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# Informed Consent and HIPAA Authorization Form for Subject Participation in a Research Study

**Protocol Title:** A PHASE 4, OPEN LABEL, NON-RANDOMIZED, OBSERVATIONAL STUDY TO COMPARE TOLERABILITY, EFFICACY, SHORT AND LONG TERM CLINICAL OUTCOMES FOLLOWING BEZLOTOXUMAB ADMINISTRATION IN PREVENTION OF RECCURENT CLOSTRIDUM DIFFICILE INFECTION (CDI) IN INFLAMATORY BOWEL DIESAEASE (IBD) PATIENTS

**Protocol Number:** MISP #58543

**Sponsor's Information:** MERCK & CO., INC.

**Study Doctor Name:** David Binion, MD, A.G.A.F; F.A.C.G

**Research Site Address(es):** UPMC
David Binion, M.D.
Division of Gastroenterology, Hepatology and Nutrition
200 Lothrop Street
Pittsburgh, PA 15261

**CO-INVESTIGATORS:** UPMC Center for Inflammatory Bowel Disease Physicians and Research Staff (Complete, current listing available upon request).

You should keep a copy of this form. If you have any questions or problems during the study, call the phone number(s) listed below.

**Daytime Telephone Number(s):** 412-383-0571

## Introduction

We invite you to take part in a research study of the investigational drug, Bezlotoxumab (also called Zinplava), sponsored by MERCK & CO., Inc. because you have Inflammatory Bowel Disease and active Clostridium difficile (C. difficile) infection.

This study is being done to determine if Bezlotuxumab works in breaking the cycle of the infection coming back among individuals with Inflammatory Bowel Disease. *Clostridium difficile* infection that come back are especially difficult to treat in the Inflammatory Bowel Disease patients and the number of patients who receive medication for the returning infection -- is high. In 2016 FDA approved Bezlotuxumab (Zinplava) for use in the prevention of *C. difficile* in the average individuals. We will compare how you will tolerate the drug and how effective the drug is if we combine it with the drug you would normally receive during active C. difficile infection. We will pay special attention to rates of --- returning infections, patient quality of life and disease activity.

**You may be eligible to participate in this research study if** you are currently treated with antibiotics for Clostridium difficile (C. diff) and have IBD.

You need to:

1. read this entire document,
2. understand the information within the document, and
3. sign your name to this document.

The study doctor or a member of the research team will go through this consent form with you and explain the study to you. Please discuss taking part in this study with your friends and family, and your personal doctor/PCP (Primary Care Physician) if you wish. You can take as much time as you like to make your decision.

Taking part in this research study is voluntary and entirely up to you. If you choose to take part you will need to sign the consent form. Once you sign this document, a copy will be given to you and you can participate in the study as long as you meet all the study conditions.

However, even if you sign this document, there is a chance that you may not be able to participate in the study (for example, if you have a health condition that is not allowed in the study or if the study enrollment is complete, etc.).

The sponsor is paying for this research study. Your study doctor will be paid by the sponsor.

**What is an Informed Consent?**
This document is an informed consent. It explains:

- The purpose and procedures of the study
- Possible discomforts and risks that you may experience
- Possible benefits that you may experience
- Other procedures or treatments available to you (other than the procedure or drug administration that is part of this study)

- How your health information will be used and disclosed in the study, and requests your permission for that use and disclosure)
- What compensation and/or medical treatment is available to you if injury occurs,
- Whom you can contact if you have any questions about the study or your rights as a research subject
- That your participation in this study is voluntary.

**Are there any Screening Assessments?**
Before you begin the main part of the study, we will review your records to find out if you can be in the study. We will especially review your past cardiac history as Bezlotuxumab poses an increased risk in patients with underlying congestive heart failure. Many of the tests or procedures may be part of your regular medical care and may be done even if you do not take part in the study. We will NOT HAVE any laboratory and/or diagnostic tests done solely for the purpose of this study except for pregnancy test for female participants:

- Review demographic information (age, sex, height, weight etc.,)
- Review past and current medical history including cardiac problems, disease duration, and history of bowel resections
- Review current and past medications
- Review blood for standard laboratory tests (blood cultures, blood counts, inflammatory markers, vitamin B and D levels, quantitative immunoglobulins etc.,) and a pregnancy test if applicable
- Admitting diagnosis and possible site of infection
- Disease related quality of life (SIBDQ)
- Disease activity scores (HBI-UCAI)
- Dietary intake (sugar and fat intake)
- Stool samples

Many of the data and tests are already part of your medical record and are collected as standard of care. Again, we will review and collect these only to find out if you qualify for the study.

**How does this drug work?**

Bezlotoxumab infusion is used to decrease the risk of *Clostridium difficile* infection (*C. difficile* or CDI); a type of bacteria that can cause severe or life-threatening diarrhea from coming back in people who are at high risk for *C. difficile* infection and who are already taking an antibiotic drug to treat it. Bezlotoxumab is a class of medications called human monoclonal antibodies. Monoclonal antibody is a type of compound made in the laboratory, which in this case, gets attached to Clostridium difficile toxin to prevent toxin B from binding to and causing damage to the lining of your gut .
*C. difficile* infection becomes a serious digestive and bowel problem when individuals

have previously received standard drug treatment , and/or have experienced a long-term hospitalization, and/or have had an extended stay in a long-term care facility. This study is being done to see if using Bexlotoxumab in Inflammatory Bowel Disease (IBD) patients like yourself during active infection can stop *C. difficile* effects on the body and either decrease recurrence or stop it from coming back in the future.

**How will I be given the drug?**

This procedure involves inserting a needle into the vein and injecting a prescribed solution. The study drug is given by an infusion (IV) into a vein in your arm. The medicine must be given slowly, and the IV infusion can take about 60 minutes to complete. The infusion will be administered at our PCTRC Center on the 6th floor of Montefiore Hospital. The study is an open label, non-randomized trial, which means there is no placebo group. Since this study has no placebo group, both your study team, doctors and you will know what drug you will be receiving. However, patients who received the study drug will be compared to our previous patients who did not receive additional treatment for difficile therapy. We call this a "control group". Bezlotoxumab has no antibacterial effects and will not treat the underlying infection. You must use antibiotic medication to treat *C. difficile* infection and the drug will be administered on top of your antibiotic therapy for the current infection. **The study drug is a one-time infusion and you will NOT receive the drug again.** However, we will follow up with you for additional 2 years (visit 2-4) to collect additional data from the date of your injection. The data collection and follow up will be conveniently scheduled during your regular doctor office visits and/or will be conducted over the phone. Visit one (1) will be your study drug administration visit. Follow up visits will completed at 90 days after enrollment (Visit 2), one year after your injection (Visit 3) and again at two-year mark following your injection (Visit 4).

**Specimen Collection**

No specimens will be collected for research purposes. All specimen collections will be performed as part of your regular medical care and only if they are required for your regular care.

**What will the follow up visit entail?**

In the event that you are unable to be seen in clinic, we will contact you via phone to check on how you have been doing since your last visit with us. To find out, we will ask you to answer 2 questions and to complete 2 questionnaires to know if you had any GI symptoms and how you have been feeling in general. We will keep all the information we receive from you by phone, including your name and any other identifying information confidential. If you are able to come to clinic, we will collect this information

by reviewing your medical records otherwise. We estimate we will complete the follow up within two weeks from the time of the study visits.

The follow up visits will include the following:

**Collection and Storing of PHI (Private Health Information)**

Visit 2 (90 days after enrollment)

Clinic visit collected by reviewing medical records or Telephone call

a. Serum Inflammatory markers: CRP, ESR, Albumin
b. CBC
c. Disease related quality of life (SIBDQ)
d. Disease activity scores (HBI-UCAI) (how the disease has been affecting you)
e. Emergency department number of visits
f. Hospital number of admissions

Visit 3 (1 year after enrollment)

Clinic visit collected by reviewing medical records or Telephone call

a. Serum Inflammatory markers: CRP, ESR, Albumin
b. CBC
c. Disease related quality of life (SIBDQ)
d. Disease activity scores (HBI-UCAI)
e. Emergency department number of visits
f. Hospital number of admissions

Visit 4 (24 months after enrollment)

Clinic visit or collected by reviewing medical records Telephone call

a. Serum Inflammatory markers: CRP, ESR, Albumin
b. CBC
c. Disease related quality of life (SIBDQ)
d. Disease activity scores (HBI-UCAI)
e. Emergency department number of visits
f. Hospital number of admissions

**What are the benefits of participating in the study?**
Bezlotoxumab has been effective in reducing CDI recurrence in the average adult , but there have been no studies done in the Inflammatory Bowel Disease (IBD) patients. Neither UPMC nor the study sponsor can guarantee any benefit to you for your

participation in this study. Your participation will provide new information on the effects of this drug in the Inflammatory Bowel Disease (IBD) patients. If Bezlotoxumab is effective it may reduce future recurrence of *Clostridium difficile* infections in you, although this cannot be guaranteed.

**What are the risks associated with this study?**

**Intravenous Access:**
You may experience soreness and/or a bruise at the site of injection, fainting, an infection, a small blood clot, swelling of the vein and the area around it, or bleeding at the site

**Possible side effects of Bezlotoxumab:**
The Food and Drug Administration (FDA) approved Bezlotoxumab (Zinplava) for use in the prevention of C. difficile infection (CDI) recurrence in the average adult in 2016. Bezlotuxumab has been generally well tolerated. Along with its needed effects, the medication may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention. The more common side effects reported with Bezlotuxumab are described below. "More common" means occurring in >10% of people who have been administered Bezlotuxumab. You may experience these, others or no side effects. Currently, known side effects are as follows:

More Common infusion related side effects:

- back pain
- chest pain
- chest tightness
- chills
- decreased urine output
- dilated neck veins
- extreme fatigue
- fever
- flushing
- headache
- irregular breathing
- irregular heartbeat
- nausea and vomiting
- swelling of face, fingers, feet, or lower legs
- tightness in the chest
- troubled breathing
- weakness
- weight gain

Uncommon:

- worsening symptoms of *C. difficile* infection, such as severe stomach pain or watery diarrhea;
- swelling in your hands, ankles, or feet;
- rapid weight gain; or
- shortness of breath (even with mild exertion)
- cardiac failure in patients with past medical history with preexisting heart failure
- fetal and infant risk cannot be ruled out

Some side effects of Bezlotoxumab may occur that usually do not need medical attention. These side effects may go away -- as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

*Incidence not known*

- Bleeding, blistering, burning, coldness, discoloration of the skin, feeling of pressure, hives, infection, inflammation, itching, lumps, numbness, pain, rash, redness, scarring, soreness, stinging, swelling, tenderness, tingling, ulceration, or warmth at the injection site.

The risks involved in giving Bezlotoxumab to an unborn child or breast-feeding mothers are not fully known, because of this **we will perform pregnancy test on all female participants**. If you are pregnant or planning to become pregnant or are nursing you cannot be in this study at this time. To make sure Bezlotoxumab is safe for you, we will review your past cardiac history as Bezlotuxumab poses increased risk in patients with underlying congestive heart failure. There is limited information about the possible side effects of Bezlotoxumab in IBD patients like yourself, or if it might benefit some people. One of the reasons for conducting this study is to learn more about the effectiveness and possible side effects of Bezlotoxumab in IBD patients.

**Allergic reaction risk:**
There is chance that you will experience an allergic reaction to Bezlotoxumab.

A severe allergic reaction requires immediate medical treatment and could result in permanent disability or death.

Some signs that you may be having an allergic reaction are:
- Rash or hives
- Having a hard time breathing
- Wheezing when you breathe
- Sudden change in blood pressure (making you feel dizzy or lightheaded)
- Swelling around the mouth, throat or eyes
- Fast pulse

- Sweating

Before you receive Bezlotoxumab, we will review your past medical history, medications you are currently on and allergies. We will also perform pregnancy test on all our female participants. You will be monitored in our infusion center (CTRC) for about an hour after the infusion for any possible side effects. If you believe you are having a severe allergic reaction, you should immediately seek emergency medical treatment, and alert the study doctor and study staff as soon as possible.

**Unforeseeable Risks**
It is possible that there will be other side effects associated with Bezlotoxumab in IBD patients, which are unknown at this time, some of which may be serious or life-threatening.

You should tell your study doctor or a member of the study staff about any new health problems that develop while you are in this study and about any new medications you start taking (including over-the counter medication, herbal remedies, and non-prescription drugs).

If you experience any changes in your health during the course of this study, you should immediately contact the study doctor.

**Remote Consenting**
Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.

**What are the other treatments available for my illness or condition?**
There are other treatments available if you decide not to be in the study, including continuation of your standard of care – for -C. difficile infection that return and make you sick again. If you should decide not to participate in or if you withdraw from this study prior to the infusion, your doctor can recommend other treatments.

If you have any questions concerning alternative treatments, please ask your study doctor. You and your doctor can decide what is best for you.

Your participation in this study will last up to 24 months (2 years).

This study has different sections. They are as follows:

| | |
|---|---|
| **Screening** | After you sing the study consent we will review your medical records to see if you further qualify for the study. The study doctor will discuss and review the study in detail with you. |
| **-** | The drug administration visit - is a one- time visit (V1) to our |

| | |
|---|---|
| **Drug Administration** | CTRC center. During this visit we will review your records for any changes to your health and/or therapies - and you will be given the study drug. If you are a female of childbearing potential, you will be given a pregnancy test to make sure you are not pregnant. The study drug is given by intravenous infusion. You may suffer from bruises, pain or discomfort at the infusion sites. We will monitor you for one hour post infusion for any side and adverse reactions. |
| **Follow-up period** | The follow-up period will be approximately for 2 years. These will be completed during your regular doctor visits or via phone call, at 90 days (Visit 2), one year (Visit 3) and two year, (Visit 4) post the infusion. The study staff will either see you in the office or call you to check on how you are doing and we will collect your health history data from your medical record. |

**Your responsibilities during the study:**

- You cannot take part in another study using another research drug while you are taking part in this study.

**Is my participation in the Research Registry voluntary?**

Your participation in this study is completely voluntary. Whether or not you provide your permission for participation in this study will have no effect on your or current or future medical care at the University of Pittsburgh Medical Center, affiliated health care provider, or your current or future relationship with a health care insurance provider. Whether or not you provide your permission for participation in this research will have no effect on your current or future relationship with the University of Pittsburgh.

**Can I change my mind about being in the study?**

Taking part in this study is your choice. You may withdraw, at any time, your consent for participation in this study, to include the additional collection of your medical record information and its further use for the research purposes described above. However, any research use of your medical record information prior to the date that you formally withdraw your permission will not be destroyed. Collected from your health information and the data will have continued scientific importance for the study and will be critical in the assessment of the study drug as well as your safety with your regular doctor.

To formally withdraw your permission for participation in this research you should provide a written and dated notice of this decision to the principal investigator of the study at the address listed on the first page of this consent form.

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**How will my information be kept confidential?**

You have a right to privacy and all information that is collected for this study will be kept confidential to the limit that this is possible by law. Except as required by law, you will

not be identified by name, address, birth date, telephone number, or any other personal identifier.

To help ensure that your medical and personal information is kept confidential, all documentation will be de-identified. You will be assigned a unique patient identification number. Your forms, records, and samples associated with this study will be labeled with this unique code (or identification number) only. They will not be labeled with your name, picture, or any other personally identifying information.

Only your study team will have access to the key that links your unique code to you. This information will not be released to the sponsor, their affiliates, or anyone outside of the study team accept where required by law – or as directed by your written request from future research.

Per University of Pittsburgh policy all research records must be maintained for at least 7 years following final reporting or publication of a project.

**Will you share my data with other researchers?**
No specimens will be collected for research purposes. We may share data from this study in the future with other researchers. If shared, the data will be de-identified before being transferred, stored, or shared with other researchers. Data sharing is not currently planned.

**What if new information becomes available?**
The information in this form reflects what is known about the study at the time it is signed. If any significant new information is discovered prior to the study drug – administration that may affect whether you want to continue to take part in the study, you will be informed in a timely manner. You may be asked to sign a new consent form if this occurs.

**Why would I be asked to discontinue the study?**
The study doctor or the sponsor of the study, MERCK & Co. Inc., can remove you from the study without your consent at any time for any reason including:

- To improve your medical care,
- If the study is stopped by MERCK or the FDA, or
- Other reasons not itemized here.

The same procedures will be followed as those that would happen if you decided to discontinue from the study.

The sponsor or the FDA may decide to stop the study at any time.

**What happens if I get injured while I am in the study?**
In the event of an emergency, seek immediate medical attention. Emergency medical treatment for injuries will be provided to you.

If you become injured during your participation in this study, contact the study doctor (Principal Investigator) at the phone number listed on the first page as soon as possible. Your study doctor will discuss with you the available medical treatment options.

If the sponsor, in collaboration with the study doctor, determine that your injury is a direct result of your participation in this research (i.e. the investigational product and/or any testing or procedures required specifically by the study protocol – and outside of routine care), you or your health plan (insurance company), will not be billed. Instead, the sponsor will pay for your reasonable and necessary medical expenses for the treatment of an injury that is directly related to your participation in the study.

If the injury is the fault of University of Pittsburgh/UPMC personnel or third parties, or the result of your own actions or inactions, such as failure to follow the informed consent document or the directions of your study doctor, the Sponsor will not offer to cover the cost of injury.

There is no plan for any additional financial compensation from UPMC or the Sponsor. Financial compensation for such things as lost wages, disability or discomfort due to the injury is not offered by the sponsor. However, by signing this form, you do not give up any of your legal rights.

Federal law requires that the study sponsor inform the Centers for Medicare & Medicaid Services (CMS, the agency responsible for administration of the Medicare program) when they are going to reimburse for research participant injury expenses or for treatment of an injury to a Medicare beneficiary. To comply with a Medicare reporting obligation, the study sponsor or its representative may need to collect and share with CMS certain personal information about you, such as your name, date of birth, sex, social security number, and Medicare ID number (if you have one).

**Will I be paid to participate in this study?**
You will be compensated $15 at the end of each research visit (V 2-4) for your participation in this study. This stipend is offered to offset the costs you might incur as a study subject such as reasonable time spent or travel expenses (to include mileage, parking fees, etc.), child care, and meals. If you complete all 3 follow-up visits and baseline visit, the total compensation is $45. You will given a reloadable Master card issued through the University of Pittsburgh Vincent system to execute the payment.

**How will these compensations be made?**
UPMC utilizes an electronic payment card as a secure payment method to disburse research study compensation and/or expense reimbursements. The electronic payment card is administered by Vincent™ (formerly WePay). The study staff will discuss the use of the electronic payment card with you and answer any questions you may have about the reimbursements. You can also learn more about Vincent™ by visiting its website: http://vincentpay.com/.

**All compensation is taxable income to the participant regardless of the amount.** If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research but the IRS requires that 26% of the payment be sent by the institution to the IRS for 'backup withholding'; thus you would only receive 74% of the expected payment.

**HIPAA Authorization for Use and Disclosure of Personal Protected Health Information:**

Federal privacy law requires that the study doctor explain to you the type of information that will be obtained about you during the study, how that information will be used, and with whom it will be shared. This explanation is provided below.

**What information will the study staff look at?**

As part of this study, the study doctor and study staff ("Researchers") will collect and review information about you that contains your name and other personal information. In addition, your treating physicians and other healthcare providers ("Providers") may disclose information from your medical records (from any doctor, hospital or other healthcare provider) to the Researchers. This information collected from or about you during the course of this study ("Personal Information") includes:

- Your medical information, including how you feel, medical and surgical history, your food intake, smoking and alcohol habits, menopausal history (women only), physical activity, sexual habits or behavior, contraception and previous and current medications.
- Other personally identifying information, including your name and other information (such as your age, race or ethnicity, gender and country location).
- Results of examinations and laboratory tests.

In addition, your treating physicians and other healthcare providers ("Providers") may disclose health information from your medical records to the Researchers.

**What information that identifies me will be collected by the study doctor?**

If you decide to be in this study, the study doctor and study staff will collect health information that identifies you and use it to conduct this study. This may include but is not limited to your name, address, and phone number, date of birth, photographs, medical history, and information from your study visits, all of which could be used to identify you. This health information may come from your family doctor or other health care workers. The information may also include the following:

- Your health and medical history, including doctors' notes and hospital records;
- Records about your study visits;
- Laboratory and test results;

- Records about phone calls made as part of the study;
- Diaries and questionnaires that you may fill out as part of the study;
- Records about any study drug you received;
- Information related to diagnosis and treatment of a mental condition.

You may also be asked to sign a separate Authorization for the release of your medical records by doctors and hospitals.

**Who else will be able to look at this information?**
Information from this study will be given to the sponsor. It may also be given to the U.S. Food and Drug Administration (FDA). Unless otherwise required by law, medical records which identify you and the consent document signed by you may be looked at and/or copied for research or regulatory purposes by:

- the study doctor and staff;
- the study sponsor;
- those working for or with the sponsor;
- the institutional review board; and
- government agencies in other countries where the study drug may be considered for approval

By signing this Authorization, you are agreeing to allow the study doctor and staff to share health information that identifies you with any government regulatory agencies in the United States, such as the United States Food and Drug Administration (FDA), as required by federal regulations – as well as any Institutional Review Board (IRB) or ethics committee that reviews the research study and with government or regulatory agencies throughout the world, such as the European Medicines Agency.

**Why will this information be used and given to others?**
If you receive Medicare or Medicaid, the study doctor may have to share health information about you in the event of injury with the Center for Medicare and Medicaid Services.

These organizations, including the Researchers, will use and disclose your health information in connection with the study to assure quality control and to analyze the health information. In addition, MERCK may use and disclose your health information to assure the safety, effectiveness and quality of research and medical products, and as required by law, including with respect to government reporting if applicable (e.g., the Centers for Medicare & Medicaid Services).

The Sponsor and those working for or with the Sponsor may use the health information sent to them:

- to see if the “investigational product” (study drug or device) works and is safe;

- to compare the “investigational product” (study drug or device) to other drugs/vaccines or devices already on the market;
- to develop new tests;
- for other activities related to the development of the “investigational product” (study drug or device) or to the approval or regulatory status of “investigational product” in the United States or in other countries.

Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical record information) related to your participation in this research study for the purposes of

- (a) fulfilling orders made by study doctors for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research participation;
- (b) addressing correct payment for tests and procedures ordered by the investigators; and/or
- (c) for internal hospital operations (e.g., quality assurance).

Your health insurance provider may also have access to information regarding your participation in this research study to address correct billing and payment.

**In addition to the investigator listed on the first page of this consent form and the research staff, the following individuals will or may have access to identifiable information related to your participation in this research study**:

• Authorized representatives of MERCK Inc., and the University of Pittsburgh Office of Research Protections may review your identifiable research information (which may include your identifiable medical record information) for the purpose of monitoring the appropriate conduct of this research study.

• In unusual cases, the investigators may be required to release your identifiable research information (which may include your identifiable medical record information) in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law.

• Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to your identifiable information (which may include your identifiable medical record information) for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (such as laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and (3) for internal hospital operations (i.e. quality assurance).

We will protect your privacy and the confidentiality of your research records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University.

**Is my information protected after it is shared?**
There is a risk that if people other than the Sponsor, or those working for or with the Sponsor, may get your health data they could re-disclose or misuse it for purposes other than those outlined in this consent. The Sponsor has strict privacy and confidentiality protection procedures in place to prevent this from occurring so the chance of this happening to you is extremely small. Once the study doctor and study staff share health information that identifies you with others, federal privacy law may no longer protect it.

By signing this form, you are giving permission for the study team to disclose some protected health information to outside groups such as the sponsor of the study, anyone acting on the behalf of the sponsor, the IRB, and any other government regulatory body or oversight organization that may audit the study in the future.

In some cases, those who receive your information may have to review your entire medical record to make sure that the study was done properly – or for other reasons as required by law. Although UPMC will take every precaution to prevent it, there is potential for these groups to be able to identify you. Those persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission – if permitted by the laws that apply to their organization.

**Will this Authorization expire?**
Your permission to use and share health information that identifies you will not expire.

**Can I participate in the study if I do not sign this Authorization?**
If you decide not to sign this Authorization, you will not be allowed to participate in this study.

**Can I see and copy my health information from this study?**
In accordance with the UPMC Notices of Privacy Practices document that you have been provided, you are permitted access to information (including information resulting from your participation in this research study) contained within your medical records filed with your health care provider. To ensure the scientific integrity of the study, you may not be able to review some of your records related to the study until after the study has been completed.

**How will my information be used?**
The Researchers and organizations listed above will use and disclose your Personal Information in connection with the study to assure quality control, analyze the data, and

comply with regulatory duties. This includes the submission of the study results, regulatory approvals of the study drug, to report adverse events, and government reporting, if applicable (for example, the Centers for Medicare & Medicaid Services). MERCK will use the study data to assess the safety and efficacy of the study drug in IBD patients.

Your coded Personal Information will be added to a computerized database. This database will be part of the study results. Data and results from this study will be presented at meetings or published in journals. To fulfill regulatory requirements and industry guidelines, the results from this study will also be provided to qualified researchers who request it for legitimate research purposes.

While your coded information may be shared with these researchers or publications, your identity (such as your name, address and email) will not be shared with these researchers and will not be in any presentation or publication.

As advancements in medical technology continue, MERCK may reanalyze the study data and the results in future research projects to find new scientific information about the study and study drug or related diseases.

Generally, your permission to use and/or share your Personal Information for the purposes described in this document does not have an expiration date, subject to applicable law, unless you withdraw your permission in writing to the study doctor at the address listed on the first page of this form.

Once your Personal Information is disclosed to MERCK and to the other organizations identified above, it may be subject to further disclosure and no longer protected by federal privacy law. These groups are committed to keeping your health information confidential.

**What are my privacy rights?**
*Your Right to Access and/or Correct Your Information*

You have the right to access, through your study doctor, all of the information collected about you in your medical record, and to ask for corrections, according to the rules of the study site. You have the right to request information on how the Personal Information reported to the Sponsor are being used and with whom the data have been shared.

Please note that your right to access certain information in your medical records may be suspended during your participation in the study. Therefore, if you would like immediate access to your records, you may not be able to continue participating in the study.

*Your Right to Object/Withdraw*

You may take away your permission to use and share identifiable health information about you at any time by telling the study doctor or study staff. If you do this, you will not be able to stay in this study. No new health information that identifies you will be gathered after that date. However, if the study doctor and/or the Sponsor has already used and relied upon your health information to conduct this study, they may continue to use it and disclose it to others as described in this Authorization.

You can withdraw your consent for use and disclosure of your personal health information, and exit the study, by notifying your UPMC study team or the Principal Investigator at the listed address on the front page of this consent form.

Your decision to withdraw or not provide your authorization for the research use and disclosure of your medical record information will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider. It will, however, prevent you from participating (or continuing to participate) in this research study.

*Your Right to Request Deletion*

If you withdraw from the study, you may also request that the Personal Information already collected from you in connection with the study be deleted. However, your right to erasure is limited due to regulatory requirements and to preserve scientific integrity, as your Personal Information must be managed in specific ways in order for the research to be reliable and accurate. The study results and coded data will be kept as long as they are needed for research purposes, any regulatory requirements, and the Sponsor's Data Retention Schedule.

Please be aware that because the Sponsor only maintains coded study data, it generally cannot respond directly to individual requests regarding your privacy rights. Therefore, you should address any of these requests regarding these rights to the study site using the contact information on the first page of this consent form.

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

**Will I have to spend money to be in this study?**
Neither you, nor your insurance provider, will be charged for the costs of the study drug or procedures or tests performed solely for the purpose of this research study. However, you and/or your insurance company will continue to pay for your regular health care (routine medications as well as clinic, hospital, and doctors services that are part of your normal care outside of the study) in the usual manner. For all routine care, you will remain responsible for any copayments and deductibles that normally apply.

Some of the procedures you receive while participating in this study are for research only and will be paid for by the sponsor of this study. This includes the investigational drug Bezlotoxumab paid for by sponsor follow up visits that are required by the study.

You could have unexpected expenses from being in this research study. Ask the study doctor to discuss the costs that will or will not be covered by the sponsor. This discussion should include who will pay the costs of treating possible side effects.

**Notice for Managed Care (Medicare Advantage Plan) Beneficiaries:**
Certain services that are required for your care as a participant in a clinical trial can be billed to, and paid by, your medical insurance. These services are referred to as "covered" clinical trial services. However, if you have a Medicare Advantage Plan as part of your medical insurance, this insurance cannot be billed for covered clinical trial services. Instead, traditional Medicare will be billed, and will pay for those services. This has an impact to you. When traditional Medicare pays for such services, you will be responsible for paying the coinsurance amounts applicable to these services.

**If your health insurance is not Medicare product:**
Charges may be submitted to your health insurance and be denied because you are participating in a research study. We encourage you to determine your health insurer's policy about paying for your "standard of care" treatment while you are in a research study – and to understand what the specific financial impact will be for you associated with participating in this clinical trial.

If you receive a bill for a research related procedure that you believe was in error, please contact the study team and the UPMC office that sent the bill.

**What if something is developed from this research?**
By participating in this study, you do not acquire any ownership rights in the samples you contribute or in any medical tests, drugs or other commercial products we may develop through this research.

If an approved product is developed from the research performed in this study, MERCK will own all rights to the product. You will not receive money or any other form of payment for participating or from the sale of any such product.

**Who do I call if I have questions?**
If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number(s) listed above on the first page.

You may ask questions before you sign the consent, at any time during your participation in the study, and after you are finished with the study.

**What do I do next?**
If you decide to participate in the study, you will need to read the statement below and sign and date it.

## HIPPA AUTHORIZATION

This Authorization document has discussed with the subject by a member of the study staff and the subject has been given an opportunity to ask questions about this document.

_____

Participant Signature Date

_____

Participant Printed Name

**********

VOLUNTARY STUDY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of my participation in this study at any time, and that such future questions will be answered by the physicians associated with the Center for Inflammatory Bowel Disease or their research staffs. I understand that a copy of this consent form will be given to me.

I understand that any questions which I have about my rights as a participant in the studywill be answered by the Human Subject Protections Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

**By signing below, I agree to participate in the study. A copy of this consent form will be given to me.**

_____

Participant's Signature

_____ _____

Participant's Printed Name Date

**CERTIFICATION OF INFORMED CONSENT**

I certify that I have explained the nature and purpose of the aforementioned research to the above-named individual, and I have discussed the possible risks and potential benefits of participation in this study. Any questions the individual has about this research have been answered, and the physicians and research staff associated with the Center for Inflammatory Bowel Disease will be available to address future questions as they arise.

_____

Printed Name of Person Obtaining Consent

_____ _____

Signature of Person Obtaining Consent Date

**ELECTRONIC SIGNATURE**

_____

Participant's Full Name

_____

Participant's Date of Birth

_____

Date

**Answer to ONE of 3 questions from drop-down box:**

What is your mother’s maiden name?

In what city were you born?

What high school did you attend?