# Permission to Take Part in a Human Research Study & HIPAA Authorization for Release of Health Information for Research Purposes

## 1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

**Study title: Haloperidol for the Treatment of Nausea and Vomiting in the Emergency Department**

**Sponsor of the study: Western Michigan University Homer Stryker M.D. School of Medicine (WMed Health)**

**Principal investigator: Jessica McCoy, MD, Department of Emergency Medicine, WMed Health**

"You" refers to the subject.
"We" refers to WMed Health and Bronson Methodist Hospital.

### 1.1 Key Study Information

You may be eligible to take part in a research study. This form has important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Be sure you understand what the research study is about before you sign.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

This research is studying two drugs, **ondansetron** (also called Zofran) and **haloperidol** (also called Haldol).

**Ondansetron** is approved by the Food and Drug Administration (FDA) to manage nausea (feeling sick) and vomiting (being sick) in cancer patients and in patients recovering from surgery. Doctors also use it regularly as the 'first-line' treatment to help patients that come into the emergency department with nausea and vomiting.

**Haloperidol** is approved by the FDA to treat certain mental/mood disorders but is also used regularly by emergency room doctors in low doses to help control nausea and vomiting.

Researchers are studying the differences between these two drugs. They would like to know if one works better than the other. This research will measure the effectiveness of both drugs in easing symptoms at 30, 60, and 90 minutes after receiving the drug and at 24 hours after your emergency department visit. Your health-related information will be collected for this research study.

This study involves a process called randomization. This means that the medicine you receive in the study is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare different treatments or

procedures. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include restlessness or anxiety. More detailed information will be provided later in this document.

This study may offer some benefit to you now or others in the future by easing nausea or vomiting symptoms more effectively. Depending on which drug you get, it may also help with abdominal pain. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be from when you get the drug until 24 hours after your emergency department visit.

You can decide not to be in this study. Alternatives to joining this study are to be treated with the hospital standard-of-care which may include getting either of the drugs described in this study.

You are free to leave at any time if you change your mind even if you decide to join the study now.

More information about this study continues in Section 2 of this document.

## 2. THE PURPOSE OF THE STUDY

### 2.1 Study purpose:

It is common for doctors to treat patients for nausea and vomiting in the emergency department. **Ondansetron** is approved by the Food and Drug Administration (FDA) to manage nausea and vomiting in cancer patients and in patients recovering from surgery. Many hospitals and doctors also use it regularly as the first drug ordered to ease patient's discomfort related to nausea and vomiting when they arrive in the emergency department. However, there is not strong evidence that ondansetron works any better or any worse than other drugs that ease nausea and vomiting.

**Haloperidol** is approved by the FDA to treat certain mental/mood disorders (anti-psychotic medicine) but when used at doses that are much lower than its FDA approved use, it is used regularly by hospitals and doctors to ease patient's discomfort related to nausea and vomiting in the emergency department setting. The use being studied here is 2.5 milligrams (mg) which is much lower than the amount for the FDA approved use and based on what other researchers have proven to be a safe dose for patients with nausea and vomiting.

This research is being done to measure the effectiveness of both drugs described above by comparing the severity of symptoms at 30, 60 and 90 minutes between the two groups. We hope to show that haloperidol does a better job of making patients feel better sooner than ondansetron does.

When patients have nausea and vomiting, they often have abdominal pain too. We are also measuring the effectiveness of both drugs described above in controlling pain by comparing the level of pain at 30, 60, and 90 minutes. We hope to show that haloperidol does a better job of reducing the level of pain in a shorter amount of time than ondansetron does.

Cannabinoid hyperemesis syndrome (CHS) is a condition that leads to repeated and severe bouts of vomiting. It results from long-term use of marijuana. As we see more-and-more patients in the emergency department seeking treatment for CHS, we are also exploring effective ways to treat the symptoms. Because the symptoms are similar to other things we see in the emergency department, we use both ondansetron and haloperidol to ease the symptoms of CHS. If you participate in this study, and have CHS, you will not receive both drugs.

## 3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

### 3.1 Who can take part in this study?

Patients that come to the emergency department at Bronson Methodist Hospital with nausea or vomiting.

### 3.2 How many people are expected to take part in this study?

We expect to enroll a total of 300 people into this study.

## 4. INFORMATION ABOUT STUDY PARTICIPATION

### 4.1 What will happen to me in this study?

We first will see if you qualify to be in the study. We will:

- Ask you some questions about yourself, including about your medical problems.
- We will ask about your allergies.
- We will ask if you mind being randomly assigned (like flipping a coin) to receive either of the study medications (ondansetron or haloperidol)

If you qualify, we will review this document – the consent document.

If you agree to be in this study, you will receive either **ondansetron** or **haloperidol**. Both of the study drugs are given by liquid through your vein. This is also called intravenously or "IV". You will have an equal chance of getting either drug (like flipping a coin).

Neither you nor the researchers will choose or know which drug you are getting. For some research studies, such as the one you are being asked to join, it is important that you do not learn the medicine you were given. Whether you mean to or not, sometimes learning this information can change your actions and behaviors in ways that may impact the results of the study.

After randomization, the hospital pharmacy will provide the drug. You will be asked to rate your level of nausea and pain at 30, 60, and 90 minutes after you have been given the medicine.

After you leave the emergency department, we will look in your medical chart for other things, including the total length of time you stayed in the emergency department, whether you have any other medical problems, whether you had any side effects from the study drug, and whether you were admitted to the hospital or discharged home.

You will also receive a phone call from a research assistant about 24 hours after your emergency department visit to ask you questions about how you are feeling and if you have had symptoms like nausea and vomiting again.

### 4.2 How much of my time will be needed to take part in this study?

You will be asked about your symptoms and pain levels at 30, 60, and 90 minutes after you get the study drug for this research. These will take 2 to 3 minutes in addition to the regular monitoring. The phone call you receive will take approximately 5 minutes.

### 4.3 When will my participation in the study be over?

You will be in the study for 24 hours after your emergency department visit.

### 4.4 What will happen with my information used in this study?

Information that may identify you will be removed before being used for future research studies or given to another researcher for future research studies without additional informed consent.

## 5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

### 5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

Some possible side effects that may be related to taking **ondansetron** and **haloperidol** include:

- Lightheadedness or dizziness
- Drowsiness or tired feeling
- Headache
- Diarrhea or constipation
- Redness/pain/burning at the injection site

Some possible side effects that may be related to taking **Haloperidol**:

- Restless feeling
- Insomnia
- Anxiety
- Difficulty urinating
- Muscle tightness or stiffness

You may be allergic or have a bad reaction to the study drugs. Although these drugs have been approved by the FDA, you may have a different reaction to them. In the case of ondansetron symptoms of a serious allergic reaction include rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. Please note that these risks would be the same if you use ondansetron outside of this study. In the case of haloperidol, these risks could include QT prolongation (a type of heart rhythm disturbance), increased motor movements or abnormal contractions of muscles, impairment of thinking or motor skills, fast heart rate, worsening of glaucoma (if you have this disease), and low blood pressure or high blood pressure.

Because you are sick, some of these side effects may not be from the drug. However, if you do have any of these or any other side effects during your hospital visit, tell the person taking care of you or the research assistant.

In addition, this study may involve other risks that are not currently known to you or your embryo or fetus if you are pregnant. Please let us know whether you are pregnant before you get any study drugs.

Someone could find out that you were in the study and learn something about you that you did not want others to know. See Section 9 of this document for more information on how the study team will protect your privacy.

### 5.2 How could I benefit if I take part in this study? How could others benefit?

Being in the study may help you because you will get treatment for your nausea and vomiting, although it may not help you more than if you got similar treatment outside of this study. We think that being in the study will help people being treated for nausea and vomiting in the future. We may learn more about how people with nausea respond to the study medications.

### 5.3 What if I get sick or hurt while I'm in this study?

- If you get hurt when you are here for the study, we will help you get the care you need. This may include emergency care and/or follow-up care.
- If you are not here and get hurt or sick, and think it is because of the study, do these things:
  - Tell your doctor or Emergency Department staff the name of this study (say "the Haldol study")
  - the name of the head researcher for this study (Dr. McCoy)
  - a copy of this form if you have it

- This treatment may be billed to you or your insurance company in the normal manner. Normally, no other form of payment is available.
- You will not give up any of your legal rights by signing this form.

## 6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

### 6.1 If I decide not to take part in this study, what other options do I have?

You do not have to be in this study. If you do not want to be in this study, your options are:

- To not be in the study. In this case, you may still receive these medications but the people monitoring you will not use your information for this research.

## 7. ENDING THE STUDY

### 7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

### 7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes, the Principle Investigator can take you out of the study if:

- You do not follow study instructions.
- The study drugs are unavailable, or if there is any other reason that we cannot give you these medications and then observe you.
- It is not in your best interest to continue.
- The study is stopped for any reason.

### 7.4 Will my information be used for future research or shared with others?

We may use or share your research information for future research studies. If we share your information with other researchers it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies.

## 8. FINANCIAL INFORMATION

**8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?**

The study will pay for both study drugs. This cost is covered by a WMed Health research grant. You and/or your insurance company will be billed for your regular medical care in the usual manner.

**8.2 Will I be paid or given anything for taking part in this study?**

No, you will not be paid for taking part in this study.

**8.3 Who could profit or financially benefit from the study results?**

The researchers, Bronson Methodist Hospital, or WMed Health do not have a financial interest in the outcome of the study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

## 9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study.

**9.1 How will the researchers protect my information?**

Research records will be kept in a separate research file that does not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you.

**9.2 Where can I find more information about this clinical trial?**

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.

**9.3 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?**

- The research team will know your name and have access to your information.
- We will do our best to make sure no one outside the study knows you are part of the study.
- When we share the results of the study in medical journals, we will not include your name or any other information that allows people to identify you personally.
- There are people who make sure the study is run the right way. These people may see information from the study about you including information that identifies you. They are:
    - WMed Institutional Review Board (IRB), which reviews all WMed Health research
    - Bronson Methodist Hospital research oversight office
    - Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
    - Information about your study participation may be included in your medical record.
    - Because this study involves the use of a Food & Drug Administration (FDA) regulated drug, the FDA may also review the information.

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- The information from the phone call will be recorded in a research database.
- Substance abuse treatment records
- Health plan/health insurance records
- All records relating to your emergency department visit, the nausea medicines you were prescribed, and your response to the nausea medicines
- Demographic information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check for side effects.
- WMed and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.

**9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?**

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help WMed/Bronson make sure that the study was conducted properly

As long as your information is kept within the WMed/Bronson Healthcare system, it is protected by the Health System's privacy policies.

**9.4 When does my permission to use my PHI expire?**

Your permission will not expire unless you cancel it. You may cancel your permission at any time by writing to or emailing the researcher listed in Section 10 "Contact Information" (below). If you cancel your permission, you may no longer be able to participate in this study.

## 10. CONTACT INFORMATION

**10.1 Who can I contact about this study?**

Please contact the researcher listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:
**Jessica McCoy, M.D.**
**1000 Oakland Drive**
**Kalamazoo, MI 49008**
Email: jessica.mccoy@med.wmich.edu
Telephone: 269-337-6600

**You may also express a question or concern about a study by contacting the Institutional Review Board listed below:**

Western Michigan University Homer Stryker M.D. School of Medicine
1000 Oakland Drive
Kalamazoo, MI 49008
Telephone: 269-337-4269
Email: irb@med.wmich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may visit https://med.wmich.edu/researchparticipants or call 269-337-4269.
*When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the protocol title (at the top of this form), and details about the problem. This will help us look into your concern. When reporting a concern, you do not have to give your name unless you want to.*

## 11. RECORD OF INFORMATION PROVIDED

**11.1 What documents will be given to me?**

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular Bronson medical record.)*

## 12. SIGNATURES

**Consent to Participate in the Research Study**

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request.

Print Legal Name:

_____

Signature:

_____

Date of Signature (mm/dd/yy): _____

**Principal Investigator or Designee**

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name:

_____

Title:

_____

Signature:

_____

Date of Signature (mm/dd/yy): _____

Time of consent: _____



Western Michigan University Homer Stryker M.D. School of Medicine
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