Partners HealthCare System
Research Consent Form

Subject Identification

General Template
Version Date: May 2014

Protocol Title: A Partners prospective study assessing the safety, feasibility and efficiency of morcellation in a containment system

Principal Investigator: Jon I. Einarsson

Site Principal Investigator: Stephanie Morris (NWH), Douglas Brown (MGH), James Greenberg (FH)

Description of Subject Population: 400 patients deemed appropriate for laparoscopic myomectomy or laparoscopic hysterectomy

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.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. 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 signed copy of this form to keep.

Why is this research study being done?

We are doing this research study to learn whether a specific way to do laparoscopic gynecological surgery is safe and effective. In a laparoscopic surgery, we use a tube with a light on the end to look inside your body so we can see inside you during your surgery without needing to make a large incision (cut).

One problem with laparoscopic surgery is that is can be difficult to remove tissue through the small opening for the laparoscope. One way to remove tissue during laparoscopic surgery is called "morcellation." Morcellation involves using a special surgical instrument (morcellator) to

chop up the tissue into small pieces so it can be removed without having to make a big incision. Morcellation can lead to seeding (spreading and re-growth) of tissue, including cancerous tissue, within the body if small pieces of diseased tissue are not removed.

On 4/17/14 the U.S. Food and Drug Administration (FDA) issued a statement discouraging the use of power morcellation because of the risk of small pieces of tissue not being removed properly. Because of this, all Partners hospitals have stopped using open morcellation for gynecologic surgery.

At this time, we are ONLY doing "closed" morcellation (done within a bag) at the Partners hospitals as part of a research study. If you do not wish to take part in this research study, we can offer you different ways to have your gynecologic surgery. We are only offering morcellation using a bag because we think it is safer, but we need to collect more information about this technique.

The device we are using to do the closed morcellation in this study **[**Storz Rotocut G1**]** is approved by the FDA for laparoscopic hysterectomy and myomectomy surgeries, however the FDA recently discouraged the use of "open" morcellation.

The bag in which the closed morcellation will be performed, is approved by the U.S. Food and Drug Administration (FDA) to remove tissue during laporoscopic procedures, but the bag is not approved by the FDA to for closed morcellation**.**

Indigo carmine dye will be used in a portion of the study population to assess leakage during the contained morcellation procedure, and is approved by the U.S. Food and Drug Administration (FDA) to be used in laparascopic procedures.

We are asking you to take part in this study because you are having a laparoscopic hysterectomy or a laparoscopic myomectomy surgery.

About 400 women will take part in this research study. This study will be done at Brigham and Women's Hospital, Faulkner Hospital, Massachusetts General Hospital, and Newton-Wellesley Hospital. We expect to enroll approximately 100 women from each hospital.

How long will I take part in this research study?

It will take you about 8 weeks to complete this research study. Most of the study will take place during your laparoscopic myomectomy or laparoscopic hysterectomy. You will not need to attend any extra visits specifically for the study. We will schedule all study procedures to be at the same time as your regular visits for your myomectomy or hysterectomy care.

What will happen in this research study?

If you choose to take part in this study, we will ask you to sign this consent form before we do any study procedures.

Surgery

If you take part in the study, we will do your laparoscopic myomectomy or hysterectomy using closed morcellation. The surgery itself will be done as usual and then once the specimen is ready for removal, it will be placed in a large containment bag. The bag will be brought to an incision on your abdominal wall and then the bag will be inflated with gas and both a camera and morcellator device inserted into the bag. The specimen (uterus or fibroids) will then be morcellated while watching with the camera. This whole process will take place within the bag so as to minimize any tissue spillage during the process.

Follow-up

Following your surgery, you will continue to receive standard care. This includes a post-operative visit scheduled 4-6 weeks following your surgery. After the surgery, we will review your medical records, including any complications from the surgery.

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

Risks of Closed Morcellation

We have been doing closed morcellation procedures for about 3 months. During this time, we have not found any additional risks related to the use of the bag.

It is possible that the bag used to collect the tissue during the closed morcellation procedure could tear or break. If this happens, the tissue could get left in your body and cause an infection, pain, or tissue growth, including cancerous growths.

There may be other risks to the closed morcellation procedure that we do not know yet.

As with any surgical procedure, there are also risks of damage to surrounding tissues or having to convert to open surgery (with a bigger incision).

Risks of Indigo Carmine Dye
There is a small risk of allergic reaction to indigo carmine in some patients.

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

You may not benefit from taking part in this study. It is possible that having your laparoscopic hysterectomy or myomectomy done with closed morcellation will reduce the risks of surgical complications like infection, bleeding, issues related to blood clots in your legs or lungs, incisional hernias or postoperative scar tissue.

We hope that what we learn in this study will help other women having a hysterectomy or myomectomy in the future.

What other treatments or procedures are available for my condition?

Currently at the Partners hospitals, morcellation can only be performed as part of this research study. You do not have to take part in this study to have your myomectomy or hysterectomy. You can have a myomectomy or a hysterectomy with a different type of surgery that does not use morcellation, for example open surgery with a bigger abdominal incision, or vaginal surgery.

Risks of open surgery include longer recovery time, more pain, higher risks of infection, bleeding and scar tissue. Benefits of open surgery include intact removal of tissue without need for morcellation.

Compared to this, the risks of closed morcellation include possible tearing of the bag or leakage/spread of tissue during the morcellation process. The benefits of closed morcellation are a less invasive surgery, smaller incisions or scars and quicker recovery.

The risks and benefits of each procedure can be discussed in more detail with your surgeon.

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.

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.

What should I do if I want to stop taking part in the 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.

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

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

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

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.

Jon Einarsson, MD PhD MPH is the person in charge of this research study. You can call him at 617-525-8582 from M-F 9-5. You can also call Sarah Cohen MD MPH at 617-525-8582 from M-F 9-5 with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call your doctor’s office.

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

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?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research

- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

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.

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.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take 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. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

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. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

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

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

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

_____	_____	_____

Study Doctor or Person Obtaining Consent | Date | Time (optional)

Subject Advocate

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 and dating 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

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

Subject Advocate (when required) | Date | Time (optional)

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Hospital Medical Interpreter | Date | Time (optional)

OR

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name	Date	Time (optional)

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