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A Randomized, Blinded Phase II Placebo-Controlled Trial With Oral Serum Bovine Immunoglobulin (SBI) to Assess Quality of Life and the Faster Post-Operative Recovery of Gynecological Cancer Patients

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MAYO CLINIC

Name and Clinic Number

Approval Date: **April 3, 2015**
Not to be used after: **April 2, 2016**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: A Randomized, Blinded Pilot Placebo-Controlled Trial with Oral Serum Bovine Immunoglobulin (SBI) to Assess Quality of Life and the Faster Post-Operative Recovery of Gynecological Cancer Patients

IRB#: 12-009448

Principal Investigator: Dr. A. Jatoi and Colleagues

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

For purposes of this form, Mayo Clinic refers to Mayo Clinic Rochester, Minnesota.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you a copy of this form to keep. A copy of this form will be put in your medical record.

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CONTACT INFORMATION

You can contact …	At …	If you have questions or about …
Principal Investigator: Dr. Aminah Jatoi	**Phone:** (507) 284-2511 **Address:** 200 First St, SW Rochester, MN 55905	▪ Study tests and procedures ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints ▪ Withdrawing from the research study ▪ Materials you receive ▪ Research-related appointments
Mayo Clinic Institutional Review Board (IRB)	**Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681	▪ Rights of a research participant
Research Subject Advocate (The RSA is independent of the Study Team)	**Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu	▪ Rights of a research participant ▪ Any research-related concerns or complaints ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information
Research Billing	**Rochester, MN:** (507) 266-5670	▪ Billing or insurance related to this research study

Other Information:

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

1. Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you have been previously operated on for a confirmed or suspected gynecological cancer.

The plan is to have about 100 people take part in this study at Mayo Clinic.

2. Why is this research study being done?

The purpose of this study is to evaluate the effectiveness and safety of Serum Bovine Immunoglobulin (SBI) and see if there is any quality of life improvement as a result of taking SBI.

3. Information you should know

Who is Funding the Study?

Entera Health, Inc. will pay the Principal Investigator or the institution to cover costs related to running the study.

4. How long will you be in this research study?

You will be in the study for up to 16 weeks.

5. What will happen to you while you are in this research study?

After your surgery you will be asked if you want to take a nutritional supplement. If you are willing to participate, and you qualify, you will receive either the supplement or a placebo. You will also be asked to have blood drawn and to complete questions about how you are feeling. These questions can be completed when you are at home and then can be mailed in with an envelope and address provided to you by the researchers.

This study uses a placebo. A placebo looks exactly like the study agent, but it contains no active ingredient. We use placebos in research studies to learn if the effects seen in research participants are truly from the study agent.

If you are eligible for the study, we will assign you by chance (like a coin toss) to the Oral Serum Bovine Immunoglobulin (SBI) group or the placebo group. You and/or the Principal Investigator can't choose your study group. You will have an equal chance of being assigned to the Oral Serum Bovine Immunoglobulin (SBI) group or the placebo group.

You will need to have the following exams, tests or procedures to find out if you can be in the study:

- Measurement of weight
- Check for any side effects that have occurred recently
- Pregnancy Test for females that are able to get pregnant, must be done 7 or fewer days prior to registering for the study
- Blood samples (approximately 2 tablespoons) will be obtained for: routine blood counts, blood chemistry tests, and other laboratory tests

These exams, tests or procedures are part of regular clinical care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to the Principal Investigator.

If you are eligible to participate in the study and agree to do so, you will proceed to the treatment phase of the study. This phase of the study lasts up to 3 cycles (12 weeks). You will take the study medication orally (by mouth) twice a day for the entire 3 cycles.

This study has mandatory laboratory tests that will be done to study your blood samples. Your doctor will use some of this blood to do some tests. The results of these tests will not be given to you by your doctor and will not be used to plan your care.

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This study has optional laboratory tests that will be done to study your blood samples. Your doctor will use some of this blood to do some tests. The results of these tests will not be given to you by your doctor and will not be used to plan your care.

Please read the following statements and mark your choice:

I permit optional blood draws in Cycles 2 and 3 to be drawn for research testing that will examine markers that help assess healing after surgery in this study.

☐ Yes ☐ No Please initial here: _____Date: _____

On the first day of cycles 2 and 3, you will have the following:

- Check for any side effects that have occurred recently
- A research blood draw times 2 (optional)

Note that it is strongly recommended you return to the clinic for these assessments**. But, if you cannot make it back to the clinic for these assessments, the side effects assessment may be done over the phone with the study coordinator and the research blood draws will be considered optional.**

At screening, weekly throughout the study, and at end of treatment, we will ask you to fill out questionnaires regarding your quality of life, any symptoms you may be experiencing, and how often you took your study medication. Even if you do not start the study agent or discontinue its use early, we will still ask you to fill out the questionnaires. We hope that you will answer all of the questions, but you can skip any questions you don't want to answer. The questionnaires will be in a booklet and will take about 10 minutes to complete.

One month after you end treatment, you will have the following:

- Check for any side effects that have occurred recently

If you cannot make it back to the clinic for these tests, the side effect assessment may be done over the phone with the study coordinator.

6. What are the possible risks or discomforts from being in this research study?

As with any other experimental treatment, there may be side effects or risks associated with Oral Serum Bovine Immunoglobulin (SBI) that are not yet known. Oral Serum Bovine Immunoglobulin (SBI) is a protein source that has been studied in healthy volunteers as well as patients with malnutrition. Below are the side effects experienced by patients in previous and ongoing studies. It is not yet possible to know for certain which of the observed side effects are directly due to Oral Serum Bovine Immunoglobulin (SBI) itself. Since Oral Serum Bovine Immunoglobulin (SBI) is being studied as a beneficial supplement, some of the observed side effects may be a part of your recent surgical procedure itself, other pre-existing diseases or other drugs you may have been taking.

SBI

Rare but serious risks of SBI *(events occurring less than 2-3% of the time)*

- Loose stools (Diarrhea)
- Difficulty passing stool (Constipation)
- Passing gas (Flatulence)
- Stomach cramps
- Worsening of pre-existing pain

General Risks

If you are sexually active and able to become pregnant, you must agree to use one of the birth control methods listed below:

- Hormonal methods, such as birth control pills, patches, injections, vaginal ring, or implants
- Barrier methods (such as a condom or diaphragm) used with a spermicide (a foam, cream, or gel that kills sperm)
- Intrauterine device (IUD)
- Abstinence (no sex)

7. Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- if it is in your best interest,
- if you don't follow the study procedures,
- if the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

8. What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries:

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. The Sponsor, Entera Health, will offer to pay for medical treatment of research-related injuries directly resulting from the proper application of the study drug if not covered by your insurance. The Sponsor may decide not to pay for several reasons. For example, the Sponsor may not pay if your insurer or someone else pays the bill. The Sponsor may not pay if the Sponsor concludes the injury happened because you did not follow the study directions or the injury

resulted from your actions. The Sponsor may not consider the worsening of an existing health condition to be a research-related injury. In the case of injury resulting from your participation in this study, you do not lose any of your legal rights to seek payment by signing this form. Contact the Principal Investigator, who can help you obtain this reimbursement.

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

This study may not make your health better. However, the information learned from this study may eventually benefit other people who have had gynecological cancer surgery.

10. What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.

11. What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- Study drug
- Research blood tests
- Research sample collection

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

12. Will you be paid for taking part in this research study?

You won't be paid for taking part in this study.

13. What will happen to your samples?

We would like to keep your blood samples for future research. You can still take part in this current study even if you don't want your sample used for future research. If you agree to give your sample, it will be the property of Mayo Clinic.

Other researchers at Mayo Clinic who aren't involved with this study may ask to use your sample for future research. Researchers at other institutions may also ask for a part of your sample for future studies. Your sample will be sent to researchers in a coded format, which protects your identity.

Some future studies may examine your DNA, which is the genetic information you inherited from your parents (genetic testing). The Principal Investigator may contact you if there are findings which may be useful for your health care. You would be given general information on the potential risks, benefits, and costs of choosing to learn about the findings.

Please read the following statements and mark your choices:

1. I permit my blood sample to be stored and used in future research of ovarian cancer at Mayo Clinic:

☐ Yes ☐ No Please initial here: _____Date: _____

2. I permit my blood sample to be stored and used in future research at Mayo Clinic to learn about, prevent, or treat any other health problems:

☐ Yes ☐ No Please initial here: _____Date: _____

3. I permit Mayo Clinic to give my blood sample to researchers at other institutions:

☐ Yes ☐ No Please initial here: _____Date: _____

There is a very small chance that some commercial value may result from the use of your donated sample. If that happens, you won't be offered a share in any profits.

You may request to have your blood sample destroyed by writing to the Principal Investigator. The address is found in the "Contact Information" section of this consent form.

Because we cannot predict how your sample will be used in the future, we cannot promise that samples can be retrieved and destroyed.

14. How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. Various methods are used to safeguard confidentiality. Some or all of the following may be used in this study: assigning a specific code or registration number to each participant's data and samples, research materials stored in locked areas, password protected data stored on a computer. If the results of the research are made public, information that identifies you will not be used.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, 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. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission.

Health information may be collected about you from:

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

Why will this information be used and/or given to others?

- To do the research.
- To report the results.
- To see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

Who may use or share your health information?

- Mayo Clinic research staff involved in this study.

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With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Other Mayo Clinic physicians involved in your clinical care. Researchers involved in this study at other institutions.
- 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 United States agencies) or government agencies in other countries that oversee or review research.
- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors or with Mayo Clinic.

You can cancel your permission to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu

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Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission lasts forever, unless you cancel it.

ENROLLMENT AND PERMISSION SIGNATURES:

Your signature documents your permission to take part in this research

	/ /	: AM/PM
Printed Name	Date	Time

Signature

Person Obtaining Consent

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

	/ /	: AM/PM
Printed Name	Date	Time

Signature