Informed Consent for Participation in a Research Study

Title of Research Study: How will an Educational Video about the Induction of Labor Process Impact Patient's Knowledge of and Satisfaction with the Induction Process.
Investigator: Dr. Sheetal Sheth, OBGYN

Key Information:

You are being asked to take part in a research study that focuses on how an educational video may help patients' knowledge and satisfaction with the induction of labor process. Some of you will be asked to watch a 3 minute video. All of you will be asked to complete two short 3 minute surveys, one before the induction process and one 24-48 hours after delivery. If you complete the study, you will be entered in a raffle to receive a $50 Amazon gift card. This page will give you key information to help you decide whether or not you want to participate in this study. More detailed information can be found on the next pages. Ask the research team questions during the consent process, and use the contact information on this form to ask questions later.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?

By doing this study, we hope to learn if a short education video will help patients learn about the induction of labor process. Your participation in this research will last about 10 minutes in total. Some of you may be asked to watch a 3 minute video and, immediately after, answer a 3 minute survey. You will also be asked to answer another 3 minute survey 24-48 hours after delivery, during your post partum stay at GW. For those of you who will not be asked to watch the video, you will be asked to answer a 3 minute survey about the induction of labor process and another 3 minute survey 24-48 hours after delivery, during your post-partum stay at GW. Once you have finished the both surveys, you will be entered into a raffle for a $50 dollar Amazon gift card. There will be one $50 Amazon gift card per 15 people in the study.

WHAT ARE THE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

For a complete Description of benefits please refer to the Detailed Consent.

- Learn about the induction of labor process
- Help us learn how to guide the education of induction of labor to our future patients
- Have a chance to win a $50 Amazon gift card

WHAT ARE THE REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

For a complete Description of risks please refer to the Detailed Consent.

- You do not want to take the time to watch the video and/or take the two surveys
- You do not want to share your information

DO YOU HAVE TO TAKE PART IN THIS STUDY?

You do not have to take part in this research. It is your choice whether or not you want to take part. You can agree to take part and later change your mind. If you choose not to take part or choose to stop taking part at any time, there will be no penalty to you or loss of benefits to which you are otherwise entitled.

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WHAT IF YOU HAVE QUESTIONS OR CONCERNS?

The person in charge of this study is Dr. Sheetal Sheth. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is ssheth@mfa.gwu.edu

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to them at 202-994-2715 or via email at ohrirb@gwu.edu if:

- You have questions, concerns, or complaints that are not being answered by the research team or if you wish to talk to someone independent of the research team.
- You have questions about your rights as a research subject.

Detailed Consent Form:

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are scheduled for an induction of labor at GW, you are 18 years or older, and you speak English.

What should I know about a research study?

- Someone will explain this research study to you. You may ask all the questions you want before you decide whether to participate.
- Participation is voluntary; whether or not you take part is up to you.
- You can agree to take part and later change your mind.
- Your decision not to take part or to stop your participation will not be held against you.
- Your decision will not affect the medical care you receive from GW. If you decide not to take part, you can still receive medical care from GW.
- You may take this document home to read or to discuss with your family members or doctor before deciding to take part in this research study.

Why is this research being done?

Video-based educational tools have been shown to be an effective form of counseling, sometimes even more effective than traditional in-person counseling methods. We have created a brief, 3-minute video, that discusses the induction of labor process. Some of you will be shown this video. The aim of this study is to evaluate if the persons who were shown the video have a higher knowledge about the induction process and higher satisfaction with the overall induction. The benefits of this study are that you will help us evaluate if video-based educational tools would be helpful in spreading knowledge to our patients in the field of obstetrics and gynecology. If you decide to not participate in the research, your induction process will not be affected and you will receive the same care.

How long will I be in the study?

We expect that you will be in this research study for total time of 2-7 days. However, there will be only two times that you are asked to fill out a survey, one at the induction of labor visit and one 24-28 hours after delivery. These surveys are not longer than 3 minutes each. If you are asked to watch a video, it is 3 minutes long.

How many people will take part in this research study?

We would like to recruit 106 people to take part in the entire study.

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What happens if I agree to be in this research?

If you agree to be in this study, you will be randomized to one of two groups: Group 1 or Group 2. The group you are assigned to will be decided by chance. You have an equal chance of being in either group (50%), like flipping a coin. Neither you, nor the research team will choose what intervention you get, because the order is randomly pre-determined.

-Group 1 will watch an educational video and complete 2 surveys.

-Group 2 will only complete 2 surveys, with no educational video to watch. See below for more details.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

1. Watch the 3 minute video if you are randomized to that group
2. Fill out a 3 minute survey (either at enrollment or after watching the video)
3. Fill out a 3 minute survey after delivery (24-48 hours after delivery, during your post-partum stay at GW)
4. Leave us your email if you would like to be entered into a raffle for a $50 Amazon gift card

What other choices do I have besides taking part in the research?

Instead of being in this research study, your choices may include not being part of the study. This will not affect your care at GW and you will still be scheduled for an induction of labor.

What happens if I agree to be in research, but later change my mind?

You may refuse to participate or you may discontinue your participation at any time without penalty or loss of benefits to which you would otherwise be entitled.
If you decide to leave the research, contact the investigator so that the investigator can shred any parts of the surveys you have filled. If you stop being in the research, already collected data will be removed from the study database. You will also not be entered in the raffle for the $50 Amazon gift card.

Is there any way being in this study could be bad for me?

The risks and discomforts associated with participation in this study are not greater than those ordinarily encountered in daily life. If you are asked to watch the video, you may have more questions or feel more anxious about the induction process, but this is unlikely. Your healthcare providers will still be able to answer any questions about and walk you through the induction process, regardless of if you were asked to watch the video. You may experience some discomfort in disclosing your honest answers in the surveys, but these will be confidential. Your answers will be linked to a study ID number, but will not be placed in or linked to your medical chart or record. Only the research team members will have access to the sheet that correlates your study ID to your name. Additionally, upon completion of the

second survey, you will be asked to leave your email address if you would like to be entered in a raffle for a $50 Amazon gift card. Only the research team will have access to this email.

There is a possible risk of breach of confidentiality. Every effort will be made to keep your information confidential, however, this can not be guaranteed. Breach of confidentiality would be extremely unlikely as there are many safeguards in place. However, the security of stored data could be compromised, but we do not anticipate this happening.

Participating in this study cannot harm or hurt your pregnancy or fetus. It will also not affect your induction of labor. You and your insurance company will not be charged anything additional if you partake or if you refuse this study.

The risks and potential complications are similar if you decide to not participate in the study. If you do not participate in the study, you may not receive access to an educational video that would discuss the induction of labor process. However, you will still receive the standard of care for an induction.

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

The researchers have taken steps to minimize the known or expected risks. Watching a video and completing questionnaires is minimal risk to you and should not cause any illness or injury. If you believe that you are injured becaused of participating in this study, please contact the person in charge: Dr. Sheetal Sheth, ssheth@mfa.gwu.edu.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include watching a video that will discuss the induction of labor process.

What happens to my information collected for the research?

To the extent allowed by law, we limit your personal information to people who have to review it. We cannot promise complete secrecy. The IRB and other representatives of this organization may inspect and copy your information.

The research team members will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

Federal law requires that hospitals, researchers, and other healthcare providers (like physicians and labs) protect the privacy of health information that identifies you. This kind of information is known as “protected health information” or “PHI.” This section tells you your

rights about your protected health information in the study. This section also lists who you let use, release, and get your protected health information if you participate in the study. You are free to not allow these uses and releases by not signing this form. If you do that though, you cannot participate in the study.

If you sign this document, you give permission to only the members of the research team at The GW Medical Faculty Associates (GW MFA) and George Washington University Hospital (GWUH) to use or disclose (release) your health information that identifies you for the research study described in this consent form.

The health information that we may use or disclose (release) for this research includes:

- This consent form;
- Demographic information (like your medical record number, date of birth, age, email address, race/ethnicity, gender.);
- Information from you medical records about your medical history, including historical exams/testing;
- Information obtained from you to be used in the Study as a result of tests or procedures;
- Results of physical examinations
- Admissions information;
- Questionnaires/surveys you complete; and/or
- Other data created or collected during this study.

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

- Researchers and their team
- GWU Institutional Review Board ("IRB") or its authorized representatives, as well as representatives of the Office of Human Research Protections (OHRP) who may review your records to ensure that your rights as a research subject are protected;
- Clinical staff who are not involved in the study who may become involved in your care, if it might be relevant to your care; and
- Other members of the GWU, GWU Hospital or GW MFA workforce who are directly, or indirectly, supporting the research;

The GW MFA and GWUH are required by law to protect your health information. By signing this document, you authorize The GW MFA and GWUH to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

You do not have to sign this Authorization, but if you do not, you may not participate in the research study. The GW MFA and GWUH may not withhold or refuse to treat you based on whether you sign this Authorization.

You may change your mind and revoke (take back) this Authorization at any time, except to the extent that The GW MFA and/or GWUH has already acted based on this Authorization. If

you revoke this Authorization, you will no longer be allowed to participate in the research described in this Authorization. To revoke this Authorization, you must write to:
Dr. Sheetal Sheth: ssheth@mfa.gwu.edu

Even if you revoke this Authorization, The GW MFA and/or GWUH may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. This Authorization does not have an expiration date.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations or interventions.
No publication or public presentation about the research described above will reveal your identity.

If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

Access to your study records will be limited to those who need the information for purposes of this study, as well as your health care providers if they need access to the information. All records will be kept in a secure location and access will be limited to research study personnel.

You generally will not have access to your personal health information related to this research until the study is complete. At the conclusion of the research and at your request, you generally will have access to your health information that The GW MFA and GWUH maintains in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at The GW MFA and GWUH to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by The GW MFA and GWUH. If it is necessary for your care, your health information will be provided to you or your physician.

Are there any costs for participating in this research?

There are zero costs associated with participation in this study.

Will I be paid for my participation in this research?

If you agree to take part in this research study you may also choose to be in a raffle for a $50 Amazon gift card for your time and effort. There will be 1 gift card for every 15 participants. If you are the raffle recipient, we will email you the gift card on the email address you have provided for us on completion of the second survey.

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Signature Block for Adult

By signing below, you agree that the above information has been explained to you and you have had the opportunity to ask questions. You understand that you may ask questions about any aspect of this research during the course of the study and in the future. Your signature documents your permission to take part in this research. Your signature documents your permission to take part in this research.

_____
Printed name of subject

_____ _____
Signature of subject Date

_____ _____
Signature of person obtaining consent Date