RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:	Double-blind, Placebo-Controlled Trial Assessing the Efficacy and Safety of CampETEC Hyperimmune Bovine Colostrum (HBC) for the Prevention of Campylobacter-Mediated Diarrheal Diseases
PROTOCOL NO.:	CIR 360 NCT06122870
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STUDY-RELATED PHONE NUMBERS:	Kawsar R. Talaat, MD 410-336-9164 (24 Hours)

Key Information about Participating in the Research Study

- We are asking you to volunteer to join a research study.
- You do not have to join this study. It is **your choice** and there is no penalty for not joining. If you join the study and later change your mind, you can withdraw from the study.
- Please read this document carefully and ask as many questions as you need to make your decision. After you have read this document, you will meet privately with a member of the study team. Please ask the study staff to explain any words or information that you are not familiar with. Feel free to ask as many questions as you need to help you make your decision.

- Do not sign this form unless your questions about the research study have been answered in terms you understand.
- **The purpose of the study** is to learn more about the safety and tolerability of an investigational dairy-based product (CampETEC HBC) designed to prevent diarrhea caused by *Campylobacter* (Campy). Campy are bacteria, or germs that cause diarrhea, mostly in lower- and middle-income countries. An investigational product is one that is not approved by the U.S. Food and Drug Administration (FDA) but is allowed to be used in this research study.
- In this study, two investigational products will be given as a drink.
- A cow milk-based product CampETEC or placebo (a fake that is just milk)
- A challenge, which is a liquid which contains the bacteria Campylobacter. The challenge will likely cause diarrhea.
- This study will last about 9 months.
- If you join the study, we will ask you to spend approximately 12 days on an inpatient unit. There will be 1 – 3 screening visits before enrollment, 5 outpatient follow-up outpatient visits after the inpatient stay, and 1 telephone follow-up call.
- Up to 15 study participants will be randomly assigned (by chance, like flipping a coin) to receive the CampETEC product and up to 15 will receive a placebo. The placebo will look the same as the CampETEC product. Neither study participants nor study staff will know who got the CampETEC product or placebo.
- To see if the CampETEC treatment works, study volunteers will be given a dose of the Campy bacteria as a drink. This will cause diarrhea and upset stomach in most people. If the CampETEC product works, the people who receive it may not get as sick. Everyone in the study will be given antibiotics to kill the Campylobacter before they are discharged home, to decrease the risk of spreading the bacteria.
- The purpose of this document is to ensure that you are fully informed about
  - the investigational products
  - the study procedures
  - your part in the study should you choose to participate
  - risks and benefits of being in the study
  - compensation
- The Center for Immunization Research (CIR) at the Johns Hopkins Bloomberg School of Public Health (JHSPH) is working with the Naval Medical Research Command (NMRC) to conduct this study. The Defense Health Agency is funding the study.
- If you join the study, there is no direct benefit to you. You will be helping us find a product that keeps people who travel safe from one kind of bacteria that causes diarrhea.
- There is no cost to you for participating in the study. We will reimburse you for your time and effort.

Details about the Study

Background

Campylobacter (Campy) is a type of bacteria (or germ) that causes foodborne disease in the US. It also causes diarrhea in children in low- and middle- income countries and in travelers to those areas. Campy mostly affects areas where waste and water treatment systems are not good enough. The world diarrhea burden caused by Campy was estimated to be roughly 172 million cases in 2016. Having diarrhea many times can affect a child's growth and make it harder for them to think and learn, which can cause problems with their health in the long term. Also, kids who have Campy diarrhea are more likely to become malnourished or to die.

In the US, Campy causes more than 1.5 million illnesses each year mostly due to the handling and consumption of raw or undercooked poultry. For travelers, Campy may cause a severe form of Traveler's Diarrhea (TD), often associated with longer illness, large numbers of loose stools, and a high rate of other symptoms (abdominal pain, nausea, vomiting, and fever) in comparison with other bacteria that cause TD. Right now, there is no approved vaccine for or other way to prevent Campy, but scientists are testing several products to see if they work to protect against it.

Why is this research being done?

- To see if the CampETEC HBC milk product is safe and well tolerated
- To see if the CampETEC HBC milk product with special antibodies decreases illness when participants are given a challenge with Campylobacter

Information about the experimental products
This study is a **C**ontrolled **H**uman **I**nfection **M**odel, or **CHIM**. A CHIM is a type of study in which study volunteers agree to get sick on purpose. Researchers expose volunteers to a specially prepared, investigational type of bacteria in a controlled environment. They study the illness that occurs and test different products to see if they can prevent or treat the illness.

- The Investigational Challenge strain - *C.jejuni* strain CG8421 (Campy)
- This Campy strain has been specially prepared for use in human studies and we are hoping that it will cause illness in about 80% of people who receive placebo.

You will receive either the CampETEC HBC milk product or placebo but not both.

CampETEC, is a freeze-dried, natural cow milk product containing lactose and reduced fat. It is high in protein and contains no artificial additives or nutrients. CampETEC has antibodies that target the Campy bacteria. These antibodies are taken from the milk of cows that have been vaccinated against Campy. To make CampETEC ready to drink, the freeze-dried milk powder is mixed with a bicarbonate (baking soda- an antacid) and water.

The placebo is a milk product with high protein but does not have Campy antibodies. It will also be mixed with bicarbonate and water.

During this study, you will be given the CampETEC or placebo as a drink three times a day, 15 minutes after each meal, for a total of 8 days. This specific product has not been given to people before, but similar products have been used. You can also buy similar products as nutritional supplements.

Who can join the study?
Up to 30 healthy adults are needed for this study. You are being asked to participate in the study because you expressed interest in our study and completed a screening visit. To join this study:

- you must be between 18-50 years old
- you must be in good health with no history of Campy infection in the last three years
- you must not be pregnant or breastfeeding.

The study is divided into an outpatient and an inpatient phase. The outpatient phase includes the first screening visit, the 5 follow-up visits after the inpatient phase and a telephone follow up. The inpatient phase includes the 12 days in unit stay.

Outpatient phase

Screening→ (Inpatient)→Outpatient follow-up→Telephone follow-up			
	Screening	Outpatient visits	Telephone follow up
Number of Visits	1-3	5	1
Study day		15, 29, 42, 57, 85	181
Read consent, do comprehension assessment, and sign forms			
Health check and medication review			
Physical exam			
ECG			
Vital signs			
Blood	 5 tbsp	 Day 15: 1 tbsp Day 29: 5 tbsp Day 57: ½ tbsp Day 85: 5 tbsp	
Finger stick		 Day 29	
Urine	 (Drug screen)	 (Pregnancy test on Day 29)	
Stool			
Drink bicarbonate (Soda)	 2/3 cup		

Key points:

- During screening, you will complete a comprehension assessment once you have read this consent form. All the answers to the questions can be found in this document. You must get a 70% to be eligible for this study. You have 2 chances to get 70%.
- The blood and urine sample you give will be tested for a variety of health markers as well as for HIV, Hepatitis B, Hepatitis C, pregnancy, and drug tests. Throughout the study, there may be additional drug tests conducted
- If you have a positive HIV, Hepatitis B or C test, we will tell you. We are required to report positive results to the Health Department. The Health Department can help you get care and counseling resources.

- We will tell you the results of all your screening tests. Your drug screening results are private information, and the study staff will keep them confidential
- **During outpatient follow up visit:** At each visit you will **bring in or provide a stool sample collected within 8 hours of your visit**, your stool will be tested for the Campy bacteria, and stool will be saved for research.
- The total volume of blood scheduled to be collected will not exceed **550 mL** in 8 weeks (about a pint, which is the same amount as if you were to donate blood).

Inpatient phase

Admission→ Investigational product and Challenge → Treatment→ Discharge							
Number of Visits	12 days						
Study day	-3 (Admission)	-2&-1	1 (Challenge)	2 to 6	7 (Treatment)	8 to 9	10 (Discharge)
Health check and medication review							
Nasal swab for Covid test							
Vital signs (3 times a day)							
Physical Exam							
Blood (Day:amount)	 5$^{1/2}$ tbsp			 Day 2 and 4: 1/2 tbsp each		 Day 8: 5 tbsp	
Finger stick				 Day 2 and 4		 Day 8	
Urine			 (Pregnancy)				
CampETEC milk product (3 times daily)					STOP		
Drink (bacteria)							
Stool (every stool)							
Antibiotics							
PVT testing (3 times a day)							

Key points:

- You will not be able to leave the unit or have visitors during the inpatient admission

- Psychomotor vigilance testing (PVT)- is an exercise that provides a measure of how alert and responsive you are. We will ask you to use a special computer for this for 5 minutes at a time, 3 times a day. You will look at the computer and push a button when you see a light.
- Starting day -2, you will be assigned mealtimes, you will be required to eat at least 3 times a day breakfast, lunch and dinner.
- Dosing with CampyETEC or Placebo will occur three times a day, approximately 15 minutes (range: 10 – 25 minutes) after breakfast, lunch, and dinner for a period of 8 days (day -2 to day 6)
- You are encouraged to take oral fluids, including Oral Rehydration Solution (ORS) or Gatorade. We may also give you IV (intravenous) fluids through a catheter inserted into a vein in your arm or hand.
- You will be discharged from the unit when your symptoms have resolved or mostly resolved, you've had at least 2 doses of antibiotic treatment, and you have 2 stools in a row that test negative for the Campy bacteria.

If you join this study, we will ask you to:

- Make sure you attend all your scheduled visits on time and agree to follow all the rules of the study.
- Provide all the samples, such as blood, urine, nasal swabs, and stool.
- Complete assessments including vital signs (like temperature, blood pressure, and pulse), and a physical exam. Tell us about your current and past health, even if you think it is not relevant. For your safety, it is very important that you provide a thorough health history. Some prior conditions may increase your risk of being in this study.
- Make sure to let the study staff know if you have any medical problems, doctor visits, go to the emergency room, or get admitted to the hospital while you are part of the study.
- Let the study staff know if you plan on taking any new medications. We don't know how other medications might interact with the investigational products being studied. It is possible that other vaccines, medications or treatments could interfere with the CampETEC product.
- You may be asked to take tests where you will need to push a button to measure how quickly you respond.
- Collect **ALL** stools you produce during the inpatient stay and provide them to study staff. If unable to produce a stool by about 1 pm, provide up to 3 **rectal swabs.**
- **To collect a rectal swab**, you will be given swabs and gloves. You will need to insert the swab(s) approximately 1 inch inside your rectum and rotate it against the inner walls of your rectum for 5-10 seconds. The swab(s) should collect a sample so we can test for the Campy bacteria
- Avoid pregnancy while you are in the study. We do not know how the investigational products might impact a pregnancy or developing fetus.
- Not take other investigational drugs from 30 days prior to taking the milk product. You may be at a higher risk of having complications if you take more than one investigational product at a time.
- Not get licensed or routine vaccines from 30 days before enrollment until 30 days after receiving the challenge.
- Drink the CampETEC milk product or placebo (which is randomly assigned, like tossing a coin), 3 times a day for up to 8 days.
- Drink the Campy bacteria one time, and follow recommended treatments and medications as prescribed by the study.
- Stay on the inpatient unit until the study doctor says it is safe for you to leave.
- Not donate blood for one year after taking the challenge product.

Recrudescence:
After you have two negative stool cultures and are discharged from the unit, we will test your stool at each outpatient in-person visit. There is a chance that you can test positive for the Campy bacteria after testing negative; this is called recrudescence. This may occur without you having any symptoms. If this occurs, we will begin a second round of antibiotic treatment that will last for 10 days. We will also have you restart your outpatient visits (day 15, 29, 42, 57 and 85), and your previous schedule will be updated. The same outpatient procedures may be completed. This will increase the number of outpatient visits. We will follow you through 181 days post recrudescence.

Recrudescence visit days:

Visit/Visit Day	**Procedures**
R1 Visit which we found you to be positive for Campy	Procedures will have previously been completed at your last visit.
R (3 – 10) First visit after you have been found to be positive.	Interim history Focused physical exam Review of symptoms Review of medications Vital signs Bloods for safety (if needed) Urine HCG Stool will be tested for Campy and for research purposes
R15, R29, R42, R57, R85, and R 181	To be conducted as above but without research blood

How long will you be in the study?
It is expected that this study will last about 6 months from the time you are admitted to the unit until the last call. If you recrudesce, then the time you will be in the study will be increased depending on the day you recrudesce. We would like to follow you for 6 months from your last Campy positive stool.

What are the risks or discomforts of the study?

In this study, there are risks related to the CampETEC product, the Campy challenge, study procedures, and risks related to medications to treat symptoms and clear the infection.

Risks related to the Investigational product – CampETEC and placebo

The CampETEC investigational product is expected to be safe although you may experience mild to moderate discomfort likely related to drinking the sodium bicarbonate buffer.

- You may not like the taste.
- It may cause bloating, nausea, and/or gas.

Risks Related to the Campy Challenge Inoculum
We expect that up to about 80% of participants will have a diarrheal illness from the challenge. Illness caused by Campylobacter ranges from mild to severe. Common symptoms include:

- abdominal pain
- abdominal cramping
- loss of appetite
- generalized muscle aches
- joint aches
- bloating
- chills
- constipation
- headache
- excessive gas
- malaise or fatigue
- urgency
- nausea
- vomiting
- fever
- lightheadedness
- diarrhea
- bloody stools

For most adults, Campy illness is not life threatening, but it can lead to dehydration and significant inconvenience associated with loss of sleep and reduced activity.

The risk of recrudescence, or the infection coming back, as mentioned above. In our previous study, this happened in 5 out of 30 volunteers (all who had no symptoms). Other studies done elsewhere had lower rates, some with no recrudescences. We don't know why some people recrudesce and others don't.

Severe symptoms rarely occur with Campy infection. The following symptoms are possible:

- Acute abdomen – sudden severe abdominal pain that may require surgery
- Severe GI bleeding
- Dehydration
- Sepsis – a more significant illness where there is high fever: temp. >102ºF (39ºC), rigors, and unstable vital signs
- After a Campy infection there may be short or long-term changes in your bowel pattern (when and how often you have stools and related symptoms). There may be increased risk for:
  - Irritable Bowel syndrome (IBS). IBS can cause frequent stomach pain or cramping, and changes in stooling with diarrhea or constipation.
  - Reactive arthritis (ReA) – ReA is joint pain and swelling caused by an infection in another part of the body.
  - Guillain-Barre syndrome (GBS) – GBS is when your body's immune system attacks your nerves. Guillain-Barre is a form of paralysis that is usually temporary and treatable but can be life threatening or lead to long-term weakness. This strain of Campy that we use for the challenge doesn't have the protein that has been shown to cause GBS.
  - Irritable bowel disease (IBD) – IBD involves chronic inflammation of tissues in the digestive tract.
  - If these side effects occur, we may refer you for further care with a specialist.
- Since the challenge products are investigational, there is a risk of side effects that are not yet known.

Risk of Severe Allergic Reactions

Allergic reactions such as rash, hives, wheezing, and anaphylaxis (difficulty breathing) are a possibility whenever you are exposed to something new. **Please tell us about any allergic reactions you have had in the past and what happened to you, especially if you had to call 911 or go to the emergency room**. We will treat you immediately for any signs of an allergic reaction.

Risks Associated with Study Procedures

- Interviews or questionnaires – You may get tired or bored while we ask you questions or while you complete questionnaires. Some questions may make you feel embarrassed or uncomfortable. Let us know if you feel distressed. You do not have to answer any question you do not want to answer.
- Blood draws or IV insertion can cause pain, bruising, bleeding, feelings of lightheadedness, or, rarely, fainting or infection as a result of the blood sampling or IV placement. If we use intravenous (IV) catheters, there is a chance they may cause swelling or discomfort by infiltrating fluid under the skin.
- Nasal swabs may cause discomfort, a nosebleed, or sneezing.
- You may experience minor discomfort, annoyance, or embarrassment related to stool collection and rectal swabs.
- Isolation from friends, family, work, school and sharing space with strangers can cause discomfort.
- There may be physical, psychological, and social risks if you test positive for hepatitis B, hepatitis C and/or HIV. If you test positive we will counsel you and referred you for treatment.
- If you are not up to date with recommended COVID-19 and Flu vaccinations, you may be at higher risk of getting sick while on the inpatient unit.
    - **COVID risk reduction strategies**
        - All participants will be tested for COVID on admission. If you test positive, you will not be able to stay on the unit.
        - You will be encouraged to wear a mask when you are in common areas.

Risk to Privacy and Confidentiality

There is a risk that information about you may become known to people outside this study. We will protect your information to reduce the chance of this happening (see Privacy and confidentiality).

Risks Associated with Antibiotics

The antibiotics given in this trial (azithromycin, ciprofloxacin, augmentin, or cefpodoxime) are licensed, approved medications that have been used for years and that are usually well-tolerated, but you could have side effects like: skin rash, diarrhea, nausea, vomiting, dizziness, headache, yeast infection (females).
Antibiotics can decrease how well birth control pills work. If you are using birth control pills as your primary method of birth control, you will be encouraged to use an additional method while on antibiotics and for at least 7 days after completion of antibiotics. Abstinence or condoms would be acceptable as additional methods of birth control.

All antibiotics can have rare side effects that can occur. Ask the study team if you have any concerns about the side effects of the antibiotics. Here are some of the specific rare side effects. Rarely, severe allergic reactions can happen such as difficulty breathing, or even death. There may be risks or side effects which are unknown at this time.

Azithromycin: The most reported side effects for azithromycin include diarrhea or loose stools, nausea, or abdominal pain. Rarely, serious allergic reactions to azithromycin have been observed, including joint aches, angioedema, anaphylaxis, heart problems increasing the risk of arrhythmias, liver problems and serious skin peeling conditions.

Ciprofloxacin: Commonly seen adverse reactions include diarrhea, nausea, vomiting, headache and rash. Rare side effects can include tendonitis and tendon rupture, which is a higher risk in older adults,

people on steroids and people who are on long courses. Peripheral neuropathy, central nervous system effects (including hallucinations, anxiety, depression, insomnia, severe headaches, and confusion), hypoglycemia and seizures may also occur and are more common in the elderly. Ciprofloxacin may exacerbate muscle weakness in patients with myasthenia gravis.

Penicillin (Augmentin) and cephalosporins (Cefpodoxime): Common side adverse reactions include rash and diarrhea. Rare side effects include Stevens-Johnson syndrome (a rare, serious disorder of the skin and mucous membranes), clostridium difficile colitis (severe diarrhea, abdominal cramps or pain) and anaphylaxis.

All antibiotics increase the risk of the development of *Clostridium difficile (C. dif.)* diarrhea, a kind of diarrhea that is due to the killing of the normal gut bacteria by antibiotics. Please let the study team know if you develop diarrhea during or after taking the antibiotics.

To decrease the risks associated with the antibiotics, we are enrolling healthy adults who are not pregnant or breastfeeding, are between ages 18 and 50, are without a history of these conditions, and who are not taking medications that increase the risk of these side effects. We also will do an electrocardiogram (EKG) to make sure your heart rhythm is normal during screening.

Risks Related to Taking Other Medications at the Same Time
Please tell us about the medications you are taking. Other vaccines, medications, or treatments might interfere with your germ-fighting response to the Campy infection or interact with the CampETEC preventative medication or antibiotic treatment.

Risk Of Transmission of Campy to Others

It is possible to pass the Campy bacteria to people who are in close contact with you. That is why we ask you to stay on the unit until the Campy bacteria are no longer in your stool. If you leave the unit before that, there is a chance you could infect someone close to you. To reduce the risk of spreading Campy to others, it's important to wash your hands regularly and clean up the bathroom after using it.

To decrease the risk of giving Campy to others, we will ask you if you live with children less than 2 years old, persons greater than 80 years old, or people who are immunocompromised. We will also ask you if you work as a food handler, in daycare, or in healthcare with direct patient care.

Risks Related to Pregnancy and Breastfeeding

We don't know how the CampETEC investigational product or Campylobacter infection might affect an unborn baby or a breastfeeding infant. If you are currently pregnant or breastfeeding, you cannot participate in the study. To prevent pregnancy during the study, you must agree to use a reliable birth control method consistently. If you do become pregnant after receiving the investigational products, we may ask you to continue in the study for safety monitoring purposes. We might also ask to keep checking on you throughout your pregnancy.

Risks Related to Participating in Other Studies at the Same Time

This study involves an investigational treatment and challenge product. We do not know what will happen if you take another investigational drug at the same time. You could increase your risk of illness and injury if you take more than one study product at a time.

Privacy and Confidentiality
What happens to data and biospecimens that are collected in the study?

Any data collected from you will be protected under Federal regulations. Personal identifiers (your name, date of birth) will not be released. Your research data will not be put in your medical record. Results from future research using your samples or data may be published in scientific journals and presented at meetings but you will not be personally identified. Your samples will be coded with numbers, not your name.

The samples you provide during this study are valuable for scientific research. Most biospecimens contain DNA, which is the genetic code for each person. Any leftover blood, stool or other specimens may be stored for future use. It is necessary to agree to sample storage if you want to participate in this study. If you do not want your samples to be stored, you should not join this study. We will do our best to protect the data you provide.

You will not own your samples after you give them to the study. There will be no direct, personal benefit to you from any future research use of your samples. You will not be paid for any product or idea created by using the data or samples collected from you.

Will research test results be shared with you?

We will share your clinical test results with you because they could impact your health care decisions. The results of research tests help us answer our research questions and do not relate to your health. There is no direct link between you and research test results. We will not share research test results with you. When the study is complete, the study results will be posted on https://clinicaltrials.gov.

Will your data and biospecimens be shared now and in the future?

Sharing data and/or biospecimens is part of research and may increase what we can learn from this study. Data and biospecimen sharing change over time and may continue after the study ends. Because science constantly advances, we do not yet know what future testing may include. If biospecimens are tested/used in ways not described above, we will ask the IRB to review and approve those new uses and the IRB will determine whether additional consent is required.

Your deidentified data and/or biospecimens may be shared:

- directly with research collaborators, other researchers, sponsors, government agencies, publishers of
  papers and other research partners.
- through government or other databases/repositories.

May I withdraw or cancel my permission for my biospecimens and health information?

You may withdraw your permission to use and share bio-specimens and disclose your health information at any time. You do this by sending written notice to the study doctor. 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 but your samples already collected will be analyzed as planned and the results used for the study.

Protecting Data Confidentiality

Medical records associated with this protocol are subject to provisions of the Privacy Act of 1974, 5 U.S.C., Section 552A, and AR 340-21. All data and medical information obtained about participants will be considered privileged and held in confidence. See Privacy and Confidentiality.

We will take the following steps to protect the safety of your research data and the information you share with us while you are a study volunteer:

- Your study data and biological samples will be identified by a study ID, not your name.
- Your study data will be stored in locked cabinets and/or password-protected and encrypted computer files.
- Your name, birth date, and social security number are not given to anyone unless required.
- Assessments and study procedures will take place in private spaces.

Information that identifies you (such as name, address) will only be available to site staff (study doctor and clinic staff on site) and may be reviewed at the study site by sponsor and others (such as agencies that approve and monitor studies) to make sure that the study is being run properly. These groups may include:

- Audit and Compliance Officers and Legal Counsel
- The Office for Human Research Protections (the government agency that makes sure that we are conducting the research as planned)
- The U.S. Food and Drug Administration (FDA) and other similar regulatory agencies
- The study's sponsor
- Naval Medical Research Center (NMRC)
- The people the sponsor may contract with for the study such as the study monitors and medical monitors
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies to which HIV and hepatitis test results must be reported
- The Johns Hopkins University Bloomberg School of Public Health
- There will be people working on the study who need to see your research information. These people may include the researchers, study and lab personnel, and other research study staff.

Confidentiality agreements have been developed with other clinical trials groups (e.g., at the University of Maryland Vaccine Research Center or Walter Reed Clinical Trials Center), and the study team may check with these sites to see if participants have screened or enrolled in studies that would prevent them from being in this study or other CIR studies. Additionally, we may be contacted by these organizations to verify if you have participated in CIR studies.

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. Maryland state law requires us to report some diseases and information about you. If reported, this information may not remain confidential. Otherwise, the information that identifies you will not be given out to people not working on the study, unless you give us permission.

Will the study require any of your other health care providers to share your health information with the researchers of this study?

The study doctors may ask to see health care records from your other health care providers if you have a health problem while you are in the study. We will ask you to sign a separate HIPAA (Health Insurance Portability and Accountability) Authorization for Disclosure of Protected Health Information.

Benefits

There is no benefit to you for participating in this research study. However, there is potential societal benefit of the development of a product to prevent Campy illness.

Participant Compensation

Compensation for participation will occur as detailed below. Compensation will be provided only for completed study procedures if enrolled in the study. If you are eligible to participate after screening, complete all study visits, procedures and follow all the inpatient unit guidelines, you will receive full compensation as described below:

- $150 total for screening (only if enrolled in the study or present as an alternate)
- $4,200 for the inpatient period, $350 per night (as long as all study requirements are met)
- $750 for all outpatient study visits: Days 15, 29, 42, 57, 85 ($150 per visit)
- $60 for the follow up telephone contact: Day 181
- $250 bonus upon completion of inpatient phase and outpatient visits

Maximum compensation for the planned schedule of the study is $5,410.

- If there is a day 113 outpatient visit, you will be compensated an additional $150.
- If you are not eligible for discharge on day 10 (12 days after admission) you will receive $300 per additional inpatient night.
- If you recrudesce, some of the visits may still be included in the compensation as above. It is likely that there will be additional outpatient visits required, for additional visits you will be compensated $150 for each additional visit not covered above.

If you are admitted and discharged prior to receiving the milk product or challenge, you will be compensated per the alternate agreement.

You will not be paid for missed outpatient visits and may forfeit some or all of your visit compensation and/or bonus as a result of missed or late visits, non-compliance, or not providing samples.

You will be required to complete a screening form that includes your Social Security number, so that a check can be processed. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service, and you will receive a 1099-MISC form from us.

What are your options if you do not want to be in the study?

If you do not want to be in the study, you may simply choose not to participate. Your decision to participate or not will not interfere with present or future employment or medical care at Johns Hopkins.

Will it cost you anything to be in the study?

There are no expected costs to you for being in this study, although we are asking you to spend 12 days on an inpatient unit. The impact at work and at home should be considered before joining the study.

Research-Related Injury

A study clinician will always be available while you are on the unit. All study-related medical care will be provided to you at no cost. If you are injured as a direct result of participating in this research project, you may be able to receive medical care at the Walter Reed National Military Medical Center (or other military- affiliated medical center), at no cost to you. You will not receive any injury compensation. You will not be compensated if you choose to seek care from your own physician. You

will only be treated for injuries that are directly caused by the research study. If you have questions about this medical care, talk to the principal investigator for this study.

During the challenge phase, if you require medical treatment beyond what can be provided safely on the inpatient unit, you will be transferred to the Johns Hopkins Hospital or Johns Hopkins Bayview Medical Center for care. If you are injured during the study, the study doctor will help you find medical care. Medical care at Johns Hopkins medical institutions is accessible to all study participants in the same way all sick or
injured people may access care. Neither Johns Hopkins Bloomberg School of Public Health nor the Johns Hopkins medical institutions can cover the cost of care for injury or other bad effects which are not the fault of the study doctors.

You should understand that signing this consent does not constitute a waiver or release of your legal rights.

Fair and Equitable Selection of Volunteers for the Study

Volunteers will not be discriminated against based on race, sex, or religion. We have excluded those under 18 because we want to enroll adults who are able to make an informed decision. We have excluded those over 50 because they are more likely to have more medical problems, lower immune responses, and be at higher risk for adverse events. Any individual who is unable to consent due to any reason will not be included in this study. You will be treated fairly and respectfully by all study staff.

Compensation for Investigators

There is no financial compensation for investigators in this study. All investigators will be required to complete a form for the disclosure of significant financial interest.

If You Become Ill

We ask that you notify the study staff if you become ill while you are in the study, even if you do not think it is related to the study.

Please contact:
The Study Doctor, Dr. Kawsar Talaat, at (410)-336-9164 (24 hours)
Study staff can be reached at 443-571-2046
The CIR Office, at (410)550-2725 (business hours)

Can you leave the study early?

You are a volunteer. You can join the study now and change your mind later.

- If you decide to withdraw from the study after you receive the CampETEC, placebo, or challenge product, the study doctor may ask you to return to the clinic for evaluation for safety reasons.
- If you decide to withdraw from the study soon after you receive the challenge, we will treat you with antibiotics to treat the Campy infection.
- We may ask you for blood and stool specimens so we can see if you are shedding the bacteria.

If you go home while you are still sick and shedding the bacteria in your stool, you could pass the infection to others.

If you decide to leave the study, your samples will be used for the research explained above. You can provide a written request for your samples to be destroyed. Data collected during the study period prior to your decision to leave will be used.

Why might the investigators take you out of the study early?

Reasons you may be taken out of the study include:

- The study is halted or cancelled.
- Staying in the study would be harmful to your health.
- You need treatment or have a medical condition that is not allowed in the study.
- You do not follow instructions.
- You become pregnant.
- The FDA or JHSPH Office for Research Subjects, study sponsor or safety monitors decide the study should be stopped for any reason.
- There may be other reasons to take you out of the study that we do not know at this time.
- You do not consent to continue in the study after being told of changes in the research that may affect you.

If you decide not to continue with the study, or we feel it is not in your best interest to continue in the study, with your permission, we may still follow you for safety. If you agree, you may have some follow up visits with limited procedures. This is called "off treatment."

What is the Institutional Review Board (IRB) and how does it protect you?

This study has been reviewed by an Institutional Review Board (IRB), a group of people including scientists and community members that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study.

You may contact the IRB at 410-955-3193 or jhsph.irboffice@jhu.edu.

Who do I call if I have questions or problems?

If you have questions, concerns, complaints, or feel you have been injured as a direct result of study participation, or just need to talk with someone about this study, call the doctor in charge of this study:

Dr. Kawsar R. Talaat at 410-336-9164 (24 hours)

Call or contact the Johns Hopkins Bloomberg School of Public Health IRB Office if you have questions about your rights as a study participant. Contact the IRB if you feel you have not been treated fairly or if you have other concerns. The IRB contact information is:

Address:	Johns Hopkins Bloomberg School of Public Health 615 N. Wolfe Street, Suite E1100 Baltimore, MD 21205
Telephone:	410-955-3193
Toll Free:	1-888-262-3242
E-mail:	JHSPH.irboffice@jhu.edu

What does your signature on this consent form mean?

- You have been informed about this study's purpose, procedures, possible benefits and risks.

- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to be in this study.
- You are not waiving or releasing any legal rights by signing this consent

_____	_____	_____	_____
Print name of Adult Participant	Signature of Adult Participant	Date	Time

_____	_____	_____	_____
Person Obtaining Consent (Print)	Person Obtaining Consent (Signature)	Date	Time