HealthPartners, Inc.
Consent to Participate in a Research Study

Study Title	The Restful Jaw Device: A New Way to Support and Protect the Jaw during Third Molar Extractions;
Study Investigator	Dr. D. Brad Rindal HealthPartners Institute 952.967.5026 952.486.3952
Study Team Coordinator	Kim Johnson 952.967.5276
Sponsor	NIH/NIDCR

Introduction

We are asking you to take part in a research study regarding a new device that supports the jaw during wisdom teeth removal. Research studies include only people who choose to take part. It is your choice if you want to be in the study. No one can force you to be in the study. You do not have to participate in this study to receive treatment for your condition. If you decide not to participate in this study, your oral & maxillofacial surgeon will continue to treat you, you will not be penalized and you will not lose any benefit you are entitled to.

Before you decide to participate in this study, it is important that you read this information thoroughly to understand why the research is being done and what it would involve for you. This informed consent form explains the purpose of the study and what will happen if you take part. Your study oral and maxillofacial surgeon or their dental assistant will describe the study and go through this consent form with you and answer any questions you have. Please take your time to make your decision about taking part. You may discuss your decision with other people.

If you decide to take part in this research study, you will be asked to sign and date this consent form and you will be given a copy of the signed and dated consent form.

Why am I being asked to participate?

You are being asked whether you would like to voluntarily participate in a research study about a jaw support device because you are having your wisdom teeth removed.

What is the purpose of this study?

When wisdom teeth are removed, the patient must tense their jaw muscles to oppose the downward forces placed on their jaw. Furthermore, when patients are sedated, it decreases their ability to counter this downward force to prevent injury to their jaw. That is why a dental assistant stands behind the dental chair to support the patient's jaw with their hands. The Restful Jaw device was developed to support the jaw instead of having the assistant do it. We would like to test this device to find out if it can relieve the dental assistant from having to support the jaw. We also want to know if using the device decreases jaw pain after surgery as compared to the dental assistant holding the jaw. This information may help surgeons in the future to care better for their patients by reducing jaw pain or discomfort after wisdom teeth are removed. This study involves an investigational device. Investigational means that the device is not approved by the FDA. This study will help inform the approval of this device to the FDA.

Who is sponsoring this study?

HealthPartners Institute is receiving financial support from the National Institutes of Health (NIH) ("the Sponsor") to assist in conducting this research study. The amount of payment is enough to cover the institution's expenses to perform the study.

Dr. Brad Rindal is the study investigator and is also an investor in Restful Jaw, LLC, the company that makes the Restful Jaw device. Dr. Rindal is not involved in the collection of any information and will not have access to the data from this study.

Where will this study take place?

This study will take place at the HealthPartners Como Clinic and the HealthPartners Eden Prairie Clinic. We expect about 50 patients will be enrolled by each surgeon in this research study. Surgeons at up to four (4) sites in Minnesota will enroll a total of about 294 patients.

What is involved?

- If you agree to be in the study, you will be asked to complete a contact form, a demographic form, and a questionnaire on a tablet *before* your wisdom teeth are removed. After your wisdom teeth are removed, you'll complete online, or over the phone, a 1-, 3-, and 6-month questionnaire. Your participation will end when you submit your 6-month questionnaire.
- You will be randomized to one of the two (2) groups. Randomized means being assigned to a group by chance, like flipping a coin or drawing names out of a hat. You have a 1 in 2 chance of being assigned to each group. Group 1 will receive usual care where a dental assistant holds your jaw during surgery. Group 2 will have the jaw device supporting their jaw. *You cannot choose which group you will be in.*
- If you are randomized into the jaw support device group, the device will be fully explained and demonstrated to you before the dental assistant or surgeon fits the device on your jaw. The device will stay on while you have your wisdom teeth removed. It will be removed when the surgery is done.
- Using the device is part of the research study. Your wisdom teeth are being removed as part of your standard care.
- You do not need to return to the surgeon's office to participate in this study. Questionnaires will be sent to you online or you will be contacted by phone and/or text message.
- You do not have to answer questions that you are uncomfortable answering. However, answering the questions related to your jaw joint, jaw muscle and temple pain will be required for you to participate in the study. These required questions will be noted on your questionnaires. If you do not answer these questions then you will be withdrawn from the study.
- Your contact information will be obtained at the time of study enrollment. We ask that you are willing to be contacted, for study purposes, by the study coordinator and the HealthPartners Data Coordinating Center by email, phone and/or text message.
- We ask that you provide contact information for one other person who will know your (the patient's) whereabouts in the event you cannot be reached. This alternative contact information must be different from your contact information.
- For the purpose of emailing you a signed copy of this consent form for your records, we will collect your email address after you sign this form. The signed copy of your consent form will be emailed to the address that you provide.

Are there any risks to me?

There are potential risks of using the Restful Jaw device. If excessive force is placed on the device by the surgeon, then the device could slide to a slightly different position. However, as soon as this force is stopped, then the device will stop moving. If the device malfunctions and loses pressure during the procedure; this could also affect the support of your jaw. This would create a brief interruption of the procedure to readjust the device to your jaw. A dental assistant will be standing behind you and will be immediately available to take over supporting your jaw.

This research involves collecting information about you and the dental care you are being provided. The collected information will be entered into tablet technology at the time of your treatment and follow-up questionnaires will be completed online. The risk related to this is confidentiality. We will reduce this risk by using a study ID number instead of your name.

Are there any benefits to me?
You will not benefit from being in this research study. However, we hope the information we learn will help others in the future.

How much will it cost to participate?
There are no costs to you for taking part in this research study. Your oral surgery treatment is not related to the study and will be billed as part of your usual care.

Research Related Injury
In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, let the site study investigator, Dr. Rindal, know right away.

Will I be paid to participate?
You will be paid for each submitted questionnaire. You will receive a $25 gift card, via email, for submitting your questionnaires when you enroll in the study, a $25 gift card for submitting your 1-month questionnaire and a third $25 gift card for submitting your 3-month questionnaire. When you submit your 6-month questionnaire, you will receive a $50 gift card. This is a maximum of $125 total payment for the study. A third party service will be used to send electronic gift cards to you by email. To send you gift cards, we will share your email address and the fact that you have completed a study questionnaire with the service provider. You may skip any question that makes you feel uncomfortable. However, answering the questions related to your jaw joint, jaw muscle and temple pain will be required for you to participate in the study.

How long will I be in the study?
You will be in the study for about 6 months. It will take approximately 10-15 minutes to complete questionnaires and to enroll into the study. You will also receive questionnaires 1, 3, and 6 months after your wisdom teeth are removed. Each of these questionnaires will take about 10 minutes to complete. Once the 6-month questionnaire is submitted, you will be done with the study.

Do I have to be in this study?
You do not have to be in this study. If you start the study, you may stop at any time. There is no penalty or loss of benefits if you don't want to participate, and your decision won't affect your regular dental care.

You may decide to participate now, but change your mind and withdraw from the study anytime without penalty or loss of benefits.

What if I am harmed from being in the study?
If you get hurt from being in this study, you should seek medical treatment from your surgeon as needed. We will bill your insurance, if you have any, and you will have to pay your usual copays or deductibles. If you do not have insurance or if your insurance does not cover your treatment, we will bill you for the costs of the treatment.

Will my records be kept confidential?
Your study records will be kept as confidential as possible. We will use a study identification number instead of your name on forms. Study staff will only have access to the information needed to do their work.

Information collected from you about the removal of your wisdom teeth will be encrypted and sent to the HealthPartners Data Coordinating Center. It will be shared with the study team at the University of Minnesota, HealthPartners, McGill University and other sites affiliated with the study. This information may include your date of birth, date of treatment, date of forms completion, oral surgeon and clinic information. This is further described in the HIPAA Authorization.

What if there is new information about this study?

If we learn any new information about this study that might make you change your mind about participating, we will tell you.

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.

Who oversees this study?

HealthPartners Institutional Review Board (IRB) has approved this study. The IRB is a committee of people who review all research studies at HealthPartners to check that they meet federal laws and ethical standards.

IRB approval only means it is ok for the study to begin. *Only you* can decide if being in this study is the right decision. Feel free to talk about this study with your family, friends and personal doctor before you decide.

Who do I contact?

If …	You should contact	Contact information
You are harmed by the research or have a questions about clinical procedures in the study	Dr. D. Brad Rindal	952.967.5026
You have questions about your rights as a research subject	IRB office	952-967-5025

Information about Confidentiality and HIPAA Authorization

The Privacy Rule of the federal Health Insurance Portability & Accountability Act (HIPAA) is a law that protects the confidentiality of your personal health information. This Authorization describes your rights and explains how your health information will be used and disclosed.

Why is access to my health information being requested?

To help answer the research questions, the investigator and research team will use and store personal health information about you. We are asking your permission to use and share it with others, as explained below. If you don't give this permission, you won't be able to take part in the research study.

What information will be collected and used?

When you are a subject, we will collect health information about you that also includes your name, address, telephone number, email address or other data that could identify the health information as yours. Under HIPAA, this health information is protected and can't be used without your permission, unless otherwise permitted by law. If you sign this authorization, you are giving permission for HealthPartners Dental Care to use and disclose your personal dental information as described below.

The collected information may contain your name, address, email address, telephone number, date of birth, dates relating to your third molar treatment procedures, and/or other identifying information. A third party service will be used to send electronic gift cards to you by email. To send you gift cards, we will share your email address and the fact that you completed a study questionnaire with the service provider.

Who will see my protected health information?

By signing this Authorization, you allow the sponsor and research study team members at all sites to use your personal health information to carry out and evaluate this study. You also allow access to your personal health information (including direct access to your dental records at HealthPartners Dental Clinic) to the following:

Who may have access:	Purpose:
The sponsor of the study and anyone working on its behalf	To oversee the study and make sure the information is correct
HealthPartners study consultants and employees, including IRB members	To protect the rights and safety of subjects and make sure the study information is correct
Organizations that regulate research (such as the FDA, Office for Human Research Protections (OHRP), or similar government agencies in the US and other countries)	To make sure applicable laws are being followed
Organizations that grant accreditation to hospitals and research programs	For HealthPartners to remain accredited
University of Minnesota study team members	To complete required study procedures and data analysis
HealthPartners Institute study team members	To complete required study procedures and data analysis
HealthPartners Data Coordinating Center	To complete required study procedures and data transfers
McGill University study team members	To complete data analysis
GiftBit	The third party service that will be used to send electronic gift cards to you by email

Will you keep my health information confidential?

We will keep your personal health information as confidential as possible. We will only share it as described above or if required or permitted by law. It is not likely your information will be given to others without your permission. However, once your information leaves HealthPartners, we can't control how it is used, and it will no longer be covered by the HIPAA Privacy Rule.

Will other people know that I was in this study?

If the results of this study are published, your name or other personal information will not be included.

How long will my personal health information be used?

Access to your personal health information begins as soon as you sign this form. This authorization expires when the study is finished, data analysis is complete, and the study records have been destroyed.

What if I change my mind?

If you don't want us to use and disclose your personal health information anymore, you must let the investigator know in writing. If you need help with this, you can ask the research team or call the HealthPartners IRB office at 952-967-5025.

If you withdraw permission for us to use your personal health information

- you can't continue in the research study;
- we will stop collecting health information from you;
- we will still use and disclose any information that we gathered while you were a subject;
- there will not be any penalty or loss of benefits to which you are otherwise entitled.

Can I see my study records?

You have the right to see and get a copy of your study records. However, by signing this Authorization, you agree that you will not be able to see your study records during the research study. You can only see them once the whole study is complete. The whole study is expected to last approximately 2 years.

Subject name (print): _____

- I have read this form and the research study has been explained to me.
- I have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions.
- I agree to be in the research study described above.
- I will receive a copy of this consent form after I sign it. A copy will be put in my medical record and/or study record.
- I am not giving up any of my legal rights by signing this form.

_____

Subject signature Date

Email address: _____

Confirm Email address: _____

For Site Use only:

- I have carefully explained to the subject the nature and purpose of this study.
- The subject has been given enough time and an adequate place to read and review this form.
- The subject has had a chance to ask questions and receive answers about this study.
- I have explained and discussed the nature of the research
- I have explained and discussed potential risks and benefits
- The alternate treatments available to the subject and the benefits and risks of each

Name of person obtaining informed consent (print)	Title	Phone number

Signature of person obtaining informed consent	Date

HealthPartners, Inc.
Consent to Participate in a Research Study

Study Title	The Restful Jaw Device: A New Way to Support and Protect the Jaw during Third Molar Extractions
Study Investigator	Dr. D. Brad Rindal HealthPartners Institute 952.967.5026 952.486.3952
Study Team Coordinator	Kim Johnson 952.967.5276
Sponsor	NIH/NIDCR

Introduction

We are asking you to take part in a research study regarding a new device that supports the jaw during surgical removal of 3rd molars. Research studies include only people who choose to take part. It is your choice if you want to be in the study. No one can force you to be in the study. You do not have to participate in this study. If you decide not to participate in this study, you will not be penalized and you will not lose any benefit you are entitled to. The study doctor will also describe the study to you.

Before you decide to participate in this study, it is important that you read this information thoroughly to understand why the research is being done and what it would involve for you. This informed consent form explains the purpose of the study and what will happen if you take part. The study coordinator will describe the study and go through this consent form with you and answer any questions you have. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family.

If you decide to take part in this research study, you will be asked to sign and date this consent form and you will be given a copy of the signed and dated consent form.

Why am I being asked to participate?

You are being asked whether you would like to voluntarily participate in a research study about a jaw support device because you work as a dental assistant in an oral & maxillofacial surgeon's office/clinic that is participating in this study.

What is the purpose of this study?

When 3rd molars are surgically removed, the patient must tense their jaw muscles to oppose the downward forces placed on their jaw. Furthermore, when patients are sedated, it decreases their ability to counter this downward force to prevent injury to their jaw. That is why a dental assistant stands behind the dental chair to support the jaw. The Restful Jaw device was developed to support the jaw instead of having the assistant do it. We would like to test this device to find out if it can relieve the dental assistant from having to support the patient's jaw with their hands. We also want to know if using the device decreases jaw pain after surgery as compared to the dental assistant holding the jaw. This information may help surgeons in the future to care better for their patients by reducing jaw pain or discomfort after wisdom teeth are removed. This study involves an investigational device. Investigational means that the device is not approved by the FDA. This study will help inform the approval of this device to the FDA.

Who is sponsoring this study?

HealthPartners Institute is receiving financial support from the National Institutes of Health (NIH) ("the Sponsor") to assist in conducting this research study. The amount of payment is enough to cover the study doctor's and/or institution's expenses to perform the study.

Dr. Brad Rindal is the study investigator and is also an investor in Restful Jaw, LLC, the company that makes the Restful Jaw device. Dr. Rindal is not involved in the collection of any information and will not have access to the data from this study.

Where will this study take place?

This study will take place at the HealthPartners Como Clinic and the HealthPartners Eden Prairie Clinic. We expect to about 50 patients will be enrolled by each surgeon in this research study. Surgeons at up to four (4) sites in Minnesota will enroll a total of about 294 patients.

What is involved?

If you agree to take part in this study, you will sign this consent form before any study-related procedures are performed. The investigator and research team will confirm your interest to participate in the study.

- You will be trained in the use of the device by the research coordinator in the dental office where the device will be used prior to starting the study.
- You will use the device when assisting the oral and maxillofacial surgeon on patients requiring surgical removal of 3rd molars.
- If the surgeon determines that there is a need to stop using the device, he/she will do so, or direct you to do so.
- You will provide feedback to the study team regarding your experience using the device.
- You will be asked to answer a brief questionnaire at the midpoint and end of the study about your experience while using the device. The questionnaire includes questions pertaining to how well the device fit, time needed to set up and remove the device, and use of the device during surgical extractions. If after reading the questionnaire, you would prefer not to answer one or more of the questions that is your choice. The total time needed to complete the questionnaire should be no more than 5-10 minutes.
- We ask that you provide your email address at enrollment so that we can send you the forms to provide your feedback to the study team about your experience with the device.

Are there any risks to me?

There are no physical risks that you should anticipate by participating in the study.

Are there any benefits to me?

You will not benefit from being in this research study. However, we hope the information we learn will help others in the future.

How much will it cost to participate?

Taking part in this research study will not lead to any costs to you.

Will I be paid to participate?

You will not be paid to participate in this study.

How long will I be in the study?

We expect that you will be in this research study for the length of time it takes to complete recruitment of patients.

Do I have to be in this study?

You do not have to be in this study. If you start the study, you may stop at any time. There is no penalty or loss of benefits if you don't want to participate, and your decision won't affect your relationship with your oral surgeon or HealthPartners. You may decide to participate now, but change your mind and withdraw from the study anytime without penalty.

What if there is new information about this study?

If we learn any new information about this study that might make you change your mind about participating, we will tell you.

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.

Who oversees this study?

HealthPartners Institutional Review Board (IRB) has approved this study. The IRB is a committee of people who review all research studies at HealthPartners to check that they meet federal laws and ethical standards.

IRB approval only means it is ok for the study to begin. *Only you* can decide if being in this study is the right decision. Feel free to talk about this study with your family and friends before you decide.

Who do I contact?

If …	You should contact	Contact information
You are harmed by the research or have a questions about clinical procedures in the study	D. Brad Rindal	952.967.5026
You have questions about your rights as a research subject	IRB office	952-967-5025

Subject name: _____

- I have read this form and the research study has been explained to me.
- I have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions.
- I agree to be in the research study described above.
- I will receive a copy of this consent form after I sign it. A copy will be put in my medical record and/or study record.
- I am not giving up any of my legal rights by signing this form.

_____

Subject signature Date

For Site Use only:

- I have carefully explained to the subject the nature and purpose of this study.
- The subject has been given enough time and an adequate place to read and review this form.
- The subject has had a chance to ask questions and receive answers about this study.
- I have explained and discussed the nature of the research
- I have explained and discussed potential risks and benefits

Name of person obtaining informed consent (print)	Title	Phone number

Signature of person obtaining informed consent	Date

HealthPartners, Inc.
Consent to Participate in a Research Study

Study Title	The Restful Jaw Device: A New Way to Support and Protect the Jaw during Third Molar Extractions
Study Investigator	Dr. D. Brad Rindal HealthPartners Institute 952.967.5026 952.486.3952
Study Team Coordinator	Kim Johnson 952.967.5276
Sponsor	NIH/NIDCR

Introduction

We are asking you to take part in a research study regarding a new device that supports the jaw during surgical removal of 3rd molars. Research studies include only people who choose to take part. It is your choice if you want to be in the study. No one can force you to be in the study. You do not have to participate in this study. If you decide not to participate in this study, you will not be penalized and you will not lose any benefit you are entitled to. The study coordinator will also describe the study to you.

Before you decide to participate in this study, it is important that you read this information thoroughly to understand why the research is being done and what it would involve for you. This informed consent form explains the purpose of the study and what will happen if you take part. The study coordinator will describe the study and go through this consent form with you and answer any questions you have. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family.

If you decide to take part in this research study, you will be asked to sign and date this consent form and you will be given a copy of the signed and dated consent form.

Why am I being asked to participate?

You are being asked to voluntarily participate in a research study regarding a jaw support device because you are an oral & maxillofacial surgeon at HealthPartners.

What is the purpose of this study?

When 3rd molars are surgically removed, the patient must tense their jaw muscles to oppose the downward forces placed on their jaw. Furthermore, when patients are sedated, it decreases their ability to counter this downward force to prevent injury to their jaw. That is why a dental assistant stands behind the dental chair to support the patient's jaw with their hands. The Restful Jaw device was developed to support the jaw instead of having the assistant do it. We would like to test this device to find out if it can relieve the dental assistant from having to support the jaw. We also want to know if using the device decreases jaw pain after surgery as compared to the dental assistant holding the jaw. This information may help surgeons in the future to care better for their patients by reducing jaw pain or discomfort after wisdom teeth are removed. This study involves an investigational device. Investigational means that the device is not approved by the FDA. This study will help inform the approval of this device to the FDA.

Who is sponsoring this study?

HealthPartners Institute is receiving financial support from the National Institutes of Health (NIH) ("the Sponsor") to assist in conducting this research study. The amount of payment is enough to cover the study doctor's and/or institution's expenses to perform the study.

Dr. Brad Rindal is the study investigator and is also an investor in Restful Jaw, LLC, the company that makes the Restful Jaw device. Dr. Rindal is not involved in the collection of any information and will not have access to the data from this study.

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 will this study take place?

This study will take place at the HealthPartners Como Clinic and the HealthPartners Eden Prairie Clinic. Seven investigators at up to four (4) sites in Minnesota will enroll approximately 294 patients.

What is involved?

If you agree to take part in this study, you will sign this consent form before any study-related procedures are performed. The investigator and research team will confirm your interest to participate in the study.

- You will be trained in the use of the device by the research coordinator in the dental office where the device will be used prior to starting the study.
- You will use the device on patients requiring surgical removal of their bilateral mandibular 3rd molar with moderate/deep sedation or general anesthesia (concurrent maxillary wisdom teeth allowed).
- If you determine that there is a need to stop using the device, you will remove it, or direct your assistant to do this
- You will complete a questionnaire regarding each patient's procedure.
- You will provide feedback to the study team regarding your experience using the device.
- You will complete a brief questionnaire at the midpoint and end of the study regarding your experience using the device. The questionnaire includes questions pertaining to how well the device fit, and use of the device during the surgical procedures. If after reading the questionnaire, you would prefer not to answer one or more of the questions that is your choice. The total time needed to complete the questionnaire should be no more than 5-10 minutes.
- We ask that you provide your email address at enrollment so that we can send you the forms to provide feedback to the study team about your experience with the device.

Are there any risks to me?

There are no physical risks that you should anticipate by participating in the study. This research involves collecting information about you and the dental care you provide to your patients enrolled into the study. The risk related to this is confidentiality. We will reduce this risk by using a study ID number instead of your name.

Are there any benefits to me?

There are no benefits that you should anticipate by participating in the study.

How much will it cost to participate?

Taking part in this research study will not lead to any costs to you.

Will I be paid to participate?

You or your institution will be paid $100 per patient, minus the cost of the iPad, for each baseline questionnaire you complete. You or your institution will only be paid for the questionnaires you complete. Payment will be made at the completion of your data collection phase and all forms have been received by the Data Coordinating Center.

If your total research study payments within one calendar year exceed $600, HealthPartners Institute must notify and report this income to the Internal Revenue Service and provide them with your name, social security number, address and amount of payment, but no information about the nature of the study(s). You will be asked for your Social Security number and address before you are compensated for participating in this study. You will receive from HealthPartners Institute an IRS form 1099 Miscellaneous Income in January of the year following your participation in this study.

How long will I be in the study?

You will remove bilateral mandibular 3rd molars on a target of 42-49 patients (may also include concurrent maxillary wisdom teeth). We anticipate a data collection phase of approximately 10 months.

Do I have to be in this study?

You do not have to be in this study. If you start the study, you may stop at any time. There is no penalty or loss of benefits if you don't want to participate, and your decision won't affect your relationship with HealthPartners. You may decide to participate now, but change your mind and withdraw from the study anytime without penalty. If you decide to withdraw from the study, let the investigator know.

Who oversees this study?

HealthPartners Institutional Review Board (IRB) has approved this study. The IRB is a committee of people who review all research studies at HealthPartners to check that they meet federal laws and ethical standards.

IRB approval only means it is ok for the study to begin. *Only you* can decide if being in this study is the right decision. Feel free to talk about this study with your family, friends and personal doctor before you decide.

Who do I contact?

If …	**You should contact**	**Contact information**
You are harmed by the research or have a questions about clinical procedures in the study	D. Brad Rindal	952.967.5026
You have questions about your rights as a research subject	IRB office	952-967-5025

Subject name: _____

- I have read this form and the research study has been explained to me.
- I have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions.
- I agree to be in the research study described above.
- I will receive a copy of this consent form after I sign it. A copy will be put in my medical record and/or study record.
- I am not giving up any of my legal rights by signing this form.

_____

Subject signature Date

For Site Use only:

- I have carefully explained to the subject the nature and purpose of this study.

- The subject has been given enough time and an adequate place to read and review this form.
- The subject has had a chance to ask questions and receive answers about this study.
- I have explained and discussed the nature of the research
- I have explained and discussed potential risks and benefits
- The alternate treatments available to the subject and the benefits and risks of each

Name of person obtaining informed consent (print)	Title	Phone number

Signature of person obtaining informed consent	Date

Information about Confidentiality and HIPAA Authorization

The Privacy Rule of the federal Health Insurance Portability & Accountability Act (HIPAA) is a law that protects the confidentiality of your personal health information. This Authorization describes your rights and explains how your health information will be used and disclosed.

Why is access to my health information being requested?

To help answer the research questions, the investigator and research team will use and store personal health information about you. We are asking your permission to use and share it with others, as explained below. If you don't give this permission, you won't be able to take part in the research study.

What information will be collected and used?

When you are a subject, we will collect health information about you that also includes your name, address, telephone number, email address or other data that could identify the health information as yours. Under HIPAA, this health information is protected and can't be used without your permission, unless otherwise permitted by law. If you sign this authorization, you are giving permission for HealthPartners Dental Care to use and disclose your personal dental information as described below.

The collected information may contain your name, clinic address, email address, telephone number, date of birth, dates relating to third molar treatment procedures, and/or other identifying information.

Who will see my protected health information?

By signing this Authorization, you allow the sponsor and research study team members at all sites to use your personal health information to carry out and evaluate this study. You also allow access to your personal health information (including direct access to dental records at HealthPartners Dental Clinic) to the following:

Who may have access:	Purpose:
The sponsor of the study and anyone working on its behalf	To oversee the study and make sure the information is correct
HealthPartners study consultants and employees, including IRB members	To protect the rights and safety of subjects and make sure the study information is correct
Organizations that regulate research (such as the FDA, Office for Human Research Protections (OHRP), or similar government agencies in the US and other countries)	To make sure applicable laws are being followed
Organizations that grant accreditation to hospitals and research programs	For HealthPartners to remain accredited
University of Minnesota study team members	To complete required study procedures and data analysis
HealthPartners Institute study team members	To complete required study procedures and data analysis
HealthPartners Data Coordinating Center	To complete required study procedures and data transfers
McGill University study team members	To complete data analysis

Will you keep my health information confidential?

We will keep your personal health information as confidential as possible. We will only share it as described above or if required or permitted by law. It is not likely your information will be given to others without your permission. However, once your information leaves HealthPartners, we can't control how it is used, and it will no longer be covered by the HIPAA Privacy Rule.

Will other people know that I was in this study?

If the results of this study are published, your name or other personal information will not be included.

How long will my personal health information be used?

Access to your personal health information begins as soon as you sign this form. This authorization expires when the study is finished, data analysis is complete, and the study records have been destroyed.

What if I change my mind?

If you don't want us to use and disclose your personal health information anymore, you must let the investigator know in writing. If you need help with this, you can ask the research team or call the HealthPartners IRB office at 952-967-5025.

If you withdraw permission for us to use your personal health information

- you can't continue in the research study;
- we will stop collecting health information from you;
- we will still use and disclose any information that we gathered while you were a subject;
- there will not be any penalty or loss of benefits to which you are otherwise entitled.

Can I see my study records?

You have the right to see and get a copy of your study records. However, by signing this Authorization, you agree that you will not be able to see your study records during the research study. You can only see them once the whole study is complete. The whole study is expected to last approximately 2 years.

Subject name (print): _____

- I have read this form and the research study has been explained to me.
- I have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions.
- I agree to be in the research study described above.
- I will receive a copy of this consent form after I sign it. A copy will be put in my medical record and/or study record.
- I am not giving up any of my legal rights by signing this form.

_____

Subject signature Date

For Site Use only:

- I have carefully explained to the subject the nature and purpose of this study.
- The subject has been given enough time and an adequate place to read and review this form.
- The subject has had a chance to ask questions and receive answers about this study.
- I have explained and discussed the nature of the research
- I have explained and discussed potential risks and benefits
- The alternate treatments available to the subject and the benefits and risks of each

_____

Name of person obtaining informed consent (print) Title Phone number

_____

Signature of person obtaining informed consent Date

Restful Jaw Dental Assistant Consent Form

Title of Research Study: The Restful Jaw Device: A New Way to Support and Protect the Jaw during Third Molar Extractions; RJ2 Feasibility

Investigator Team Contact Information:

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Clinical Site Principal Investigator Name: Dr. Rachel Uppgaard Investigator Departmental Affiliation: Department of Developmental and Surgical Sciences Phone Number: 612.301.2233 Email Address: uppg0003@umn.edu	Study Staff/Study Coordinator: Kimberly S. Johnson Phone Number: 651.210.7077 Email Address: knigh118@umn.edu

Supported By: This research is supported by the National Institute for Dental and Craniofacial Research (NIDCR).

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

Oral and maxillofacial surgeons and study investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of clinical care is to help you get better or to improve your quality of life. Oral surgeons can make changes to your clinical care plan as needed.

Research and clinical care are often combined. One purpose of this informed consent document is to provide you clear information about the specific research activities of this study.

Why am I being asked to take part in this research study?

You are being asked whether you would like to voluntarily participate in a research study about a jaw support device because you work as a dental assistant in an oral & maxillofacial surgeon's office/clinic that is participating in this study.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

When 3rd molars are surgically removed, the patient must tense their jaw muscles to oppose the downward forces placed on their jaw. Furthermore, when patients are sedated, it decreases their ability to counter this downward force to prevent injury to their jaw. That is why a dental assistant stands behind the dental chair to support the jaw. The

Restful Jaw device was developed to support the jaw instead of having the assistant do it. We would like to test this device to find out if it can relieve the dental assistant from having to support the patient's jaw with their hands. We also want to know if using the device decreases jaw pain after surgery as compared to the dental assistant holding the jaw. This information may help surgeons in the future to care better for their patients by reducing jaw pain or discomfort after wisdom teeth are removed. This study involves an investigational device. Investigational means that the device is not approved by FDA. This study will help inform the approval of this device to the FDA.

How long will the research last?

The oral and maxillofacial surgeons participating in this study will extract mandibular wisdom teeth in 42-29 patients (may also include concurrent maxillary wisdom teeth). We anticipate a data collection phase of approximately 10 months.

What will I need to do to participate?

You will be asked to complete the consent process, be trained on how to use the device, assist oral and maxillofacial surgeon(s) during the study and complete two (2) forms about your experience with the device.

Will being in this study help me in any way?

This research will not directly benefit you. However, we hope the information we learn will help others in the future.

What happens if I do not want to be in this research?

You do not have to participate in this research. Your decision whether or not to participate in this study will not affect your current or future relations with the University of Minnesota Dental School or your Oral & Maxillofacial Surgeon in any way.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

There are seven (7) oral and maxillofacial surgeons participating in this research study enrolling a total of 294 patients across four (4) sites. Dental assistants who work with the participating oral & maxillofacial surgeons may enroll in the study.

What happens if I say "*Yes, I want to be in this research*"?

- If you are interested in the study, we ask that you assist while the device is used during 3rd molar surgical extraction cases for up to 25 patients who consent to participate in the study and are randomized into the device group.
- Dental assistants will be formally and uniformly trained on site by the research coordinator in the dental office where the device will be employed prior to any procedure being performed by the surgeon who will utilize the device.
- We ask that you provide feedback to the study team about the device and your experience using the device on patients requiring moderate/deep sedation or general anesthesia for bilateral mandibular 3rd molar surgical extractions.
- If the surgeon determines that there is a need to disengage the device, he/she will do so, or direct the dental assistant to do so. At that that time the team focus will be on the patient, the depth of anesthesia and the need, if any for airway support, which includes "holding the jaw".
- You will be trained at the protocol training on how to press either the red button on the chair or the foot pedal for the device when directed to do so by the surgeon performing the procedure.
- You will be asked to answer a brief questionnaire at the midpoint of data collection and at the end of data collection about your experience while using the device. The questionnaire includes questions pertaining to how well the device fit, time needed to set up and remove the device, and use of the device during surgical extractions. If after reading the questionnaire, you would prefer not to answer one or more of the questions that is your choice. The total time needed to complete the questionnaire should be no more than 5-10 minutes.

- We ask that you provide your email address at enrollment so that we can send you the forms to provide your feedback to the study team about your experience with the device.
- The research is being done through the University of Minnesota, HealthPartners and one additional clinic in the community.

What happens if I say "Yes", but I change my mind later?

You can leave the research study at any time and no one will be upset by your decision. Let your oral surgeon or the research coordinator know you do not want to continue.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. This means that your choice not to be in this study will not negatively affect your present or future employment.

What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)

There are no physical risks that you should anticipate by participating in the study.

This research may hurt you in the following ways:

The only possible difficulty would be the loosening of the device with loss of jaw support during the procedure. If that did occur, you would need to immediately provide support to the patient's jaw. In addition to these risks, this research may impact you in ways that are unknown.

Will it cost me anything to participate in this research study?

There are no costs to you for taking part in this research study.

Will being in this study help me in any way?

There is no direct benefit to your participation in this study. However, we hope the information we learn will help others in the future.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance.

Study data will be encrypted according to current University policy for protection of confidentiality. De-identified data collected for this study will be shared with study team members at the University of Minnesota, McGill University, HealthPartners Institute, HealthPartners Coordinating Center, NIDCR (the funder) and other sites affiliated with the study.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 or go to https://research.umn.edu/units/hrpp/research-participants/questions-concerns. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.

- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let your surgeon know right away.

Will I be compensated for my participation?

You will receive no monetary compensation for your time involved in the study.

Who is sponsoring this study?

The University of Minnesota School of Dentistry is receiving financial support from the National Institutes of Health (NIH) ("the Sponsor") to assist in conducting this research study. The amount of payment is enough to cover the study doctor's and/ or institution's expenses to perform the study.

What if there is new information about this study?

If we learn any new information about this study that might make you change your mind about participating, we will tell you.

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.

Use of Identifiable Health Information

The results of this study may be used for teaching, publications, or for presentation at scientific meetings. Results will be aggregated and not identifiable.

Statement of Consent

I have read the above information. I have asked questions and have received satisfactory answers. Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent

Restful Jaw Patient Consent Form

Title of Research Study: The Restful Jaw Device: A New Way to Support and Protect the Jaw during Third Molar Extractions

Investigator Team Contact Information:

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Clinical Site Principal Investigator Name: Dr. Rachel Uppgaard, DDS Investigator Departmental Affiliation: Department of Developmental and Surgical Sciences Phone Number: 612.301.2233 Email Address: uppg0003@umn.edu	Study Coordinator: Kimberly S. Johnson Phone Number: 651.210.7077 Email Address: knigh118@umn.edu

Supported By: This research is supported by the National Institute of Dental and Craniofacial Research (NIDCR).

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

Oral and maxillofacial surgeons and study investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of clinical care is to help you get better or to improve your quality of life. Surgeons can make changes to your clinical care plan as needed.

Research and clinical care are often combined. One purpose of this informed consent document is to provide you clear information about the specific research activities of this study.

Why am I being asked to take part in this research study?

You are being asked to voluntarily participate in a research study regarding a jaw support device because you are having your wisdom teeth removed.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

When wisdom teeth are removed, the patient must tense their jaw muscles to oppose the downward forces placed on their jaw. Furthermore, when patients are sedated, it decreases their ability to counter this downward force to prevent injury to their jaw. That is why a dental assistant stands behind the dental chair to support the patient's jaw with their hands. The Restful Jaw device was developed to support the jaw instead of having the assistant do it. We would like to test this device to find out if it can relieve the dental assistant from having to support the jaw. We also want to know if using the device decreases jaw pain after surgery as compared to the dental assistant holding the jaw. This information may help surgeons in the future to care better for their patients by reducing jaw pain or discomfort after wisdom teeth are removed. This study involves an investigational device. Investigational means that the device is not approved by the FDA. This study will help inform the approval of this device to the FDA.

How long will the research last?

We expect that you will be in this research study for about 6 months. It will take approximately 10-15 minutes to complete questionnaires and to enroll into the study. You will also receive questionnaires 1, 3 and 6 months after your wisdom teeth are removed. Each of these questionnaires will take about 10 minutes to complete. Once your 6-month questionnaire is submitted, you will be done with the study.

What will I need to do to participate?

If you are interested in the study, you will be randomly assigned to either have the device support your jaw or not during your wisdom teeth removal.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

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

There are potential risks of using the Restful Jaw device. If excessive force is placed on the device by the surgeon, then the device could slide to a slightly different position. However, as soon as this force is stopped, then the device will stop moving. If the device malfunctions and loses pressure during the procedure, this could also affect the support of your jaw. This would create a brief interruption of the procedure to readjust the device to your jaw. A dental assistant will be standing behind you and will be immediately available to take over supporting your jaw.

This research involves collecting information about you and the dental care you are being provided. The collected information will be entered into tablet technology at the time of your treatment and follow-up questionnaires will be completed online. A risk of this research is loss of privacy (revealing to others that you are taking part in this study) or confidentiality (revealing information about you to others whom you have not given permission to see this information). Confidentiality will be maintained by keeping research records in locked file drawers within a locked office. Each participant will be given an identification number instead of names to ensure confidentiality of the data files. The information linking participants' names and identification number will be kept in a locked room in locked file cabinets. Once collected, your data will not be available to anyone other than the investigators involved in this project. Most text messaging and email communication does not involve secure servers. Using these procedures diminishes the extent to which confidentiality can be assured. Subjects should be informed of this limitation.

Will being in this study help me in any way?

You will not benefit from being in this research study. However, we hope the information we learn will help others in the future.

What happens if I do not want to be in this research?

You do not have to participate in this research. Your decision whether or not to participate in this study will not affect

your current or future relations with the University of Minnesota Dental School or your dental practitioner in any way.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect about 50 patients will be enrolled by each surgeon in this research study. Surgeons at up to four (4) sites in Minnesota will enroll a total of about 294 patients.

What happens if I say "*Yes, I want to be in this research*"?

- If you agree to be in the study, you will be asked to complete a contact form, a demographic form, and a questionnaire on a tablet *before* your wisdom teeth are removed. After your wisdom teeth are removed, you'll complete online, or over the phone, a 1-, 3-, and 6-months questionnaire. Your participation will end when you submit your 6-month questionnaire.
- You will be randomized to one of the two (2) groups. Randomized means being assigned to a group by chance, like flipping a coin or drawing names out of a hat. You have a 1 in 2 chance of being assigned to each group. Group 1 will receive usual care where a dental assistant holds your jaw during surgery. Group 2 will have the jaw device supporting their jaw. *You cannot choose which group you will be in.*
- If you are randomized into the jaw support device group, the device will be fully explained and demonstrated to you before the dental assistant or surgeon places the device in a position that will support your jaw. The device will stay in place while you have your wisdom teeth removed. It will be removed when the surgery is done.
- Using the device is part of the research study. Your wisdom teeth are being removed as part of your standard care.
- You do not need to return to the surgeon's office to participate in this study. Questionnaires will be sent to you online or you will be contacted by phone and/or text message.
- You do not have to answer questions that you are uncomfortable answering. However, answering the questions related to your jaw joint, jaw muscle and temple pain will be required for you to participate in the study. These required questions will be noted on your questionnaires. If you do not answer these questions then you will be withdrawn from the study.
- Your contact information will be collected at the time of study enrollment. We ask that you are willing to be contacted, for study purposes, by the study coordinator and the HealthPartners Data Coordinating Center by email, phone and/or text message.
- We ask that you provide contact information for one other person who will know your whereabouts in the event you cannot be reached. This alternative contact information must be different from your contact information.
- For the purpose of emailing you a signed copy of this consent from for your records, we will collect your email address after you sign this form. The signed copy of your consent and HIPAA forms will be emailed to the address that you provide.

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

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

- Allowing the device to be placed in a comfortable position that will support your jaw.
- Completing questionnaires including any questions about your pain.

What happens if I say "Yes", but I change my mind later?

You do not have to be in this study. If you start the study, you may stop at any time. There is no penalty or loss of benefits if you don't want to participate, and your decision won't affect your dental care.

You may decide to participate now, but change your mind and withdraw from the study anytime and no one will be

upset by your decision.

What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)

There are no additional risks beyond what has already been stated above.

Will it cost me anything to participate in this research study?

There are no costs to you for taking part in this research study. Your oral surgery treatment is not related to the study and will be billed as part of your usual care.

Will being in this study help me in any way?

There is no direct benefit to your participation in this study.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and dental records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance.

The sponsor, monitors, auditors, the IRB, the University of Minnesota Research Compliance Office and other University compliance units, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), the US Food and Drug Administration (FDA) may be granted direct access to your dental 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.

Information collected from you about the removal of your wisdom teeth will be encrypted according to University policy for protection of confidentiality. Your information will be sent to study team members at the University of Minnesota, McGill University, HealthPartners Institute, HealthPartners Coordinating Center, NIDCR (the funder) and other sites affiliated with the study. For example, this information may include your date of birth, date of treatment, date of forms completion, email address, oral surgeon and clinic information. This is further described in the HIPAA Authorization.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 or go to https://research.umn.edu/units/hrpp/research-participants/questions-concerns. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study oral surgeon know right away.

Will I be compensated for my participation?

You will be paid for each submitted questionnaire. You will receive a $25 gift card, via email, for submitting your questionnaires when you enroll in the study, a $25 gift card for submitting your 1-month questionnaire and a third $25 gift card for submitting your 3-month questionnaire. When you submit your 6-month questionnaire, you will receive a $50 gift card. This is a maximum of $125 total payment for the study. A third party service will be used to send electronic gift cards to you by email. To send you gift cards, we will share your email address and the fact that you completed a study questionnaire with the service provider. You may skip any question that makes you feel uncomfortable. However, answering the questions related to your jaw joint, jaw muscle and temple pain will be required for you to participate in the study.

Who is sponsoring this study?

The University of Minnesota School of Dentistry is receiving financial support from the National Institutes of Health (NIH) to assist in conducting this research study. The amount of payment is enough to cover the study surgeon's expenses to perform the study.

What if there is new information about this study?

If we learn any new information about this study that might make you change your mind about participating, we will tell you.

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.

Use of Identifiable Health Information

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your dental records and information that can identify you. For example, personal health information may include your name, address, phone number, date of birth, date of treatment, date of forms completion, email address. oral surgeon or clinic location. Those persons who get your health information may not be required by Federal privacy laws (such as the 1099 Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Statement of Consent

I have read the above information. I have asked questions and have received satisfactory answers. Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

Email address: _____

Confirm Email address: _____

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent

UNIVERSITY OF MINNESOTA

PERMISSION TO USE PERSONAL HEALTH INFORMATION FOR RESEARCH
HIPAA[1] AUTHORIZATION FORM

IRB Study Number: 5987
Study Title: The Restful Jaw Device: A New Way to Support and Protect the Jaw During Third Molar Extractions
Principal Investigator Name: Dr. Rachel Uppgaard
Principal Investigator Mailing Address: Department of Developmental and Surgical Sciences, Room 7-174 Moos Tower, 515 Delaware St SE, Mpls, MN 55455

A. What is the purpose of this form?

State and federal privacy laws protect the use and release of your health information. Under these laws, your health care provider cannot release your health information for research purposes unless you give your permission. The purpose of this form is to give your permission to your health care provider to release your personal health information to the research team. Your information may then be used by the research team for the research described in the Consent Form, and may also be shared by the research team with others, including those who support the research, have oversight over the research, or sponsor the research, as explained below. This form also describes the type of personal health information that would be released by your health care provider. If you decide to give your permission and to participate in the study, you must sign this form and the Consent Form. You should be aware that once your personal health information is released by your health care provider it may not be protected by privacy laws, and might be shared with others beyond those described in this form or the Consent Form. If you have any questions about this form or the use of your information, ask a member of the research team.

B. What information will be released?

The research team has marked the boxes below for information needed to participate in this study. If you sign this form, your health care provider will release your personal health information as marked below:

- ☐ All Hospital Records
- ☐ All Clinic Records
- ☐ Emergency Dept. Records
- ☒ Dental Records
- ☐ Immunization Records
- ☐ History & Physical Exams
- ☐ Imaging Reports
- ☐ Progress Notes
- ☐ Psychological Tests
- ☐ EEG/EKG/ECHO Reports
- ☐ Lab & Pathology Reports
- ☐ Financial Records

[1] HIPAA is the Health Insurance Portability and Accountability Act of 1996, a federal law related to privacy of health information.

☐ Images	☒ Other (describe): Name, address, date of birth, date of treatment and treatment provided, telephone number(s), email address, demographic information, date of forms completion, clinic location, oral surgeon, name and phone number of a second contact in case we can't reach you during your enrollment in the study, and information relating to your wisdom teeth extraction and your jaw and temple pain.

C. What about more sensitive health information?

Certain personal health information is so sensitive that it requires your specific permission. If the research study you are participating in requires any of this information, the boxes below will be marked and you will be asked to initial to permit the release of this information to the research team.

☐ I agree to the release of drug and alcohol abuse, diagnosis and treatment records. ____(initial)
☐ I agree to the release of HIV/AIDS testing records.____ (initial)
☐ I agree to the release of genetic testing records._____ (initial)
☐ I agree to the release of mental health diagnosis or treatment records._____ (initial)
☐ I agree to the release of sickle cell anemia records._____ (initial)

D. Who will receive and use my health information?

Your personal health information may be shared with:

1. The research team conducting the research described in the Consent Form, including any affiliated research institutions involved in conducting the research described in the Consent Form;
2. Others at M Health and the University of Minnesota who provide support for the research or who have authority to oversee research (such as systems administrators and other technical and/or administrative support personnel, compliance and audit professionals, individuals involved in processing any compensation you may receive for your participation, and others);
3. The research sponsor(s), any affiliates or partners of the sponsor(s) involved in the research, organizations funding the research, and any affiliates or partners of the funding organization(s) involved in the research;
4. Other organizations who provide accreditation and oversight for the research team; and Others who are authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration or the Office of Human Research Protections, or government agencies in other countries).

E. Am I required to sign this document?

No, you are not required to sign this document. However, if you do not sign the document, you will not be able to participate in this research study and will not receive any treatment that may be provided through the study. Any other treatment, payment, enrollment or eligibility for benefits will not be affected by your decision about signing this document.

F. Will I be able to view my records?

To make sure that the research study is not impacted by any actions you take, it is possible that the research team may not allow you to see the information collected for this study, including information placed in your medical records, until after the study is complete. Once the study is over, you may view the records.

G. Optional research activity

The study that you are participating might have optional research activities associated with it, such as the creation of a database for possible future research, as described in the Consent Form and as marked below by the research team. If you agree to permit your information to be used for those optional research activities, you must initial below.

☒ There are no optional research activities**.** _____ (initial)

☐ The research I am participating in has an additional optional research activity to create a database for possible future research, as explained in the Consent Form. I understand I can agree to have my information shared for this purpose or not. _____(initial)

☐ The research I am participating in has an additional optional research activity to create a tissue or biospecimen repository for possible future research, as explained in the Consent Form. I understand I can agree to have my information shared for this purpose or not. _____ (initial)

H. Does my permission expire?

This permission expires when the research ends and all required study monitoring is over, including any optional research activities I agree to above.

I. Can I cancel my permission?

You can cancel your permission at any time. To cancel your permission, you can write to the researcher at the address at the top of this form. If you cancel your permission, you will no longer be in the research study. You may want to ask someone on the research team if canceling will affect any research related medical treatment. If you cancel, information that was already collected and disclosed about you may continue to be used for the research study. Also, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

J. Signature

If you agree to the use and release of your personal health information as described in this document, please print your name and sign below. You will be given a signed copy of this form**.**

_____
Research Participant's Name (print) (*required even if signed by parent/legal representative*)

_____ _____
Research Participant's Signature Date

Parent or Legally Authorized Representative

If you agree to the use and release of the Personal Health Information of the Research Participant named above, please print your name and sign below.

_____
Parent or Legally Authorized Representative's Name (print)

_____
Relationship to the Research Participant

_____ _____
Parent or Legally Authorized Representative's Signature Date

Witness

If this form is being read to the Research Participant because s/he cannot read the form, a witness must be present and is required to print his/her name and sign here:

_____
Witness' Name (print)

_____ _____
Witness' Signature Date

Instructions for Researchers: <u>Do not make any changes</u> to this form other than the following items:

The IRB **will not** be confirming the accuracy of the information you complete on this form. The researchers are responsible for accurately completing the HIPAA Research Authorization as follows:

1. Section B: Mark all sources of PHI that will be released to the research team from M Health or other providers.

2. Section C:
   a. Check the box ***only*** for each specific type of information that will be collected for this study
   b. Records for drug and alcohol abuse, diagnosis and treatment are records related to admissions to treatment centers; records for mental health diagnosis or treatment are records related to admissions to mental health units
   c. Obtain the participant's initials ***only*** *for the specific types of information checked*

3. Section G:
   a. Check the boxes indicating if there are optional research activities or not
   b. Obtain the participant's initial *only if the study involves optional research activity*

4. Section J: Obtain the participant's name, signature, and date; *complete subsequent signature lines* ***if applicable***

5. Provide the subject with a signed copy of the form

Note: This form allows you to check the boxes electronically. You can make a 'master version' of this form for this study with all pertinent boxes checked.

GUIDELINES AND CONSENT FOR TEXT MESSAGE CORRESPONDENCE FOR RESEARCH PARTICIPANTS

1. Purpose. By signing this form, you agree that we may communicate with you by text message. This form identifies some of the risks of text message use, provides guidelines for its use, and documents your consent.

2. Text Message Risks. Text Messages can be inadvertently misdirected by the sender or intentionally intercepted by third parties. The University of Minnesota cannot and does not guarantee the confidentiality of text messages, nor is it responsible for text messages that are lost due to technical failure during composition, transmission and/or storage.

3. Privacy and Confidentiality. Text messages are an insecure method of communication. The content of a text message may be viewed by any person who has access to your phone. Text messages that you send us may be viewed by other staff depending on the nature and timing of your messages, and may be monitored by the University to ensure appropriate use. Text messages may be viewed by your employer if you are using a work phone. Different University staff may view and process text messages depending on the time of day you send them, or when your typical point of contact is not available. Communication by phone, postal mail, and Secure E-mail are considered secure. You should consider using these forms of communication.

4. Content. Text messages should be used only for non-sensitive and non-urgent issues. You should limit the amount of health information in your text messages to us to the minimum necessary.

5. Ending Text Message Communication. This authorization does not have an expiration date. We may discontinue using text message as a means of communication with you by notifying you by text message or letter. You may discontinue using text messages as a means of communication by notifying us by e-mail to privacy@umn.edu or by letter to:

Health Information Privacy & Compliance Office
410 ChRC (MMC 501)
426 Church Street SE
Minneapolis, MN 55455.

6. Authorizing Signature. I am the research participant or personal representative authorized to act on behalf of the participant. I have read and understand the information regarding guidelines for text message correspondence and had any questions answered to my satisfaction. By signing and providing my contact information below, I agree to communicate by text message using the phone number below:

Signature of research participant or legally authorized representative.	Phone number for SMS communication
Printed name of research participant or legally authorized representative.	Date

Description of legally authorized representative's authority to act on behalf of the research participant.