss medication or from other study procedures that are not known at this time. The initial screening process is in place to minimize the risk of side effects from the weight loss medication, which are listed below.

**Use of weight loss medication may possibly be associated with the following side effects:**

| Risk Level | Associated Risk |
|---|---|
| Most common risks: | • Headache<br>• Oily rectal discharge<br>• Gas<br>• Urgent need to have a bowel movement |
| Less common risks: | • Inability to control bowel movement |
| Rare but possible risks: | • Oxalate kidney stones/oxalate kidney damage<br>• Pancreatitis<br>• Liver injury or failure |

**Risks of Blood Collection:** Collecting blood from a vein in someone's arm is a standard medical procedure, although sometimes there may be some discomfort or bruising. Other risks from a blood draw may include fainting or lightheadedness and very rarely the possibility of an arterial puncture.

Please keep the prescribed medication out of the reach of children or anyone else who may not be able to read or understand the label. You are the only person who should take the prescribed medication. Do not let anyone else take the prescribed medication.

It is possible that a new risk of study participation will be discovered after the study begins. If this happens, the researchers will tell you about it. If this happens, you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

**Will I benefit directly from the study?**

This study is not designed to benefit you directly. Through diet and exercise participants are likely to lose some weight. This may improve your health overall and help your body get rid of some of the PBB and other chemicals. The study results may be used to help others in the future.

**What about results?**

The results of your clinical screening tests, if abnormal, will be reported to you. The blood levels of PBB and other chemicals will become part of your PBB Registry record. It is your choice whether or not you want to know these results. No results will be reported until the Principal Investigator is confident of the accuracy and interpretation. If your remaining blood samples are used for other tests, including genetic tests, the results may not be made available to you. The overall results of the study WILL be reported to all study participants and all members of the PBB Registry.

The analyses conducted during this study will be reviewed **for research purposes only**, not for healthcare purposes. These results will not be reviewed to make decisions about your personal health or treatment, and any questions about how results from this study may affect your health should be addressed with your physician. Participation in this study **does not replace your usual medical care**.

Note: Chemical analyses will be conducted after all participants have completed the study, which may take up to two years from when you finish the study.

**Will I be compensated for my time and effort?**

You will be sent $40 once you complete 3 months of participation and then $60 once you complete all 6 months of the trial, to compensate you for your time and effort. You will be sent $100 total, if you complete all study visits.

**What are my other options?**

The alternative to participating in this study is to not participate. The study team is available to discuss this and any other options for participating in PBB research studies. The study team is also available to discuss your concerns regarding PBB exposure. There are other methods and treatments for weight loss that you can discuss with your doctor without participating in this study.

**How will you protect my private information that you collect in this study?**

Emory will keep any research records we create private to the fullest extent allowable by law. An identification number, rather than your name, will be used on study records and blood samples. Your samples, data and health information may be shared with other qualified researchers. All study data and samples are kept in locked cabinets and secure computer files available to a limited number of study personnel, only when it is necessary. Your name and other identifying information will not appear when we present or publish the study results.

Certain offices and people other than the researchers may look at study records, for example, Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration. These include the IRB, Compliance Offices, and the Office for Clinical Research. Our study funder, National Institutes of Health, may also look at your study records.

**Genetic Information:**

Your genetic information is also protected under the Genetic Information Nondiscrimination Act (GINA), a federal law that generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, and does not apply to employers with less than 15 employees.

**Certificate of Confidentiality:**

We will do everything we can to keep others from learning about your participation in the research. To further help protect your privacy, the investigators have obtained a Confidentiality Certificate.

*What the Certificate of Confidentiality protects:*

The National Institutes of Health has given this study a Certificate of Confidentiality. This Certificate allows Emory to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records that identify you, we would say no. The Certificate allows Emory to legally say no to this type of request. This Certificate allows Emory to refuse to share information about you that could harm your image, finances, your chances at a job, or chances for getting insurance.

*What the Certificate of Confidentiality does not protect:*

The Certificate does not prevent you or someone other than you from disclosing your information. The Certificate also does not prevent Emory from releasing the below information about you:

- Information to state public health offices about certain infectious diseases.
- Information to law officials if child abuse has taken place.
- Information Emory gives to prevent immediate harm to you or others.
- Information Emory gives to the study funder as part of the research.

*Research Information Will Not Go Into an Emory Medical Record:*
If you are or have been an Emory Healthcare patient, you have an Emory medical record. If you are not and have never been an Emory Healthcare patient, you do not have an Emory Medical Record.

**In Case of Injury**
If you get ill or injured from being in the study, Emory will help you get medical treatment. Emory and the Principal Investigator have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory investigator or employee. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact Dr. Michele Marcus at telephone number [redacted]. You should also let any health care provider who treats you know that you are in a research study.

**Costs**
There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

If the study procedures result in any medical complications that would not fall under "injury" as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

**Withdrawal from the Study**
You have the right to leave the study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to stop the study treatment. If you leave the study before the final planned study visit, the researchers may ask you to complete some of the final steps.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

**Contact Information**
Contact the Principal Investigator, Dr. Michele Marcus at [redacted].

- If you have any questions about this study or your part in it,
- If you feel you have had a research-related injury or a bad reaction to the prescribed medication, or
- If you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- If you have questions about your rights as a research participant.
- If you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

**Receiving Results**

Please check a box below to indicate if you **"do"** or **"do not"** want to receive the results of your blood levels of PBB and other chemicals.

☐ **I do** ☐ **I do NOT**

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***TO BE FILLED OUT BY PARTICIPANT ONLY***

Please **print** your name, **sign**, and **date** below if you agree to be in the main study. By signing this consent form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____

**Name of Participant**

_____ _____

**Signature of Participant (18 or older and able to consent)** **Date** **Time**

**Date of Birth**: ☐☐/☐☐/☐☐☐☐

**Current Mailing Address:** _____

**Street** **City, State** **Zip code**

**Primary (**☐☐☐☐**)** ☐☐☐ **-** ☐☐☐☐ **Phone Type:** ☐ **Home** ☐ **Cell**

**Secondary (**☐☐☐☐**)** ☐☐☐ **-** ☐☐☐☐ **Phone Type:** ☐ **Home** ☐ **Cell**

**May we send you text messages regarding the study?** ☐ **No** ☐ **Yes**

_____

**E-mail Address**

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***TO BE FILLED OUT BY STUDY TEAM ONLY***

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**Name of Person Conducting Informed Consent Discussion**

_____ _____

**Signature of Person Conducting Informed Consent Discussion** **Date** **Time**