Informed Consent Form:

Jowl Improvement with Injectable Fillers: Jaw line Injections alone vs Jawline and Cheek Injections

NCT04389866

Document date

07/20/2020

INFORMED CONSENT FORM AND AUTHORIZATION (PERMISSION) TO USE AND DISCLOSE YOUR HEALTH INFORMATION FOR RESEARCH PURPOSES

TITLE: Jowl Improvement with Injectable Fillers: Jawline Injections alone vs Jawline and Cheek Injections

PROTOCOL NO.: 10001
IRB Protocol # 20201394

SPONSOR: Advanced Dermatology
275 Parkway Drive, Suite 521
Lincolnshire, IL 60069

FUNDED BY: Allergan
2525 Dupont Drive
Irvine, CA 92612

INVESTIGATOR: Amy Forman Taub, MD
275 Parkway Drive
Suite 521
Lincolnshire, Illinois 60069
United States

STUDY RELATED PHONE NUMBER(S): 847-459-6400 (24 hours)

Advanced Dermatology is a Dermatological Office that carries out medical research. Research is different from normal treatment because research aims to find better ways of preventing and treating illness in the future for everybody's benefit. We are asking your permission for you to participate in a research study. You do not have to take part if you do not want to. Your participation is voluntary. Before choosing to be a part of this study, you need to understand why this research is being done and what will happen if you choose to take part. This informed consent form tells you about the study and your role in it.

Allergan is paying for this research study. Your study doctor and evaluator will be paid by Allergan. Your Study Doctor owns stock and receives consulting fees from the Sponsor of this study.

What is this research about?
The purpose of this clinical investigation is to study the perceived reduction of jowling following a volume replacement treatment using JUVÉDERM VOLUMA™ XC injectable gel in the jawline or in the jawline and the cheek.

JUVÉDERM VOLUMA™ XC is an injectable gel that is approved by the U.S. Food and Drug Administration (FDA) for use in the cheek area to correct age- related volume loss. It is not currently approved by the FDA for use in the jawline to reduce jowling, therefore it is considered investigational in this study.

This research study is looking for sixteen participants who desire improvement in the jowling of the jawline. There will be two physicians involved in the study: the study doctor, who is also the unblinded evaluator, and a blinded evaluator.

The decision on which person gets which treatment will be decided by a system based on chance, not by any of the research team. To make sure the findings of this study are accurate, it is important that the blinded evaluator does not know which treatment you have received until the end of the research.

Is there anything else I can do for my condition?
You do not have to be in this study to receive treatment to improve the jowling of the jawline. If you choose not to take part in this study, other treatments may be available to improve the jowling of the jawline and you can choose to receive a different treatment as recommended by your healthcare provider. Some different treatments may include: a face lift, the dissolvable suture lift, radiofrequency needling technique, and skin tightening treatments with radiofrequency or focused ultrasound.

Your study doctor will discuss these options, and their risks and benefits, with you.

How long will I be in this study?
It is expected that there will be up to 6 In office study visits, 1 safety follow up call, and 2 telemedicine video conference visits over a period of approximately 13 months. If you are retreated, there will be a total of 6 in office visits, 2 safety follow up calls, and 2 telemedicine video conference visits over approximately 14 months. You may also need to attend additional unscheduled visits for safety or other reasons

What will it involve for me to take part in this study?

- If you fit the requirements of this research, you will be randomized to one of 2 groups (like a coin toss):

    - JUVÉDERM VOLUMA™ XC 1-2 cc injected into the Jawline
    - JUVÉDERM VOLUMA™ XC 1-3 cc injected into the Cheek Areas plus JUVÉDERM VOLUMA™ XC 1-2cc injected into the Jawline on both sides

  You have a 50% chance of being placed in either group. You cannot choose your study group.

- Photographs will be taken prior to treatment with the VISIA CR system and Fotofinder and with an iPad. Frontal, 45-degree, and 90-degree angle shots at standard illuminations will be taken.
- Safety eye exams will be performed prior to and 30 minutes after treatment. These tests include the Snellen Eye Exam, Ocular Motility Exam, and Confrontational Visual Fields Exam. Cranial Nerve evaluations will also be performed prior to and 30 minutes after treatment.
- During treatment cold air will be directed toward the injection sites to reduce discomfort.
- Any complications will be noted at each visit and patient will complete a diary via email or text every day. If you receive a touch-up treatment you will be expected to complete a 30 day diary for 30 days after the repeat treatment.
- You will need to return at 2 weeks, 4 weeks, and 3 months following the treatment for follow up visits. You will be contacted via phone for a 72 hour safety follow up visit following treatment. A telemedicine video call will be conducted at 6 months and 12 months following last treatment. If a touchup injection is given at 1 month, then you will also have a follow up at 8 weeks after initial treatment.
- Patient questionnaires will be completed noting discomfort from the treatment, downtime following treatment, perception of results, if you would have the treatment performed again in the future, and if you feel you need a touch-up.
- You or your treating physician may request a touchup. If this takes place at the one-month mark, you will return for another follow up the following month, including photographs and evaluations (exactly the same as the 4-week visit).
- Description of procedure: Your skin will be cleansed with alcohol and chlorhexidine prior to the procedure. Dr. Taub will inject the Voluma XC, a sterile hyaluronic acid gel designed to give lift and volumization of the cheek, into both the cheeks and the jawline. The filler syringe has a needle on the end which will be placed deeply into the skin and small amounts will be deposited at different points along your jawline (experimental) and if in group 2 along your cheek bones (FDA-approved on label) as well. Cold air will be used to reduce discomfort. This is a typical procedure performed in our office and the vast majority of patients find it tolerable. If you find it intolerable, you are free to stop at any time.

Subject instructions after each study treatment

- Avoid excessive sun and Ultraviolet (UV) lamp exposure until any initial swelling and redness have resolved.

- The treated areas may be washed with soap and water. If required, light makeup may be applied with clean fingers following treatment.
- Cool compresses or ice packs for 48 hours may help to reduce swelling.
- Until the initial swelling and redness have resolved, do not expose the treated area to intense heat (e.g. sauna and sunbathing) or extreme cold.

What do I need to do if I decide to participate?
As a participant, you are responsible for following the study directions and any additional directions your study doctor and study staff may give you. This includes returning promptly to your study doctor's office for all necessary study follow-up visits.

As part of monitoring your health and safety during the study, you will be asked to report any changes in your health or medical history, including all medications and supplements or over-the- counter and prescriptions, and reporting any changes in how you feel to the study doctor or study staff. If female of child bearing potential, you will need to have a urine pregnancy test. You cannot enroll in this study if you are pregnant.

During the study, you will be asked to complete questionnaires and safety diaries relating to the study treatment and any associated symptoms. At your in-office visits, an evaluator will perform safety assessments to monitor any changes or possible side effects related to the treatment. You will be asked to complete a safety call with the study coordinator 72 hours after treatment, and complete telemedicine video visits at 6 and 12 months.

You should not enroll in this study if you do not want to have the safety assessments or visits indicated above or if you do not intend to complete the study.

If you experience any illness or discomfort during the study, you should notify your study doctor or study staff. Your study doctor will then evaluate you to determine if you should continue the study. If you think you are in an emergency situation, obtain immediate medical treatment and notify your study doctor. Should you have any questions throughout the study, you should contact the study staff.

Will it cost me anything to participate in this study?
There are no costs to you for taking part in this study. The study is funded by Allergan, which will pay for study treatment, tests, exams and medical procedures required by the study. You or your insurance company will have to pay for routine care you would receive whether or not you are in the study. You may talk to the study staff and your insurance company about what is covered.

Will I be paid to take part?
You will not receive any payment for taking part in this research study.

Are there any benefits to me taking part?
The benefits of participating in this study are to potentially improve moderate to severe facial volume loss leading to an aging appearance of the jowls. However, this is not guaranteed. Your participation will provide information about JUVÉDERM VOLUMA™ XC. This might benefit others in the future.

Are there any risks or disadvantages to me by taking part?
There may be risks which are currently unforeseeable.

The following is a list of possible adverse reactions that have been reported with facial injection procedures in the area or at the injection site:

- Bleeding
- Bruising
- Redness
- Swelling
- Lumps/bumps mass or nodule
- Itching
- Discoloration

In rare circumstances, facial fillers have been associated with:

- Allergic reaction
- Herpes Simplex Virus 1 outbreak
- Giant cell reaction or granuloma formation (tissue inflammation)
- Vision changes (blurred vision, double vision, loss of peripheral vision, partial loss of the visual field)
- Blindness (complete or partial)
- Stroke
- Vascular occlusion or compromise
- Scarring
- Skin necrosis (skin destruction or breakdown), ulceration and/ or nerve damage

The incidence of serious adverse events associated with intravascular injection is very low.

There is also a very small chance that there may be a reaction we do not expect. If we learn anything new about JUVÉDERM VOLUMA™ XC injectable gel during this study, we will tell you. If this occurs, you may need to sign a new informed consent form. If for any reason the doctors think that, for your best interest, you should no longer continue, you will be withdrawn from the study.

What should I look out for that indicates a serious adverse event?
Serious adverse events are known rare complications of injectable fillers. These are not anticipated side effects but we must prepare for if they do occur. Please read the following section carefully and if any of these symptoms pertain to you please call our office immediately at the phone number(s) listed above on the first page. You will be given a card to present to emergency providers or other healthcare providers.

While rare, unintentional injection into a blood vessel, reducing blood flow to that vessel, has been reported for facial injections which can be serious and may be permanent. The most common areas for this to occur is between the brows, under the eyes, around the nose, the mid center of the face, and the upper lip. While these are not the exact injection areas in this particular study, it is important that you recognize the signs and symptoms, as

early intervention is important for a favorable outcome.

Early signs of a vascular occlusion or vascular compromise will include immediate blanching (paleness, tissue turns white) when the blood flow is interrupted. This may or may not be in the area of injection. You may also have pain in this area. Delayed signs of a vascular compromise might include worsening or increasing redness, pain, and discoloration that does may or may not resemble bruising. Additionally, any scabbing, crusting or scarring can be a sign of vascular compromise.

Other very concerning side effects include: blurry vision, double vision, loss of vision, change in ability to move eyeballs, pain in or around the eye, blind spot or shadow in the visual field, trouble moving eyes, inability to see as well as you did before may be signs of damage to the retinal artery.

If you have any of the above signs or symptoms or are unsure if you are experiencing any of the above, CALL OUR OFFICE IMMEDIATELY at the phone number(s) listed above on the first page.

CALL 911 IMMEDIATELY if:

- Severe dizziness (difficulty standing or maintaining a standing position)
- Confusion
- Weakness or numbness of the arms or legs
- Changes to consciousness or alertness
- Difficulty speaking or speech impairment
- Facial drooping

Washout risks

If you are taking medication that inhibits your blood's ability to clot (for example aspirin, Coumadin®, Plavix®, or certain food or supplements), you may be asked to stop some or all of these medications 10 days before each treatment and 3 days afterwards. If you are on a regular regimen of prescription anticoagulation medication that was prescribed by your physician to treat a specific condition, your condition may get worse if you stop taking this medication. The physician who prescribed this medication will need to give permission for you to stop this medication. If it is not safe for you to stop your medication, you will not be eligible to take part in this study. If you are allowed to stop this medication and your symptoms get worse, tell the study doctor or study staff immediately. If you are taking non-prescribed medications with anticoagulation properties or supplements that can cause you to bleed more easily, you will need to stop these 10 days before each treatment and 3 days afterwards.

Allergic reaction risks in clinical studies

As with any treatment, there is a risk of allergic reaction. Allergic reactions may be caused by things such as the treatment product, the topical anesthetic and the antiseptic cleanser. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of allergic reactions are:

- Rash

- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- A fast pulse
- Sweating

If any of the above symptoms occur, you should seek immediate medical attention by dialing 911. Additionally, CALL OUR OFFICE at the phone number(s) listed above on the first page if you have any of these symptoms, or any other side effects, during the study.

Reproductive risks
We do not know the effect of JUVÉDERM VOLUMA™ XC on babies before they are born, or on nursing children. There may be unknown risks.

If you are pregnant, planning to get pregnant or are nursing, you cannot be in the study. Pregnancy tests will be done on all women who might be able to get pregnant.

If you are able to get pregnant, you must use reliable birth control during the study. Your study doctor will talk to you about the methods of birth control you can use.

If you become pregnant, you will be withdrawn from the study.

Are there ways in which I can be withdrawn from the study?
Your doctor or the sponsor, may withdraw you from the study without your consent. Reasons for early discontinuation from the study include:

- Serious Adverse Event
- Vascular Occlusion or Compromise
- Pregnancy
- Protocol deviation
- Physician decision
- Subject withdrawal
- Lost to follow-up
- Death
- You do not follow the study procedures as instructed
- The study is canceled by the FDA or the sponsor

Should a serious adverse event (AE) occur, enrollment and treatment will be suspended and a root cause investigation will be conducted to determine the cause of the event and whether the outcome was anticipated (the investigator did not properly follow the treatment SOP) or unanticipated (the investigator DID properly follow the treatment standard operation procedures [SOP]). If the event was unanticipated, the study will be immediately suspended and enrollment will be halted until the event can be properly characterized and an appropriate treatment strategy to avoid this unanticipated event can be devised.

You will be informed of any new events or risks to the study treatment and may choose to continue participation or be withdrawn at any time.

What will happen if I don't agree to participate?
All participation in research is voluntary. You are free to decide if you want to take part or not. You will still receive the recommended standard of care if you do not take part. If you do agree you can change your mind at any time and withdraw from the research. A decision to discontinue participation will not prejudice your medical care now or in the future. There will not be any penalty or loss of benefits to which you are otherwise entitled if you decide not to take part or if you leave the study early.

You may be asked to return to the clinic for a follow-up visit.

Who will have access to information about me in this research?
This study is confidential. Information made public regarding subjects enrolled in this study will not disclose the name of any individual. The information collected about you usually will not directly identify you (for example, by name, address, or social security number). Instead, a code number will be used for your information. All our research records are stored securely in locked cabinets and password protected computers. Only a few people who are closely concerned with the research will be able to view information from participants.

The results of this study will be provided to Allergan, including photographs, but no identifying information will be disclosed.

Your records may be reviewed by:

- the study sponsor
- people who work with the sponsor on the study
- Government agencies, such as the FDA
- The Institutional Review Board (IRB) that reviewed this research. The IRB is a group of scientists and non-scientists who review the ethics of research. The goal of the IRB is to protect the rights and welfare of study subjects.

These people may look at your records to make sure the study has been done the right way. They also want to make sure that your health information has been collected the right way, or for other reasons that are allowed under the law.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity will not be disclosed in any of these meetings or publications.

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.

Images/Photographs/Videotapes
Photographs or digital images may be taken of your face during the study. You can be identified from the photographs or digital images. If you do not want to have the

photographs or digital images taken, you cannot take part in the study. The Sponsor may use the photographs or digital images to evaluate the results of the study and/or for general research, education, or informational purposes. These photographs or digital images may identify you. The Sponsor will own the copyright of the photographs or digital images.

Who has allowed this research to take place?
All research at Advanced Dermatology is reviewed by an Institutional Review Board (IRB) to make sure the research is conducted properly and that participants' welfare and rights are respected. This research is funded by Allergan.

What if I get hurt or sick while I am in the study?
If you are hurt or get sick while in the study, you should seek medical care and call the study doctor immediately. The study doctor may treat you or refer you for treatment. Neither Advanced Dermatology nor Allergan will routinely offer compensation in the event of an injury or any complications.

What if I have any questions?
If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number(s) listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (888)-303-2224 or (800) 562-4789, irb@cgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

REGULAR DOCTOR NOTIFICATION OPTION
Please indicate below (by checking your choice) whether you want us to notify your regular doctor of your participation in this study.

____Yes, I want the study doctor to inform my regular doctor of my participation in this study:

_____ _____
Name of Doctor **Phone**

____No, I do not want the study doctor to inform my regular doctor of my participation in this study

STATEMENT OF CONSENT

I have had the trial explained to me. I have understood all that has been read and had my questions answered satisfactorily. I understand that I can change my mind at any time and it will not affect the benefits otherwise entitled to me. I will receive a signed and dated copy of this consent form.

I agree to take part in this research.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date

DOCUMENTATION OF CONSENT PROCESS

I certify that the above Consent form explained verbally to the patient, and that she understands the nature and the purpose of the study and consents to the participation in the study. She has been given the opportunity to ask questions which have been answered satisfactorily.

Person obtaining consent to initial each completed step in the process:

____ Informed consent was discussed with subject for the above referenced study. Copy of the consent form was provided for subject (in language understandable to the patient) review.

____ Subject was given adequate time to read the consent form and discuss the study with study investigators and/or family members.

____ All questions were answered. Subject was given time to discuss.

____ Subject signed and dated the informed consent. A copy of the signed and dated consent form will be provided to the subject upon conclusion of the consent process.

____ Informed Consent process was conducted in a manner and location that ensured patient privacy.

____ Consent has been signed prior to any study procedures being performed.

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

Appendix 1: Study Schematics No Retreatment

Visit #	1	2	3	4	5	6	7	8	9
	Screening	Treatment	Safety Follow Up Call	In Office Follow Up	In Office Follow Up	In office Follow Up	In Office Follow Up	Tele medicine Video Call	Tele medicine Video Call
			72 hours +/- 4 hours	2 weeks +/- 3 days	4 weeks +/- 3 days	8 weeks +/- 3 days	12 weeks +/- 3 days	6 months after Tx +/- 3 days	12 months after Tx +/- 3 days
Informed Consent	X								
Inclusion/Exclusion	X								
Medical History	X								
Pregnancy Test	X	X							
Photography		X		X	X	X	X		
Blinded/Unblinded Evaluation	X				X	X	X		
Adverse Events		X	X	X	X	X	X	X	X
Physical Exam		X		X	X	X	X		
Safety Eye Assessments		X*		X	X	X	X		
Cranial Nerve Assessments		X		X	X	X	X		
Patient Questionnaire/ Evaluation	X			X	X	X	X	X	X
Patient Pain Evaluation		X	X	X	X	X	X	X	X
Patient Safety Diary**		X	X						
Retreatment***									

* Safety Eye Assessments will be performed prior to treatment and 30 minutes after treatment

**Patient diary to be completed daily by email for 30 days following treatment

***No Retreatment done per patient and/or physician

Appendix 1: Study Schematics Retreatment

Visit #	1	2	3	4	5	6	7	8	9	10
	Screening	Treatment	Safety Follow Up Call	In Office Follow Up	In Office Follow Up	Safety Follow Up Call	In office Follow Up	In Office Follow Up	Tele medicine Video Call	Tele medicine Video Call
			72 hours after treatment	2 weeks +/- 3 days	4 weeks +/- 3 days	72 hours after RTx	8 weeks +/- 3 days	16 weeks +/- 3 days	6 months after RTx +/- 3 days	12 months after RTx +/- 3 days
Informed Consent	X									
Inclusion/Exclusion	X									
Medical History	X									
Pregnancy Test	X	X			X					
Photography		X		X	X		X	X		
Blinded/Unblinded Evaluation	X				X		X	X		
Adverse Events		X	X	X	X	X	X	X	X	X
Physical Exam		X		X	X		X	X		
Safety Eye Assessments		X**		X	X		X	X		
Cranial Nerve Assessments		X		X	X		X	X		
Patient Questionnaire/ Evaluation	X			X	X		X	X	X	X
Patient Pain Evaluation		X	X	X	X	X	X	X	X	X
Patient Safety Diary***		X	X		X	X				
Retreatment					X*					

***If requested by physician or patient and agreeable to both**
****Safety Eye Assessments will be performed prior to treatment and 30 minutes after treatment**
*****Patient diary to be completed daily by email for 30 days following treatment**

AUTHORIZATION (PERMISSION) TO USE AND DISCLOSE YOUR HEALTH INFORMATION FOR RESEARCH PURPOSES

Purpose of this form

State and/or federal privacy laws protect the privacy of your health information. These include the right to know who will receive the information and how it will be used. Under the law, health information that includes identifiable participant information may not be used for research purposes unless you give written permission in advance. You do not have to sign this Authorization. If you do not sign this Authorization, you will not be allowed to take part in this research study. Your decision not to sign this Authorization will not involve any penalty or affect any other treatment, healthcare, enrollment in health plans or eligibility for benefits to which you are otherwise entitled.

Your health information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What health information will be obtained, used or disclosed?

The study doctor and study staff will use and share your health information as part of this research study. Except when required by law, you will not be identified by name, address, telephone number or other facts that could identify the health information as yours.

Health information related to this study may be used, shared or disclosed in connection with this research study. Health information shall mean information contained in your medical or other healthcare records. Health information may include, protected health information that can identify you. Health information collected in connection with this research study may also be found in the following:

- Progress notes
- Personal questions
- Health and medication questions
- Vital sign measurement
- Medical History and Physical exam
- Laboratory Reports
- Menstrual or menopausal status
- Pregnancy tests

- Questionnaires and Safety Diaries
- All research related information and study data
- Photographs

Who may use and disclose your health information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Principal Investigator
- Allergan and any other affiliates, subsidiaries, agents, contractors and related companies of Allergan, as necessary
- Institutional Review Board (IRB)
- Study doctor's Research staff
- The U.S. Food and Drug Administration (FDA)

Who may receive or use the information?
The parties listed in the above section may disclose your health information to the following persons and organizations in connection with this research study:

- The Sponsor and/or its representatives, including affiliates, agents and contractors
- Allergan
- Independent Review Boards/Ethics Committees (IRB/IEC) who oversee this research study;
- The Office for Human Research Protections in the US Department of Health and Human Services (DHHS);
- Federal and regulatory authorities (e.g. United States Food and Drug
- Administration-FDA, etc.) including those outside of the United States.

Your health information may be further shared by the groups above. If shared by them, the information will no longer be covered by this Authorization. These groups are committed to keeping your health information confidential.

How will my health information be utilized in the study?
Your information about you and your health, and information that may identify you is being collected for the purposes of the research study. The Sponsor will use your information to study best practices for body contouring in order to achieve optimal fat reduction and body contouring in the midsection area.

Regulatory authorities (such as the FDA) and the IRB/IEC may also review and copy your information to make sure that the research study is done properly or for other purposes required by law.

The results of this research study may also be presented at scientific or medical meetings or published in scientific journals. Your identity will not be disclosed in any of these meetings or publications.

Your information may also be used along with the medical information of others to make and keep a research database. The database will be used for follow-up or future research and/or statistical purposes regarding medical conditions such as yours.

Do I have to sign this authorization form?
You do not have to sign this authorization form. But if you do not, you will not be able to take part in this research study and you will not be able to receive any research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I cancel my permission or withdraw from the research study later?
You are free to withdraw or cancel your permission regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any cancellation or withdrawal, your health information will no longer be used or disclosed in the research study, except to the extent that the law allows us to continue using your information (e.g. information necessary to maintain the integrity or reliability of the research). If you wish to cancel or withdraw your permission for the research use or disclosure of your health information in this research study, you must provide written notice to the study doctor.

If you cancel or withdraw (or stop participating) from the research study and cancel and withdraw this Authorization, no new information will be collected for the research study purposes unless the information concerns an adverse event (a bad effect) related to the research study. If an adverse event occurs, your entire medical record may be reviewed. If you withdraw your permission, you will not be able to continue being in the research study.

If you withdraw from the study but do not withdraw your Authorization, new health information may be collected until this study ends.

Your decision to withdraw your Authorization will not involve any penalty or loss of access to treatment or other benefits to which you are otherwise entitled.

When will my authorization expire?
If you do not withdraw this Authorization in writing, it will remain in effect.

If the research site is located in California, Delaware, Indiana, Washington, or Wisconsin this authorization will expire on 31Dec2070.

There is no expiration of this authorization except for research conducted in the states listed above.

Will access to my medical record be limited during the research study?
To maintain the scientific integrity of this research study, you may not have access to any health information developed as part of this study until the study is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if it was included in your official medical record). If it is necessary for your care, your health information will be provided to you or your doctor.

AUTHORIZATION
The research site is required by law to protect your health information. By signing this document, you authorize the research site and study doctor to use and/or disclose (release) your health information for this research study. Those persons who receive your health information may not be required by national or 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 acknowledge that you will receive a signed and dated copy of this form.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date (dd-MMM-yyyy)