Protocol Title: PaTH Clinical Data Research Network (CDRN) Study of Healthy Lifestyles, Body Weight and Health Care: Johns Hopkins University Site

Application No.: IRB00064599

Sponsor: Patient-Centered Outcomes Research Institute (PCORI)

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- You are being asked to join a research study. This consent form explains the research study and your part in the study. Please read it carefully and take as much time as you need.
- Contact the study team (contact information above) to explain any words or information in this informed consent that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.
- The Johns Hopkins School of Medicine’s Institutional Review Board (IRB) has reviewed this study on behalf of the 4 PaTH institutions to ensure the research participants are adequately protected. Each PaTH institution is solely responsible for conducting the study safely and according to the protocol that the Johns Hopkins IRB has approved.
- Prior to being reviewed by the Johns Hopkins Institutional Review Board (IRB), this protocol was reviewed and approved by the PaTH Network Protocol Review Committee.
This committee consists of research participant protection experts and patient representatives from each of the 4 PaTH institutions.

- Contact information for the investigators responsible for conducting the research at each PaTH institution is included on the first page of this form. When multiple institutions are conducting the study, the word “we” in this consent form may include both Johns Hopkins and the participating institution.

1. **Why is this research being done?**
The PaTH Clinical Data Research Network (CDRN) Study of Healthy Lifestyles, Body Weight and Health Care will create a large registry of patients with both medical record information and patient reported information. This information will be used to answer questions about health behaviors, preventive health and weight management that are important to patients, their families, and their healthcare providers.

2. **What you should know about the PaTH Clinical Data Research Network (CDRN) Study of Healthy Lifestyles, Body Weight and Health Care:**
   - The PaTH network consists of 4 Mid-Atlantic health systems – the University of Pittsburgh Medical Center, Penn State Hershey Medical Center, Temple Hospital Health System, and the Johns Hopkins University Health System.
   - The PaTH Clinical Data Research Network (CDRN) Study of Healthy Lifestyles, Body Weight and Health Care aims to follow patients from these 4 institutions to learn more about healthy habits and health care.

3. **What will happen if you join this study?**
If you agree to be in this study, the PaTH Clinical Data Research Network (CDRN) Study of Healthy Lifestyles, Body Weight and Health Care will collect and study several types of your information:

   1. **Surveys**—you will be asked to complete a health survey when you join the study, and then about every 6 months thereafter. When you are due to complete a survey, you will be notified by mail, e-mail, and/or phone. The surveys include questions about your quality of life and health behaviors (for example, diet and exercise).

   Your survey responses may be entered into your Johns Hopkins electronic medical record, where they may be viewed by your health care providers. However, do NOT assume that your health care provider reviewed your survey responses. Because it is available in your record, you can ask your health care provider to review your survey responses with you if you wish.

   If you do not want your survey responses made part of your medical record you have the option of providing survey data outside of the electronic medical record via a survey data collection instrument called REDCap.
2. **Health records**—selected health information, important to health and weight management, will be extracted from your Johns Hopkins medical record and included in the study. This health information will include (but is not limited to): hospitalizations and outpatient visits you have had at Johns Hopkins, weight, blood pressure, test results (e.g., blood tests, biopsies), prescribed medications, billing records and advice for obesity, alcohol and tobacco use.

3. **Biospecimen tracking**—if you have had biospecimens (samples of your blood, saliva, urine or tissue) collected and stored at Johns Hopkins University, Johns Hopkins Hospital or its affiliates’ for research purposes, the PaTH network will record what type of biospecimen is stored, when it was collected, and where it is stored.

4. **Insurance claims data**—Because parameters from PCORI (the funder) emphasizes the need for complete health data for each PaTH study participant, we will request claims data from health insurers to link with survey responses. Claims data will allow us to assess, for example, how health behaviors are associated with health care utilization.

If your insurer agrees; we will include data about healthcare that you have received outside of one of the PaTH institutions (that is, care received from a non-Johns Hopkins site).

The research data will be collected at Johns Hopkins from the sources described above. After all identifying information is removed; your data will be securely transferred electronically to the PaTH network data storage center at the University of Pittsburgh.

This information (Surveys, Biospecimen tracking, Health records, and Insurance claims data) could be used in the future to (1) determine if you have been a patient at one of the other PaTH institutions. In the event that you have received health care at another PaTH institution, that data may also be included into your research record, (2) check with the Social Security Death Index once a year so that we can keep track of what happens to participants in this study, (3) allow us to contact you about future studies, and (4) link your survey and medical record data to your biospecimen data if permitted in another study (5) re-identification for contact for future studies.

Accurate identification of patients who seek care in more than one PaTH health system is necessary to avoid identifying a single patient as multiple patients, and also to let us know when to merge data on the same patient from multiple sites. In order to accomplish this we will send an encrypted file called a “hash file,” which means the file is scrambled in such a way that it cannot be re-identified. The hashed data will include your full name, gender, date of birth, zip code, and social security number (if available in your medical record) to the University of Pittsburgh.
4. **How long will you be in the study?**
   We want to follow you for as long as you are a patient at Johns Hopkins. If you are unable to complete the health surveys we will continue to collect and study your health records unless you formally withdraw from the study.

5. **What are the risks or discomforts of the study?**
   If there were a breach in the security of the PaTH Clinical Data Research Network (CDRN), that could result in unauthorized persons accessing your personal health information. To minimize that risk, the PaTH network has undertaken strict data security measures.

6. **Are there risks related to pregnancy?**
   For women participants: You will still be eligible to continue in this study if you were to become pregnant during this study. There will not be any additional risk to you or your baby as a result of participating in this study.

7. **Are there benefits to being in the study?**
   You will not experience any direct benefit from being in the study.

8. **What are your options if you do not want to be in the study?**
   You do not have to join this study; your participation is purely voluntary. If you do not join, your care at Johns Hopkins or its affiliates will not be affected.

9. **Will it cost you anything to be in this study?**
   There is no cost to you for taking part in this study.

10. **Will you be paid if you join this study?**
    You will not be paid to be in this study.

11. **Can you leave the study early?**
    If you want to leave the study, please let us know why and we will attempt to address your concerns. If you still wish to leave the study you can do so at any time by contacting Wendy Bennett, MD, Jeanne Clark, MD, or Daniel E. Ford, MD, with a letter, email or phone call (their contact information is on page 1 of this consent form).

12. **How will your privacy be protected?**
    We have rules to protect information about you. Federal and state laws and the Federal Medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your “authorization,” for the use and disclosure of information protected by the Privacy Rule.

    The research team working on the study will collect information about you. This includes things learned from the questionnaires described in this consent form. They will also collect other information including your name, address, date of birth, and information
from your medical records. This could include information about HIV and genetic testing, or treatment for drug or alcohol abuse or mental health problems.

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and the sponsor of the study.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator’s name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

13. **Will the study require any of your other health care providers to share your health information with the researchers of this study?**

There will be no action required on the part of any of your health care providers. However, when we extract relevant health information from your health record, it may include information that was collected during both your primary care health care visits (e.g., blood pressure, weight) and other health care visits, and any testing you have had or may have done.

14. **What treatment costs will be paid if you are injured in this study?**

In the very unlikely event that you would be injured in this study, your insurance company would be responsible for the costs.

15. **What other things should you know about this research study?**
a. What is the Institutional Review Board (IRB) and how does it protect you? The Johns Hopkins Medicine IRB is overseeing this study. It is made up of:
   - Doctors
   - Nurses
   - Ethicists
   - Non-scientists
   - and people from the local community.

   The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

b. What do you do if you have questions about the study?
   Contact the principal investigators, Wendy Bennett, MD, Jeanne Clark, MD, or Daniel E. Ford, MD or the study project manager, Megan Gauvey-Kern. Their contact information is on the first page of the consent form. If you cannot reach them or wish to talk to someone else, call the Johns Hopkins IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study? If you have an urgent medical problem related to your taking part in this study, call Wendy Bennett at 410-502-6081 during regular office hours and at 410-955-4331 after hours and on weekends.

d. What happens to Data that are collected in the study?
   Johns Hopkins University and our PaTH network research partners are working to better understand health behaviors and weight management. The data you provide are important to this effort. As described above, your data will be transferred to the PaTH network data storage area at the University of Pittsburgh, where it will be prepared for the PaTH research team to study.

   The data we collect may be shared with other researchers at universities or for profit companies if the research team and the IRB thinks it will lead to new knowledge related to healthy lifestyles and weight management.

   If you join this study, you should understand that you will not own your data, and should researchers use them to create a new product or idea, you will not benefit financially.

e. What are the Organizations that are part of Johns Hopkins?
   Johns Hopkins includes the following:
   - The Johns Hopkins University
   - The Johns Hopkins Hospital
   - Johns Hopkins Bayview Medical Center
• Howard County General Hospital
• Johns Hopkins Community Physicians
• Suburban Hospital
• Sibley Memorial Hospital
• All Children’s Hospital.

16. What does your signature on this consent form mean?
Your signature on this form means that:
• you understand the information given to you in this form
• you accept the provisions in the form
• you agree to join the study
• you will not give up any legal rights by signing this consent form
• you agree to be contacted if we think you may be eligible for future studies.