INFORMED CONSENT and HIPAA AUTHORIZATION

KEY INFORMATION

Short Study title: SMILE Study
Study title: Study for Dexamethasone Mouthwash in Lowering Episodes of Oral Mucositis among Patients with Cancer
Study Sponsor: Foundation for Woman's

- This first part gives you *key information* to help you decide if you want to join the study.
- We will explain things in more detail later in this form.
- Taking part in this study is *completely voluntary*. It is up to you whether or not to take part in this research study. Even if you decide to join the study today, you are free to leave at any time if you change your mind.
- *We are asking* if you want to volunteer for a research study testing if a steroid mouthwash can help prevent mouth sores caused by chemotherapy in patients with cancer. By doing this study, we hope to learn if this mouthwash that is used to treat mouth sores, can also help prevent them.

What will happen if you join the study?

If you join, *your part* in this research will last about 8 weeks. *During the study*, you will use a mouthwash about 4 times a day, starting during the first week of your chemotherapy. Each time, you will swish a measured amount in your mouth for about 2 minutes and then spit it out. You will do this every day through your chemotherapy treatment. Our research team will check your mouth during your chemotherapy visits to see if sores are forming and ask you questions about your pain.

Do you have to join this study?

No. It is okay to say no. You will not lose any services, benefits, or rights you would normally have if you decide not to join.

What are the risks and benefits if you join this study?

Risks to being in this study are the possible side effects of mouth wash, which are oral thrush (a yeast infection in the mouth), a burning or unpleasant taste, or minor effects from the steroid (such as changes in blood sugar). The possible risks are believed to be minimal. You may *benefit* from this study by having fewer or less severe mouth sores during chemotherapy.

What do you need to know to decide if you should join this study?

People decide to join studies for many reasons.

Main reasons you may want to join the study:

- Joining this study could make your chance of getting mouth sores smaller.
- Results from this study could help make recommendations for future patients with cancer.

Main reasons you may not want to join the study:

- Using a mouthwash up to 4 times a day is too burdensome/not possible for you.

Will you be compensated for being in this study?

You will not be compensated for joining this study.

These are just some of the reasons to help you decide if you want to join the study. We will explain more about the risks, benefits, and other options to joining the study later in this form.

Tell the study team if you decide that you do not want to be in the study. Remember, it is okay to say no.
You can still get your medical care from Woman's if you are not in the study.

Woman's IRB

Initial Approval Date: November 10, 2025
Study Expiration Date: November 10, 2026
RP Number: RP-25-033-WH

Informed Consent Form and HIPAA Authorization

The SMILE Study: Study for Dexamethasone Mouthwash in Lowering Episodes of Oral Mucositis among Patients with Cancer

Principal Investigators: ***Hunter Collins, PhD***
Mary Salario, RN
Woman's Hospital
100 Woman's Way, Baton Rouge, LA 70817

Medical Monitor: ***Lauren Zatarain, MD***
Louisiana Hematology Oncology Associates
4950 Essen Lane Suite 500, Baton Rouge, LA 70809

Who do you contact in case of research injury? Call Dr. Zatarain at (225) 767-1311
Who do you contact for questions about the study? Call Dr. Collins at (225) 924-7142

- We are asking you to be in a research study. You do not have to join the study.
- You can still get your medical care from Woman's even if you are not in the study.
- Take as much time as you need to read this form and decide what is right for you.

Why are you being asked to be in this research study?

- The study team wants to learn more about preventing mouth sores in patients with cancer.
- By doing this study, the researchers hope to find out if a mouthwash that is used to treat mouth sores among patients with cancer receiving chemotherapy, can also help prevent them.
- We are asking people like you, who have cancer and are receiving a chemotherapy with a possible side effect of mouth sores, to help answer this question.
- 45 people at least 18 years old, with a cancer diagnosis, who are receiving a chemotherapy with a possible side effect of mouth sores will be part of this study at Woman's Hospital's Cancer Pavilion.
- The medication in the mouthwash (dexamethasone) is FDA approved but is being used off-label in this study.

What if you don't understand something?

- This form may have words you do not understand. If you would like, research staff will read it with you.
- You are free to ask questions at any time – before, during, or after you are in the study.

What if you say you don't want to be in this study?

- Nothing bad will happen because of what you decide.
- You can still get medical care at Woman's.

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What will happen if you decide that you want to be in this study?

First, we will ask you questions about your age, health, and type of chemotherapy to see if you qualify for the study.

1. **FIRST VISIT:**
   If you qualify, we will do these things for your **first study visit**:
   - **Review and sign the informed consent form (this document)**
   - **Collect your health information***:* You will be asked some questions about your medical history, cancer diagnosis, and the type of chemotherapy you are receiving.
   - **Check your mouth health:** We will ask you questions about your mouth health.
   - **Record your medicines:** We will ask you about the medicines you are taking- name of medicine, how much, and how often you take it. We will want to know about any prescription medications, over the counter medicines as well as any vitamins or supplements (probiotics, herbal supplements).
   - **Mouthwash education***:* You will be taught how and when to use the mouthwash.
   - **Mouthwash dispensing**: You will be given a prescription for the mouthwash. The cost of this prescription will be covered by the study.
2. **ON YOUR OWN:**
   You will start using mouthwash during the first week of chemotherapy as the prescription's instructions say.
3. **STUDY CHECK-INS:**
   We will visit you at your infusion visits and do these things each time:
   - **Check-in:** You will be asked how you are feeling and if you have experienced any illness or injury lately. We will also ask you questions about your mouth health.
   - **Mouthwash reminder:** You will be reminded how and when to do the mouthwash. We will ask how often you have done it since the last check-in.

We will try to schedule your study visits at the same time as your doctor's appointments or infusion appointments. We can also complete them virtually or electronically if needed.

What is expected of you if you join the study?

As a participant in the study, the study team asks that you:

- Complete your first visit and then check-in during or around the time of your chemotherapy infusions
- Use mouthwash as prescribed

How long will you be in this study?

You will be in this study for up to 3 months. It will include one study visit before or during your first week of chemotherapy, and then check-ins at each chemotherapy infusion.

What are the risks of being in this study?

The risks for this study are no more than what happens in everyday life as a person having chemotherapy infusions. There are also side effects about being in the study that might affect you, such as:

- A burning or unpleasant taste
- Oral thrush (a yeast infection in the mouth)
- Minor effects from the steroid, such as changes in blood sugar

There is also the risk that someone could find out that you were in the study and learn something about you that you do not want others to know. We will do our best to protect your privacy, as explained in more detail later in this form.

What if you say you don't want to be in this study?

- Nothing bad will happen because of what you decide.
- You can still get medical care at Woman's.
- You have the choice at any time not to join this research study.
- The care you get from your doctors will not change if you decide not to be in the study.
- You can join now and change your mind later and quit.
- You do not have to be in this study to use the mouthwash. If you and your doctor think the dexamethasone mouthwash might help you, you can talk to your doctor about getting a prescription for it outside of the study.
- If you don't want to join, there is no other option.

What happens if you say yes but change your mind later?

- You can stop being in the study at any time.
- Nothing bad will happen because you change your mind and leave the study.
- You can still get medical care at Woman's.
- If you decide to stop being in the study, you must let the study team know and talk to your healthcare provider about stopping or continuing to use the mouthwash.

Joining this study is your choice. You may decide not to join the study or quit the study at any time. The care you get from your doctors will not change if you decide to quit the study. *To stop being in the study or discuss stopping*, you should contact the study coordinator by phone (call or text) at 225-888-4368 (24 hours) or email research@womans.org.

Can you be taken out of the study even if you want to continue?

Yes, the study doctor or head researcher can take you out of the study if:

- You do not follow study instructions.
- It is not in your best interest to continue.
- The study is stopped for any reason.

Will it cost you anything to be in the study?

There is no charge for study participation or monitoring visits.

Will you be paid for being in the study?

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

Will being in this study help you in any way?

You may benefit from this study by having fewer or less severe mouth sores during chemotherapy treatment. At the end of the study, some of your results can be shared with you if you choose.
It is possible that you may not receive any benefit from this study.

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What if information becomes available that might affect your choice to stay in the study?

We will tell you if we learn anything that may change your mind about being in the study.

What information will be collected about you in the study?

During the study, we will need to learn private things about you, including:

- General contact and background information, such as name, address, phone number, and other demographic information
- Medical information about you,
- Personal information about you,
- And information about the health of your mouth.

Who will see this information? How will it be kept private?

- The local study team will know your name and have access to your information.
- We will do our best to keep your information confidential, but absolute confidentiality cannot be guaranteed.
- We will give your information a code, so that no one can identify you.
- When we share the results of the study in presentations, hospital reports, and medical journals, we will not include your name or anything else that could identify you.
- There are people who make sure the study is run the right way. These people may see information that identifies you. They are
    - OHRP (Office for Human Research Protections), a federal agency
    - Woman's Institutional Review Board
    - Woman's Hospital Research department
    - Woman's Research and Development Committee
- State law requires that we tell the authorities if we learn about possible abuse or that you might hurt yourself or someone else.
- 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.

Where and for how long will your information be kept?

- Your information will be labeled with a code that is kept in a database only the study team can access.
- Once we give your information a code, we will keep the key to this code in a database that only the study team can see. Your study information will be stored by Woman's Research indefinitely.
- Only the study team will be able to link it to you in the database.
- We will also put information about you from the study in your medical record.
- If you stop being in the study, we will be able to take your information out of the study after it has started. If you wish to have your information taken out of the study, call Dr. Collins at 225-924-7142.
- Your information may be used for future research about cancer and women's health. Your information may be shared with other researchers who are not part of this study.

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What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you will be collected. If you sign this form, you agree for the researchers at Woman's Hospital to use or give (disclose) your health information/record that identifies you for this study. The information that will be given to the researchers is for this study only. Your information will be used by the study team connected with this project. Woman's Hospital is required by law to protect your health information. By signing this form, you let Woman's Hospital use and/or release your health information for this research. Those persons who get your health information may not be required by laws to protect it and may share your information with others without your permission, if allowed by laws governing them.

What health information may be used or released for this study? This will include information from your medical records, procedures, interviews, and tests. Information related to your medical care at Woman's Hospital will go in your research record. This could include anything in your medical record, including physical exams, imaging studies or tests done in the lab. Medical records are available to Woman's Research staff. Staff will view your records only when needed as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone unless you provide your written consent, or it is required or allowed by the law.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples.

The health information listed above may be used by and/or released to:

- Members of the research team and other authorized staff at Woman's Hospital, Mary Bird Perkins, and Our Lady of the Lake
- Federal agencies as required by law
- State law requires that we tell the authorities if we learn about possible abuse or that you might hurt yourself or someone else

We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be shared if required by law. The results of this study may be shown at meetings or published in journals to inform other doctors and health professionals about the study and its findings. We will keep your identity private in any publication or presentation. The information from this study could be used for future research studies or given to another investigator for future research without additional informed consent from you. Before the information is shared, any information that could identify you will be removed from your identifiable information.

When I sign this form, how long does my permission last? There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years, and it is not possible to know when they will be completely done.

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By signing this form, you are saying you understand that:

- This form is to allow the release of my health information for use in the research study listed on the first page.
- Plans for how my health information will be used is written in this form.
- Researchers may use my information to see if I can be in this study.
- Researchers may use my information to check results for the study.
- Researchers may use my information to check on side effects from the study.
- Woman's Hospital staff may use this information to see that the study is being done how it should be.
- Study monitors may use this information to see that the study is being done how it should be.
- This health information may be given to insurance companies for medical bills.
- I can cancel this permission to release information at any time before the information has already been released. To cancel, I should contact anyone on the study team or send a written letter to the person on the consent form.
- If my health information has been added to a research database or registry already and there is no identifying information, my information cannot to be taken out.
- If I do not sign this form, I will not be able to take part in this study. But I understand that Woman's Hospital will not change my medical care based on if I sign this form or not.
- I understand there is a chance that information released by this agreement may be re-disclosed by whomever gets my information, that it may no longer be protected by HIPAA.
- I understand a photocopy of this form may be relied upon as if it were the original.

Will we tell you the results of the study?

No. We will not tell people in the study about what we find. However, we plan to publish the results in an academic journal. (What we publish will not include anything that can identify you.)

How will the study team reach you?

The study team may contact you by email, phone, or text message about this research. By giving Woman's Hospital Research your email and/or phone number, you agree to receive communications by unencrypted email and/or text message.

If you have any questions or problems, whom can you call?

- Please call the study coordinator at 225-888-4368 or the head researcher of the study Dr. Collins at 225-924-7142 if you have any questions about this study or feel you have been injured in any way by being in the study.
- You can also call the research office at Woman's if you cannot reach the study team, have questions about your rights as a research participant, or want to speak to someone not directly involved with this study: call Ericka Seidemann, Human Protections Administrator, at 225-231-5296 or email research@womans.org.

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Signatures

By signing the document, I am saying:

- ✓ I agree to be in the study.
- ✓ I know that joining this study is voluntary.
- ✓ Someone has talked with me about the information in this form and answered all of my questions.

I know that:

- ✓ I can stop being in the study at any time without any penalty.
- ✓ I can still get medical care at Woman's no matter what I decide.
- ✓ This study has been reviewed and approved by an Institutional Review Board.
- ✓ I can call the research office at Woman's at 225-231-5296 if I have any questions about the study or about my rights or I can call the study investigator at the number at the top of this form.
- ✓ I do not give up any of my legal rights by signing this form.
- ✓ I have been given a copy of this form.

_____	_____	____/____/____	____:____
Printed Name of **Subject**	Signature of **Subject**	**Date**	**Time**

_____	_____	____/____/____
Printed Name of **Person Obtaining Consent**	Signature of **Person Obtaining Consent**	**Date**

The study subject has indicated to me that the subject is unable to read. I certify that I have read this consent form to the subject and explained that by completing the signature line above the subject has agreed to take part.

_____	_____
Signature of Reader	Signature of Witness

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