

## CONSENT TO USE THE DARTMOUTH CENTER FOR SURGICAL INNOVATION (CSI)

*Dartmouth-Hitchcock Medical Center and Dartmouth College*

The Dartmouth Center for Surgical Innovation

*Director: Sohail Mirza, MD, MPH*

Dartmouth- Hitchcock Medical Center has a research facility referred to as the **Dartmouth Center for Surgical Innovation (CSI)**. The CSI is a research facility. It is different from a standard operating room in a few ways that we will describe below. You have the choice whether or not to have your surgery (or other procedure) in the CSI. If you are not having surgery, there are parts of this form that will not apply to you.

One difference between the CSI and a standard operating room is that it is a “dual use facility”, which means that research with animals and with people both happen here. Before new operations are done on people, researchers use animals to develop the new techniques. Until now the experimental surgery on animals could only be done in a separate facility and under different conditions than operating rooms for people. By having the animal research happen in the same place as patients have surgery, both kinds of operations are done under exactly the same conditions. This makes the transition from animal surgery to human surgery more reliable.

Animals and patients will never be in the CSI at the same time, so there will never be contact between patients and animals. Later in this form we describe the safety precautions we are taking to keep patients and animals separate in order to prevent contamination and infection.

Another difference is that the CSI operating rooms are equipped with advanced imaging equipment and computer technology. The imaging equipment and computers allow the doctors to get CT scans, MRIs and X-Rays during surgery and other procedures and see 3 dimensional images of how the procedure is progressing. This is not possible in standard operating rooms or radiology suites.

If you decide to have your surgery in the CSI **your medical record data will be collected** to learn about safety factors and the effects of using the CSI on the outcomes of surgery and other non-surgical procedures.

In addition, if you decide to have your surgery in the CSI, you will be asked to complete a short survey now and around 6 months and one year after your procedure.

**Will you benefit from the use of the CSI?** You might benefit from having your surgery or non-surgical procedure in the CSI because of the special imaging equipment. This allows the doctor to get MRIs, CT scans or X-Rays during the procedure without having to move you to a radiology suite and back again. The advanced computer equipment immediately provides the doctor with 3-D images projected onto large screens.

### **What are the risks involved with the use of the CSI ?**

For surgery patients there is concern about the risk of infection transmission from animals to humans in a dual use facility, however there is no information available about this. We cannot say for sure what the risk is. We assure you that we are using the highest level of infection control possible. These are the things we are doing to prevent transmission of infection from animals to humans:

- The CSI is never used for animal surgery and human surgery at the same time. There is never any contact between patients and animals at any time.
- There is separate surgical equipment for animal and human surgery.
- The imaging equipment and operating tables undergo high level disinfection after each use.
- There is a very high level ventilation system, with HEPA filters, that allows for a complete exchange of air in the room 25 times an hour, more than in a standard operating room.

In addition, the CSI has surveillance cameras throughout the facility to ensure only authorized people come into the facility. The cameras are on 24 hours a day, therefore your procedure will be recorded on camera. The images are stored on a secure server within the CSI. We are happy to provide you with more detailed information about the safety precautions if you wish.

You should report any problems to your doctor or to the director of this research: Sohail Mirza, MD, MPH at (603) 650-2225

If X-ray and/or CT scans are used during your procedure, you will be exposed to radiation that you would not otherwise be exposed to in a traditional operating room. However, it is possible that being able to use images during the surgery will prevent complications that could lead to further radiation exposure from imaging in the future.

If MRI scans are used during your surgical procedure, there are no known exposure risks to you from the magnetic and electromagnetic fields used to acquire images. There are potential risks of injury related to items that might interact with the MRI and cause harm such as mechanical injury or burns. For this reason, all items that will remain connected to you for monitoring or support purposes during an intraoperative MRI are subjected to rigorous testing and safety procedures especially developed for the CSI.

Standard surgical suites use medical tools which have been FDA approved. All medical tools being used in CSI have been approved for use in the standard surgical setting, however, the FDA has not specifically approved the use of the tools for use in the special environment of the CSI. We do not believe the use of standard medical tools in the CSI setting adds significant risk to the surgical procedures but there may be rare or yet unknown risks. We are constantly evaluating our process to be sure it is as safe as possible.

### **What are the options if you do not want to use the CSI ?**

If you do not want to have your procedure in the CSI you can have your surgery in a standard operating room and/or radiology suite.

### **How will your privacy be protected?**

The information collected as data for this research includes information from your medical record. We are careful to protect the identities of the people in this research. We keep the information collected for this research secure and confidential. The information collected for this research will be used only for the purposes of research as stated earlier in this form.

### **Who may use or see your health information?**

By signing this form, you allow the research team to use your health information and give it to others involved in the research. The research team includes the research director plus others working on this research at Dartmouth-Hitchcock Medical Center. You also permit any health care provider holding health information needed for this research to give copies of your information to the research team.

The information collected for this research may be used by researchers or officials of the following institutions and companies that make the imaging and monitoring equipment:

- Dartmouth College
- Dartmouth-Hitchcock Medical Center
- The Food and Drug Administration
- IMRIS
- Medtronic
- TechnoMed
- RhythmLink

During this research, information that identifies you may be given to some organizations that may not have a legal duty to protect it. These organizations may also use and disclose your information for other purposes.

Your permission to use your health information for this research will not end until the research is completed. During this research, you and others who take part in the research may not have access to the research data. You may ask for research data once the research is over.

It is possible for a court or government official to order the release of research data including information about you.

### **What if you decide not to give permission to use and share your personal health information?**

If you do not allow use of your health information, you may not use the CSI.

If you choose to stop taking part in this research, you may cancel permission for the use of your health information. You should let the researcher know if you want to cancel your permission. The research team will assist you in putting your wishes in writing. Information collected for the research before your permission is cancelled will continue to be used in the research.

### **Whom should you call with question related to the CSI?**

If you have questions about this research or need to report a research related injury, you can call your doctor or the director for this research: Dr. Sohail Mirza at 603-650-2227 during normal business hours.

If Dr. Mirza is not available, other staff members in the CSI will be available to answer your questions during normal business hours.

If you have questions, concerns, complaints, or suggestions about human research at Dartmouth, you may call the Office of the Committee for the Protection of Human Subjects at Dartmouth College 603-646-6482 during normal business hours.

**What about the costs of the CSI?**

There is no additional cost for using the CSI. You or your insurance company will be billed for your treatment as usual.

**What happens if you get sick or hurt from the use of CSI for your procedure?**

If you get sick or hurt from using the CSI, Dartmouth-Hitchcock Medical Center will provide treatment but has no plans to pay costs not covered by insurance.

If you have any questions or concerns about the legal responsibility of Dartmouth-Hitchcock Medical Center, please call the Mary Hitchcock Memorial Hospital Office of Risk Management at 603-653-1250 during normal business hours.

If you agree to take part in this research and you sign this consent form, you are not giving up any of your legal rights.

**CONSENT**

I have read the above information about “The Dartmouth Center for Surgical Innovation Facility” and have been given time to ask questions. I agree to participate in the parts of this research indicated below and I have been given a copy of this signed consent form.

**For Research participants 18 years of age and over:**

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Participant's Signature	PRINTED NAME	DATE	TIME
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Researcher or Designee Signature	PRINTED NAME	DATE	TIME
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Legally Authorized Representative / Guardian / Next-of-kin	PRINTED NAME	DATE	TIME
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**For research participants under age 18:**

I have explained to this child what taking part in this research will involve and have answered any questions that he or she has asked.

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Researcher or Designee Signature	PRINTED NAME	DATE	TIME
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Assent of minor	PRINTED NAME	DATE	TIME
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Legally Authorized Representative (Parent/legal guardian)	PRINTED NAME	DATE	TIME
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**Optional Consent to use donate leftover tissue to the Dartmouth-Hitchcock Genetic Research Biobank**

For surgery and biopsy patients only:

If you are having surgery you have the option to donate some of the tissue that is removed during your surgery to research. If there is tissue leftover after the doctors are finished using it for your clinical care, we would like to store it in the Dartmouth-Hitchcock Genetic Research Biobank for possible use in future research.

A biobank is a collection of biological specimens, or samples, such as tumor tissue, blood and saliva. The specimens are donated by patients. Scientists study the genes and other molecules in the specimens to learn more about diseases and discover new treatments. We would like to obtain leftover tissue from this procedure and future procedures here at Dartmouth-Hitchcock that includes the removal of tissue in the future. We may be interested in collecting a blood sample from you in the future. This is optional. Please check the box below to say whether or not this is okay with you.

You will not know if or when your tissue will be used. We can't guarantee that there will be enough left over to be used for research. You should not expect to receive any results from tests done on your specimens. The tests that will be done using your specimens are for research purposes only and will not usually result in information that is useful for your medical care. However, as we learn more in the future, it is possible that clinically useful information could be learned from the research. If that happens we will tell your doctor.

There are no health risks to you for donating leftover tissue to the biobank. The only risk is of breach of confidentiality. We do everything we can to safeguard your information and keep it private. It is very unlikely that your information would be released to the wrong people but we need to explain to you what the risks could be. Genetic research studies your DNA, which contains information about you and your family. If this information got out there is the potential for it to result in certain kinds of discrimination against you or your family. There is a law in the United States called "The Genetic Information Non-Discrimination Act" or GINA that protects you against employers or health insurance companies using your genetic information to make decisions. Because technology is developing very quickly in genetic science, there may be risks in the future that we can't predict.

Your specimens and health information will be available to researchers at Dartmouth-Hitchcock and Geisel School of Medicine who have approval from the Committee for the Protection of Human Subjects to do research using your samples and health information. In addition we may share your results with central databases such as the National Institutes of Health. Your name and other directly identifiable information would not be provided to these central repositories. Sometimes researchers here collaborate with or receive funding from private companies outside of D-H. In those cases the companies would see your information but not anything that could directly identify you.

Participation in the Biobank is voluntary and you can still have your procedure in the CSI even if you do not want to participate. You can stop your participation in the Biobank at any time. Data collected before you withdraw will be kept but we will destroy what remains of your specimen and no new research will be done with it. If you wish to withdraw, contact Judi Forman, MPH at 603-653-0638.

You will not be paid for donating your tissue. You will not receive any money if the results of research on your tissue are used to develop a product sold for profit.

We will give you a brochure with more information about the Biobank. If you have more questions about the biobank after you sign this form or if you change your mind, contact Judi Forman at 603-653-0638.

**CONSENT**

I have read the above information about “Dartmouth-Hitchcock Genetic Research Biobank” and have been given time to ask questions. I agree to donate leftover tissue to be used for future research.

- I agree to be contacted in the future to donate a blood sample.
- Please do not contact me in the future to donate a blood sample.

**For Research participants 18 years of age and over:**

Participant's Signature	PRINTED NAME	DATE	TIME
Researcher or Designee Signature	PRINTED NAME	DATE	TIME
Legally Authorized Representative / Guardian / Next-of-kin	PRINTED NAME	DATE	TIME

**For research participants under age 18:**

I have explained to this child what taking part in this research will involve and have answered any questions that he or she has asked.

Researcher or Designee Signature	PRINTED NAME	DATE	TIME
Assent of minor	PRINTED NAME	DATE	TIME
Legally Authorized Representative (Parent/legal guardian)	PRINTED NAME	DATE	TIME

