

**Partners HealthCare System  
Research Consent Form**

Subject Identification
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General Template  
Version Date: November 2005

Protocol Title: Finding Genes for Uterine Fibroids  
Principal Investigator: Cynthia C. Morton, Ph.D.  
Site Principal Investigator: Cynthia C. Morton, Ph.D.  
Description of Subject Population: Women with fibroids

**About this consent form**

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called “subjects.” This term will be used throughout this consent form. If you have any questions about the research or about this form, please ask us. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a copy of this form to keep.

**Why is this research study being done?**

We would like permission to enroll you as a participant in a research study. The purpose of the study is to search for the hereditary causes of uterine fibroids (benign uterine tumors). Specifically, current scientific research indicates that many women with fibroids may have certain gene(s), which predispose them to the development of fibroids. We are searching for these gene(s) to understand how these tumors form and develop. Ultimately, we hope to use this information to design better treatment options for women with fibroids. In addition, genes involved in uterine fibroid formation may also play a role in the growth of related tumors such as lipomas (benign fatty tumors) and hamartomas (benign chest tumors). Therefore, genetic information about fibroids may help us understand and treat other tumors as well.

To achieve these goals, we hope to recruit at least 1000 women (500 pairs of sisters) with a history of fibroids to participate in our study. You have been asked to be in this study because

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you have had surgery or other treatment for fibroids, or you are a family member of a person diagnosed with this disorder. Because the inherited causes of this disorder are being studied, some of your family members may be asked to participate in this study. The doctor in charge of this study is Dr. Cynthia Morton who can be reached at 617-525-4535. To contact study staff regarding information about the study, administrative questions, and/or requests for withdrawal and destruction of your study materials, please see page 9 below (24-hour contact).

## How long will I take part in this research study?

The study requirements include signing a consent form, completing surveys and submitting a DNA (blood or saliva) sample. The expected time commitment to complete the paperwork is approximately 30 minutes. The blood drawing process takes approximately 5-10 minutes.

## What will happen in this research study?

### For Initial Contact Person

If you agree to participate, we will ask you to fill out a short screening survey (Phase One Questionnaire) about your background, general health, and family history to document some of the characteristics associated with fibroids. We may also ask you to complete a more detailed Phase Two Questionnaire. If there are blanks, or illegible or incomplete information on the questionnaires, we may send them back requesting you to provide the necessary information. Upon receiving the signed consent form and completed surveys, we will ask you to provide a single blood sample (approximately four tablespoons of blood will be drawn). This blood sample will be used to isolate your DNA. DNA is the genetic material from which genes are made. As an alternative to the blood draw, you may elect to submit two saliva samples using a mouthwash procedure. This procedure, however, may produce less DNA that may be of lower quality than DNA from a blood sample. Because it is crucial to our study that we obtain the highest yield and quality of DNA possible, we request that you opt for the mouthwash procedure only if you are unable to submit a blood sample.

You may also be asked to tell other family members about this research study so that more samples can be obtained for analysis. If you are willing, you will be asked to tell interested family members to call the study staff for more information or to have them tell you that is okay for the study staff to contact them. You should not feel obligated in any way to recruit family

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members. If you do tell family members about this study, you should refer their questions to the study staff. Our study staff will not contact family members who have not given permission to be contacted, and we will not discuss with any family member information regarding who does and does not participate in the study.

In addition, if you have been diagnosed with fibroids, we will want to review those medical records. This information is helpful in connecting our research results with specific medical findings. The last page of this consent form is an authorization form to release your fibroids-related medical records to the investigators of this study.

### For Family Members

If you agree to participate, we will ask you to fill out a Phase Two Questionnaire. If there are blanks, or illegible or incomplete information on the questionnaires, we may send them back to you requesting you to provide the necessary information. Upon receiving the signed consent form and completed surveys, we will ask you to provide a single blood sample (approximately four tablespoons of blood will be drawn). This blood sample will be used to isolate your DNA. DNA is the genetic material from which genes are made. As an alternative to the blood draw, you may elect to submit two saliva samples using a mouthwash procedure. This procedure, however, may produce less DNA that may be of lower quality than DNA from a blood sample. Because it is crucial to our study that we obtain the highest yield and quality of DNA possible, we request that you opt for the mouthwash procedure only if you are unable to submit a blood sample.

In addition, if you have been diagnosed with fibroids, we will want to review those medical records. This information is helpful in connecting our research results with specific medical findings. The last page of this consent form is an authorization form to release your fibroids-related medical records to the investigators of this study.

### For All Participants

We would like the opportunity to ask you to complete additional questionnaires if new information on fibroids develops in the future. If you wish to be sent additional supplemental questionnaires, initial the line marked "YES" below.

I wish to be sent additional supplemental questionnaires:

\_\_\_\_\_ **YES, send me the supplemental**                      \_\_\_\_\_ **NO, do not send me the**

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Initials **questionnaires**

Initials **supplemental questionnaires**

Confidentiality is observed regarding the information collected from participants. All information and samples obtained for this study will be permanently stored, assigned a code, and entered into a database. No names are entered into this database, only the codes assigned to the research record. Similarly, no names or other identifiers will be used on samples to link information to a specific person. A key to the code will be kept in a separate locked file in Dr. Morton's office. Only the study coordinator will have access to the key to the codes and the keys to the data files.

Furthermore, because no clinically or diagnostically relevant information can be learned from this research, the research results from this study are unlikely to be shared with you. Instead, this research is a stepping-stone toward understanding the causes of uterine fibroids and how they may be inherited. Therefore, it is possible relevant general information about uterine fibroids may be learned from this study. Whenever general information is learned, a newsletter that discusses the new findings can be sent to you. If you choose to receive the newsletter, it will be addressed to you. However, no information regarding your participation in, or results of, your genetic research will be in the newsletter. If you wish to receive this newsletter, initial the line marked "YES" below.

I wish to receive the newsletter if general information is learned about uterine fibroids:

           **YES, send the Newsletter**  
Initials

           **NO, do not send the newsletter**  
Initials

As mentioned above, because no clinically or diagnostically relevant information may be learned from this research, the research results from this study are unlikely to be shared with you. However, it is possible that relevant information about you and/or your family could eventually be learned that would be important in your future medical care or that of your family. If this occurs, you will need to sign a separate consent form to authorize the release of information. If you wish to be contacted in the event that relevant information is learned about you and/or your family, initial the line marked "YES" below.

I wish to be contacted if relevant information is learned about me and/or my family:

           **YES, contact me**  
Initials

           **NO, do not contact me**  
Initials

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In addition, you may be contacted in the future and asked for additional samples to continue research in this area. You may choose whether or not you wish to participate in additional research. If you wish to be contacted about participation in future research, initial the line marked "YES" below.

I wish to be contacted about participation in future research:

\_\_\_\_\_ **YES, contact me**  
Initials

\_\_\_\_\_ **NO, do not contact me**  
Initials

We have enclosed two copies of the Consent Form. Please sign and date **both** copies, and keep the "**Participant Copy**" of the Consent Form for your records. We ask that you return the other copy along with your questionnaire in the enclosed white envelope. As you have received the "**Participant Copy**" of the Consent Form, please initial the line below marked "YES". If you did not receive two copies, one for your records, please initial the line below marked "NO".

\_\_\_\_\_ **YES, I received a copy of this Consent**  
Initials **Form for my records, which I have signed**

\_\_\_\_\_ **NO, I did not receive a copy of this**  
Initials **Consent Form, which I need to**  
**sign for my records**

**What are the risks and possible discomforts from being in this research study?**

There are minor risks and discomforts associated with blood sampling. This includes a small amount of pain and possibly a small bruise at the needle site. Occasionally, a person feels faint when their blood is drawn. Very rarely, an infection develops that can be treated.

With regard to the mouthwash protocol, the label on the bottle of mouthwash states that "In case of ingestion, seek professional assistance, or contact a poison control center immediately. Do not use in children under six years of age. Children over six should be supervised when using the mouthwash," and that the mouthwash should be kept "Out of reach of children." The Poison Control Center number is 1-800-222-1222. There are no risks associated with proper usage.

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Another unlikely, but potential, risk concerns disclosure of research results. In general, information about a person's participation in a genetic study may influence insurance companies and/or employers regarding one's health status. The passage of GINA (Genetic Information Nondiscrimination Act) this year into law (public Law 110-233) provides protection for individuals who have genetic testing for diagnostic purposes or who participate in genetic studies. Therefore, the following safeguards are in place to prevent unintentional disclosure. First, genetic information gained from this study does not have medical or treatment implications at this time, and no diagnostic information can be learned from the results. Therefore, neither information about your participation in this study nor the results of the research will be placed in your medical records. Your samples will be coded and stored permanently; the key to the code kept in a separate, locked file. Similarly, no information will ever be released or published in a way that will identify you as a specific participant. If you choose to receive the newsletter, no remarks or statements will be made that indicate that you participated in a genetic study. Any materials mailed to you will not identify you as a patient or participant in a genetic study. Finally, by not sharing information about your participation in this study with others, you will further minimize the risk of unintentional disclosure.

Although every effort will be made to keep your participation confidential, we cannot guarantee absolute confidentiality.

## What are the possible benefits from being in this research study?

There are no direct benefits to you from participation in this study. It is possible that the genetic causes of uterine fibroids may be learned in the future as a result of this study. Ultimately, we hope to use this information to design better treatment options for women with fibroids.

## Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

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Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

It is possible that we will have to ask you to drop out before you finish the study. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

## What will I have to pay for if I take part in this research study?

No charges will be billed to your insurance company or to you for this study. A pre-paid blood kit and mailing envelope will be sent to you if you choose to have your blood drawn by someone other than the phlebotomists at Brigham and Women's Hospital. You should be sure that no charges for the blood draw are filed with your insurance company. If the person who draws your blood intends to bill you, you should pay for this yourself and send a copy of the bill to Dr. Morton who will reimburse you. There is also no charge for shipping the saliva sample.

## What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them.

Giving you care does not mean that Partners hospitals or researchers are at fault, or that there was any wrongdoing. There are no plans for Partners to pay you or give you other compensation for the injury. However, you are not giving up any of your legal rights by signing this form.

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If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

## If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

### Study Contacts:

Raghava Shree Kavalla (Study Coordinator)  
Brigham and Women's Hospital  
77 Avenue Louis Pasteur, 160 New Research Building, Boston, MA 02115  
Office Number: 617-525-4434 or 1-800-722-5520 and ask operator for 525-4434 (U.S. only)  
Email: [fbroids@rics.bwh.harvard.edu](mailto:fbroids@rics.bwh.harvard.edu)  
Web Address: [www.fibroids.net](http://www.fibroids.net)

Cynthia C. Morton, Ph.D.  
Brigham and Women's Hospital  
77 Avenue Louis Pasteur, 160D New Research Building, Boston, MA 02115  
Office Number: 617-525-4535 or 1-800-722-5520 and ask operator for 525-4535 (U.S. only)  
Email: [cmorton@partners.org](mailto:cmorton@partners.org)  
Web Address: [www.fibroids.net](http://www.fibroids.net)

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 617-424-4100.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

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Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

## If I take part in this research study, how will you protect my privacy?

Federal law requires Partners (Partners HealthCare System and its hospitals, health care providers and researchers) to protect the privacy of health information that identifies you. This information is called Protected Health Information. In the rest of this section, we refer to this simply as “health information.”

If you decide to take part in this research study, your health information may be used within Partners and may be shared with others outside of Partners, as explained below.

We have marked with a  how we plan to use and share your health information. If a box is not checked , it means that type of use or sharing is not planned for in this research study.

We will also give you the **Partners Notice for Use and Sharing of Protected Health Information**. The Notice gives more details about how we use and share your health information.

### ▪ Health Information About You That Might be Used or Shared During This Research

- Information from your hospital or office health records within Partners or elsewhere, that may be reasonably related to the conduct and oversight of the research study. If health information is needed from your doctors or hospitals outside Partners, you will be asked to give permission for these records to be sent to researchers within Partners.
- New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study

### ▪ Why Health Information About You Might be Used or Shared with Others

The reasons we might use or share your health information are:

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- To do the research described above
- To make sure we do the research according to certain standards - standards set by ethics and law, and by quality groups
- For public health and safety - for example, if we learn new health information that could mean harm to you or others, we may need to report this to a public health or a public safety authority
- For treatment, payment, or health care operations

## ■ People and Groups That May Use or Share Your Health Information

### 1. People or groups within Partners

- Researchers and the staff involved in this research study
- The Partners review board that oversees the research
- Staff within Partners who need the information to do their jobs (such as billing, or for overseeing quality of care or research)

### 2. People or groups outside Partners

- People or groups that we hire to do certain work for us, such as data storage companies, our insurers, or our lawyers
- Federal and state agencies (such as the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections) and other U.S. or foreign government bodies, if required by law or involved in overseeing the research
- Organizations that make sure hospital standards are met
- The sponsor(s) of the research study, and people or groups it hires to help perform this research study
- Other researchers and medical centers that are part of this research study
- A group that oversees the data (study information) and safety of this research study
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow. We share your health information only when we

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must, and we ask anyone who receives it from us to protect your privacy. However, once your information is shared outside Partners, we cannot promise that it will remain private.

## ▪ Time Period During Which Your Health Information Might be Used or Shared With Others

- Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

## ▪ Your Privacy Rights

- You have the right **not** to sign this form permitting us to use and share your health information for research. If you don't sign this form, you can't take part in this research study. This is because we need to use the health information of everyone who takes part in this research study.

- You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. This includes information used or shared to carry out the research study or to be sure the research is safe and of high quality.

If you withdraw your permission, you cannot continue to take part in this research study.

- You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study.

## ▪ If Research Results Are Published or Used to Teach Others

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

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**Consent/Assent to take part in this research study, and authorization to use or share your health information for research**

**Statement of Subject or Person Giving Consent/Assent**

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other options for treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.

If you understand the information we have given you, and would like to take part in this research study, and also agree to allow your health information to be used and shared as described above, then please sign below:

**Signature of Subject:**

\_\_\_\_\_  
Adults or Minors, ages 14-17

\_\_\_\_\_  
Date/Time

**OR**

If you understand the information we have given you, and would like to give your permission for your child/the person you are authorized to represent to take part in this research study, and also agree to allow his/her health information to be used and shared as described above, then please sign below:

**Signature of Parent(s)/Guardian or Authorized Representative:**

\_\_\_\_\_

\_\_\_\_\_

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\_\_\_\_\_  
Parent(s)/Guardian of Minor

\_\_\_\_\_  
Date/Time

**OR**

\_\_\_\_\_  
Court-appointed Guardian or Health Care Proxy

\_\_\_\_\_  
Date/Time

**OR**

\_\_\_\_\_  
Family Member/Next-of-Kin

\_\_\_\_\_  
Date/Time

Relationship to Subject: \_\_\_\_\_

**Signature of a Witness:**

\_\_\_\_\_  
Witness (when required by the PHRC or sponsor)

\_\_\_\_\_  
Date/Time

**Statement of Study Doctor or Person Obtaining Consent**

- I have explained the research to the study subject, and
- I have answered all questions about this research study to the best of my ability.

\_\_\_\_\_  
Study Doctor or Person Obtaining Consent

\_\_\_\_\_  
Date/Time

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In certain situations, the Partners Human Research Committee (PHRC) will require that a subject advocate also be involved in the consent process. The subject advocate is a person who looks out for the interests of the study subject. This person is not directly involved in carrying out the research. By signing below, the subject advocate represents (or “says”) that the subject has given meaningful consent to take part in the research study.

**Statement of Subject Advocate Witnessing the Consent Process**

- I represent that the subject or authorized individual signing above has given meaningful consent.

\_\_\_\_\_  
Subject Advocate (when required by the PHRC or sponsor)

\_\_\_\_\_  
Date/Time

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