Version 2 06/08/20

Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above.

Title of Research Study: **Intraoperative Use of Intravenous Indocyanine Green (ICG) to Assess Ovarian Perfusion Using Infrared Imaging: A Feasibility Pilot Study**

Investigator: ***Dr. Magdy Milad***

Supported By: This research is supported by Karl Storz

Your doctor, who is also responsible for this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Key Information:

The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are undergoing a laparoscopic surgery with one of the physicians at the Center for Comprehensive Gynecology.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

Indocyanine green (ICG) is a Food and Drug (FDA)-approved tricarbocyanine dye that is fluorescent under near-infrared (NIR) light. Since the 1950s, ICG has been approved in the United States for intravenous administration. Early uses for ICG included measurement of liver function, cardiac blood flow and retina circulation (Rahimtoola & Swan, 1965; Yannuzzi, 2011). Today, ICG has been applied across several surgical specialties to improve intraoperative assessment and to reduce unnecessary tissue trauma.

The purpose of this study is to assess ovarian perfusion (flow) in both ovaries intraoperatively or during the operation. We are performing this research to evaluate whether ICG can be used to diagnose ovarian pathology or disease by ovarian perfusion or flow. Near infrared fluorescence imaging will be used to illuminate the ICG. The extent of perfusion will be determined using digital imaging software.

How long will the research last and what will I need to do?

We expect that you will be in this research study for approximately 10 minutes during your procedure. No other procedures or visits are necessary for pariticpants.

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You will show up to your scheduled procedure as you normally would. The study procedure will take place during you scheduled surgery, while you are in the operating room. Participation will not cause significant delay during your procedure or change the planned procedure.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

Is there any way being in this study could be bad for me?

ICG is a commonly used medical dye used in tests of cardiac and heptatic function as well as in the field of opthamology. The most common adverse events, although rare, are allergic reactions from hives to anaphylaxis (allergic reaction ranging from nauseua to swelling to trouble breathing). Patients with a history of allergy to iodides (potassium iodide which is an iodine component of iodidzed salt, sodium idodide, silver iodide, iodine) should avoid study participation due to the sodium iodide presence in ICG.Because you will be under general anesthesia as is standard protocol for laparoscopy, the surgical and anesthesia teams will be able to manage any adverse reactions.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

Will being in this study help me any way?

There are no benefits to you from taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits include a better understanding of your ovarian perfusion in both ovaries. You participation may one day benefit other women.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled. Your alternative to participating in this research study is to not participate.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team. Dr. Magdy Milad is the person in charge of this research study. You can contact him or study personnel at 312-472-4673 during business hours and via a pager system after hours by calling 312-694-6447. You can also contact the study coordinator, Jeremy Cornelius at Jeremy.cornelius@northwestern.edu with any questions

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.

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- You want to get information or provide input about this research.

How many people will be studied?

We expect about 30 people to be enrolled in this research study.

What happens if I say "Yes, I want to be in this research"?

- If you consent to participate, you will be sign this consent form and receive a copy of it including the study coordinators signature
- You will arrive at your schedulued surgery date and time as you would normally
- ICG administration will take place intraoperatively (this will be performed during standard survey of the abdomen and pelvis so no surgical delays will be incurred)
- After ICG administration, visibility of the ICG fluorescence should occur within 20 seconds. Total study procedure will take 10 minutes. Study duration includes the time during ICG administration, visualization and imaging. ICG will remain active for a duration of 20-120 minutes. Study team surgeons will take images during the surgery of the ovaries illuminated by ICG
- Study team will analyze images for pixel intensity and compare them to other participants. All images will be coded with a number rather than patient name to keep patient anonymity

What happens if I say "Yes", but I change my mind later?

You can leave the research at any time; it will not be held against you.

If you decide to leave the research, contact the investigator so that the investigator can notify the study team and withdraw you from the study.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

If you decide to stop pariticpating in this research at any time until the final data is analyzed, you may request to have your data removed from analysis. If you agree, this data will be handled the same as research data.

Detailed Risks: Is there any way being in this study could be bad for me?

Rare adverse events include allergic reactions that range from urticarial (hives) to anaphylaxis (ranging from nausea, swelling, bloating and difficulty breathing). Patients with a history of allergies to iodides (potassium iodide which is an iodine component of iodidzed salt, sodium idodide, silver iodide, iodine hypersensitvity) should avoid study participation due to the sodium iodide presence in ICG.

ICG should be used with caution in patients with renal failure or uremia and those who are on dialysis. In 1 case report, anaphylactoid reactions with various manifestations occurred in 4 of 43 (9.3%) patients on hemodialysis who received ICG for cardiac output studies. Specific reactions included dyspnea, palpitations, anxiety, nausea, edema, and hypotension.

Because you will be under general anesthesia as is standard protocol for laparoscopy, the surgical and anesthesia teams will be able to manage any adverse reactions.

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This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?".**

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research.However, possible benefits include a better understanding of your ovarian perfusion in both ovaries. You participation may one day benefit other women.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.
No biological specimens will be collected in this research study.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

If you have an injury or illness from the study device, taking the study drug, or the procedures required for this study, the reasonable medical expenses required to treat such injury or illness may be paid for by the study sponsor.

The coverage for such injury or illness is only available if the Northwestern University principal investigator and study sponsor, if applicable, have decided that the injury/illness is directly related to the study drug, device, or procedures and is not the result of a pre-existing condition or the normal progression of your disease, or because you have not followed the directions of the study doctor. If your insurance is billed, you may be required to pay deductibles and co-

payments that apply. You should check with your insurance company about any such payments.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study medication or drugs
- Records about study devices
- Billing information
- Genetic health information: regarding predispositions to bleeding or malignancy

Unless you revoke your consent, it will not expire

During this study, you may be coming to a Northwestern Memorial Healthcare Corporation entity (for example, Northwestern Memorial Hospital, Prentice Women's Hospital) for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH),

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Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers

- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- Karl Storz who is sponsoring the study, and that company's contractors and partners.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings. Unless you revoke your consent, it will not expire. Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Magdy Milad, MD
Institution: Northwestern University, Northwestern Medicine
Department: Obstetrics and Gynecology – Division of Minimally Invasive Gynecologic Surgery
Address: 259 E. Erie, Suite 2450, Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

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Printed Name of Person Obtaining Consent