The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:	**Does Adjuvant Bezlotoxumab Therapy with Surgical Intervention Improve Morbidity Associated with Fulminant Clostridioides colitis and multi-system organ failure**
Principal Investigator:	**Jonathan Wisler, MD, MS**
Sponsor:	**The Ohio State University - Department of Surgery - Acute Care Surgery**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

This study is being done to see if adding a medication called bezlotoxumab to the treatment of patients with fulminant *C diff.* infection will help patients to recover from the infection.

If you agree to participate in the study, you will receive either bezlotoxumab or saline in addition to your regular treatment and you will be followed for the study for 6 months after your discharge from the hospital.

1. Why is this study being done?

You are being asked to participate in this study because you have a fulminant *Clostridioides difficile* (*C. diff*) infection that requires surgery. A fulminant *C. diff* infection is a severe infection with the bacteria *C. diff* along with symptoms such as pain in your abdomen and fever.

This study is being done to see if adding the medication bezlotoxumab to the treatment of patients with fulminant *C. diff* infections will help patients to recover from the infection.

2. How many people will take part in this study?

Approximately 100 patients will participate in this study.

3. What will happen if I take part in this study?

Screening and Enrollment:

A member of the research team will review your medical record and ask the emergency medicine doctors and surgeons to make sure that you are able to safely participate in the study. The emergency medicine doctors and surgeons will make this decision based on carefully reviewing the standard of care tests and procedures that you had when you first came to the emergency room. We will discuss the treatment options with you at length, to help you decide whether or not you would like to participate. You will have the opportunity to ask questions and to further discuss the study with the research staff.

If you are eligible to participate in the study and you decide to take part, you will review and sign this consent form. You will then be randomly assigned (like the flip of a coin) to receive either bezlotoxumab or saline. Regardless of whether you receive bezlotoxumab or saline, you will also receive standard of care treatment for your condition. Standard of care means that you would receive the treatment even if you did not participate in this study. The standard of care treatment is the use of the antibiotic medications Vancomycin and Flagyl.

Follow-up:

There will be additional phone-based, clinical, and mailed follow-up questions after today. You will be asked to return to clinic after your surgery for standard follow-up. The information gathered at that time will be used to complete this study.

A day or two after you leave the hospital, the study coordinator will contact you to answer any questions you have about the study and to review the follow-up visit

schedule. Study staff will also remind you of your follow-up appointment with your medical care team.

At the 1 month follow-up, you will be asked to complete questionnaires about your quality of life and experience as a patient with colitis. We will ask you about your pain level and severity, your symptoms, your satisfaction with your treatment, and your ability to return to your work, school, or daily activities.

Additional follow-ups will take place 3 months and 6 months after your discharge from the hospital. These visits may take place in person or over the phone. At these visits, the study team will ask questions about your pain level and severity, your symptoms, your satisfaction with your treatment, and your ability to return to your work, school, or daily activities.

The information that you provide in these follow-up questionnaires is confidential and will not be shared back with your physician unless you report any symptoms suggesting colitis-related health concerns.

4. How long will I be in the study?

You will be in the study for a total of 6 months following your discharge from the hospital.

You will have follow up visits 1 month, 3 months, and 6 months after your hospitalization. Each follow up visit will take approximately 30 minutes.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

<u>Risks of Bezlotoxumab</u>
Heart failure may happen in people who receive bezlotoxumab and can be serious. People with a history of congestive heart failure (CHF) who received bezlotoxumab had a higher rate of heart failure and death than those who did not receive bezlotoxumab.

The most common side effects that may happen on the day of or the day after receiving bezlotoxumab are nausea, headache, fever, feeling tired, shortness of breath, feeling dizzy, and high blood pressure.

The most common side effects that may happen up to four weeks after receiving bezlotoxumab are nausea, fever, and headache.

7. What benefits can I expect from being in the study?

Although it is possible that you may not receive any direct benefits from your participation in this study, you will contribute to medical knowledge that may help improve future patient choices in their treatment decisions about colitis.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. If you choose not to participate, you will still be treated for your colitis. However, you will not be able to obtain bezlotoxumab as part of your treatment if you do not participate in the study.

9. What are the costs of taking part in this study?

There are no foreseeable costs to you for taking part in this study. You are responsible for the cost of your clinical care that includes, but is not limited to, the costs for surgery and/ or antibiotics. These treatments are considered routine treatments for fulminant colitis. All medications, laboratory fees, physician fees, and hospital costs will be charged to you in the same way as if you were not a part of this study. You are responsible for either paying for or having insurance pay for all the clinical care you receive during the study.

10. Will I be paid for taking part in this study?

You will not be paid for participating in this study.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

13. Will my de-identified information (and bio-specimens) be used or shared for future research?

No.

14. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If we find information that significantly impacts your health, we will share it with you, however it is not expected that any information like this will be found as a part of the research.

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 the website at any time.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  Physical exams
  Laboratory, x-ray, and other test results
  Diaries and questionnaires

- Records about any study drug you received

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;
- Others: Merck & Co, Inc.

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

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

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact ***Jonathan Wisler, MD, MS at 614-366-5933.***

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact **HIPAA Privacy Officer in the College of Medicine Office of Health Sciences, Suite E2140, 600 Ackerman Road, Columbus, Ohio 43202 or by phone at 614-293-4477.**

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact ***Jonathan Wisler, MD, MS at 614-366-5933.***

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
Relationship to the subject	**AM/PM** **Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time