Study Title:	Open, Label, Single-Center study, Evaluating the Efficacy and Safety of JUVÉDERM VOLUMA™ XC for the facial temporal regions
Study #:	Voluma Temporal 2014
Sponsor:	Baumann Cosmetic & Research Institute
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INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY AND AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

Study Title: Open, Label, Single-Center study, Evaluating the Efficacy and Safety of JUVÉDERM VOLUMA™ XC for the facial temporal regions

Study #: Voluma Temporal 2014

Sponsor: Baumann Cosmetic & Research Institute

Study Doctor: Leslie S. Baumann, M.D., C.P.I.
Baumann Cosmetic & Research Institute
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Miami, Florida, 33137

Telephone Number: 305-531-5788

After Office Hours: 305-531-5788

The study doctor wants to know if you would like to be part of a research study.

If you have any questions about or do not understand something in this form, you should ask the study doctor or study staff. You should also discuss your participation with anyone you choose in order to better understand this study and your options.

Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information.

WHAT IS THIS STUDY ABOUT?

Researchers want to find out more about using a device called JUVÉDERM VOLUMA™ XC in the temporal areas of the face. Using JUVÉDERM VOLUMA™ XC in the temporal areas of the face is an investigational use of the device. An investigational use is a use that is being tested and is not approved in the United States by the U.S. Food and Drug Administration (FDA). The FDA approved JUVÉDERM VOLUMA™ XC in October 2013 for the improvement and correction of age-related volume deficit in the mid-face area.

The main purpose of this study is to determine the efficacy (helpfulness) and safety of JUVÉDERM VOLUMA™ XC when used in the facial temporal regions to help improve the appearance of age-related volume deficit. Researchers also want to find out about subject's satisfaction with the study device.

The researchers will be asking participants to keep a daily diary for 2 weeks after the injections to track any side effects of the injections. Participants will also have follow up visits on week 2, month 1, month 3, and month 6, month 9 and month 12. If you agree to be in the study, it is important that you return for these follow up visits for safety assessments.

It is planned that about 30 subjects with age-related volume deficit in the temporal regions of the face will be in this study.

Be aware that this form refers to JUVÉDERM VOLUMA™ XC as the study device.

HOW DOES JUVÉDERM VOLUMA™ XC WORK?

JUVÉDERM VOLUMA™ XC is a gel implant composed of 20 mg/mL hyaluronic acid (HA) formulation, produced by *Streptococcus equi* bacteria, and 0.3 w/w (weight in weight) lidocaine. JUVÉDERM VOLUMA™ XC is a clear, sterile, and biodegradable gel given by injection.

Hyaluronic acid injections are commonly used in people as dermal fillers in the nasolabial folds. The purpose of this study is to evaluate the efficacy and safety of Voluma injections in the temple.

WHAT IS THE STUDY PROCEDURE?

JUVÉDERM VOLUMA™ XC will be injected into the temple area on both sides of the face. The injection technique for this study will begin with palpation of the temple area for a pulse indicating the presence of arterial vessels in the area to be injected. Subjects with any palpable arteries in the area of injection will be excluded from this study. During the injection procedure, the area will first be cooled with ice to minimize pain, then a 27 gauge needle (attached to a 1 cc syringe) will be placed in the skin at approximately a 90 degree angle. The HA material will be slowly injected into the skin. The procedure will take about 5 minutes per side of the face.

After the injections, slight pressure will be placed on the area with a gauze to minimize swelling and/ or bruising. It is expected that there will be minimal pain during the procedure. If you experience intense pain, nausea, dizziness or eye pain, tell the study doctor or study staff immediately.

IS THERE ANYTHING ELSE I CAN DO FOR MY AGE-RELATED VOLUME DEFICIT IN THE TEMPORAL REGIONS OF MY FACE?

You do not have to be in this study to get help for your age-related volume deficit in the temporal regions of the face. Some other things you may be able to do are:

- Other dermal fillers
- Surgical treatment methods

You should discuss your alternatives to participating in this research with the study doctor or study staff. In addition, you may discuss your options with your regular health care provider.

WHO IS PAYING FOR THIS STUDY?

Baumann Cosmetic & Research Institute, the sponsor of the study, is paying for this study with money received from a grant from Allergan the makers of JUVÉDERM VOLUMA™ XC.

WILL IT COST ANYTHING TO BE IN THIS STUDY?

You and/or your health-care payer/insurer will be billed for the costs of regular medical care that are not part of this study.

You do not have to pay for JUVÉDERM VOLUMA™ XC dermal filler injections in the temporal regions of your face, study visits or tests that are part of this study including visits to Bascom Palmer hospital or other medical professionals that occur as a result of adverse events that occur during or after this study.

HOW LONG WILL I BE IN THE STUDY?

If you decide to be in this study and the study doctor decides you qualify for this study, you will receive JUVÉDERM VOLUMA™ XC dermal filler injections in the temporal regions of your face and your participation will last 12 months.

You will visit the study center to have the procedures and tests described in this form. Ask the study doctor or study staff if you have questions about your study visit schedule. Please do not agree to do the study if you do not believe that you can make the follow-up visits.

WHAT WILL HAPPEN DURING THIS STUDY?

If you decide to be in this study, you might have to stop taking anti-coagulation, anti-platelet, or thrombolytic medications (for example, warfarin), anti-inflammatory drugs (oral/injectable corticosteroids or nonsteroidal anti-inflammatory drugs [NSAIDs], for example, aspirin, ibuprofen), or other substances known to increase coagulation time (vitamins or herbal supplements, for example, Vitamin E, garlic, gingko) 10 days prior to study injections to 3 days post study injections.

The study doctor or study staff will inject you with JUVÉDERM VOLUMA™ XC dermal filler on the right and left facial temporal regions at the baseline visit. You will receive up to 4, 1 mL syringes of JUVÉDERM VOLUMA™ XC for your initial injections and a maximum of 6, 1mL syringes of JUVÉDERM VOLUMA™ XC for the entire study. You may undergo one touch-up injection approximately 2 weeks post initial injection, and will continue to be evaluated at 1, 3, 6, 9, and 12 months after your initial injections.

While you are in the study, you must:

- Follow the instructions you are given.
- Come to the study center for all visits with the study doctor or study staff.
- Tell the study doctor or study staff about any changes in your health or the way you feel.
- Tell the study doctor or study staff if you want to stop being in the study at any time.

<u>What happens when I come for study visits?</u>

After you sign this form, the study doctor or study staff will do the things listed below when you come in for study visits. If you would like more information about which tests and procedures will be done at each study visit, ask the study doctor or study staff.

SCREENING/ VISIT 0

Before enrollment into the study, you must sign the informed consent form and the HIPAA form. Once you have signed the informed consent and HIPAA, the following procedures will be conducted:

- Your study inclusion and exclusion criteria will be reviewed.
- Your demographic information (gender, date of birth, etc.) will be recorded.
- Your medical/surgical history and concomitant medications will be obtained and recorded.
- You will have a physical exam (including height and weight).

- The study doctor will do a visual assessment.
- Your vital signs will be taken (blood pressure, pulse, breathing rate).
- The study doctor will complete the following scales:
  - Temporal Fossa Rating scale
  - Investigator's Satisfaction with Temple Appearance

VISIT 1/DAY 0/BASELINE

If you meet the criteria to enter into the study and score a 3, 4, or 5 on the Temporal Fossa Rating by the study doctor, you will qualify for injection. You may complete visit 0 and visit 1 on the same day, if no stopping of medications (wash out) is required. If you qualify for injection, the following procedures will be conducted in addition to those listed under "Screening/Visit 0"

- Your baseline photos using the VISIA camera will be taken
  - The study doctor, study staff, and sponsor will use these photographs for the purpose of this study. In addition, the study doctor, study staff, and sponsor may use these photographs for scientific or educational presentations and publications. If you agree, the photos may also be used for marketing purposes.
  - When the study doctor or study staff takes the photographs, you will close your eyes. There are no plans to crop the photos or use masking to hide your identity.
  - You do not have to let the study doctor or study staff take photographs if you don't want to. However, you cannot be in the study if you do not want the study doctor or study staff to take photographs.
- You will complete self-assessments:
  - Subject's Satisfaction with Temple Appearance
  - Subject Self-Perception of Age
- A urine pregnancy test will be completed for women of childbearing potential.
  - The study doctor or study staff will tell you if the pregnancy test results are positive. The results of the pregnancy testing must be negative in order for you to be in the study.
- You will receive up to 4, 1 mL injections of JUVÉDERM VOLUMA™ XC, by the study doctor.
- You may receive ice packs to reduce the risk of swelling and bruising.
- You will be monitored in the clinic for at least 15 minutes post injection.
- You will be given a vision test before and after the injections
- You will receive a diary to record daily for 2 weeks any reaction to the study product prior to Visit 2.

DAY 3 POST INITIAL INJECTION FOLLOW UP PHONE CALL (±1 DAY)

- You will be called and questioned about Adverse Events (AEs), Serious Adverse Events (SAEs), changes in concomitant medications, or concomitant procedures.
- You will be reminded to complete your study diary and call the office if any issues may arise.
- You will be reminded of exclusionary concomitant medications/procedures.

VISIT 2/WEEK 2 FOLLOW UP/ POSSIBLE TOUCH UP/ (±3 DAYS)

You will come for a follow up at week 2 (±3 days) after initial injection. The following procedures will be conducted:

- Your study diary will be collected and reviewed.
- Your changes in adverse events and concomitant medications/procedures will be documented.
- Your vital signs and weight will be documented.
- You will complete a vision test on an iPad.
- The study doctor will do a physical exam and visual assessment.
- Your photos using the VISIA will be taken.
- You will complete your assessments:
    - Subject's Satisfaction with Temple Appearance
    - Subject Self-Perception of Age
- If the study doctor determines a touch-up is indicated, your vital signs will be taken and you will receive a touch-up injection.
    - The combined initial injection and touch up injection total per subject will not exceed 6, 1 mL injections of JUVÉDERM VOLUMA™ XC.
    - You may receive ice packs to reduce swelling and bruising post-injection.
    - You will receive a diary to record any reaction to study product or comments prior to visit 3/month 1.
    - You will be scheduled for the next visit
    - You will receive a diary to record daily for 2 weeks any reaction to the study product prior to the next visit.
    - You will be monitored in the clinic for at least 15 minutes post injection.

If you report any unexpected side effects at this visit or at any time after injection, you will be scheduled to come to the office for evaluation.

DAY 3 POST TOUCH-UP INJECTION FOLLOW UP PHONE CALL (±1 DAY)

- You will be called and questioned about AEs, SAEs, changes in concomitant medications, or concomitant procedures.
- You will be reminded to complete your study diary and call the office if any issues may arise.

- You will be reminded of exclusionary concomitant medications and procedures.

VISIT 3/MONTH 1 (±7 DAYS)

At this visit, the following procedures will be conducted:

- Your changes in adverse events and concomitant medications will be documented.
- Your vital signs and weight will be documented.
- Your photos using the VISIA will be taken.
- You will complete your assessments:
  - Subject's Satisfaction with Temple Appearance
  - Subject Self-Perception of Age
- The study doctor will complete the following scales:
  - Temporal Fossa Rating scale
  - Investigator's Satisfaction with Temple Appearance
- You will be scheduled for your next visit.

If you report any unexpected side effects at this visit or at any time after injection, you will be scheduled to come to the office for evaluation.

VISIT 4/MONTH 3 (±7 DAYS)

At this visit, the following procedures will be conducted:

- Your changes in adverse events and concomitant medications will be documented.
- Your vital signs and weight will be documented.
- Your photos using the VISIA will be taken.
- You will complete your assessments:
  - Subject's Satisfaction with Temple Appearance
  - Subject Self-Perception of Age
- The study doctor will complete the following scales:
  - Temporal Fossa Rating scale
  - Investigator's Satisfaction with Temple Appearance
- You will be scheduled for your next visit.

If you report any unexpected side effects at this visit or at any time after injection, you will be scheduled to come to the office for evaluation.

VISIT 5/MONTH 6 (±7 DAYS)

At this visit, the following procedures will be conducted:

- Your changes in adverse events and concomitant medications will be documented.
- Your vital signs and weight will be documented.

- Your photos using the VISIA will be taken.
- You will complete your assessments:
  - Subject's Satisfaction with Temple Appearance
  - Subject Self-Perception of Age
- The study doctor will complete the following scales:
  - Temporal Fossa Rating scale
  - Investigator's Satisfaction with Temple Appearance
- You will be scheduled for your next visit.

If you report any unexpected side effects at this visit or at any time after injection, you will be scheduled to come to the office for evaluation.

VISIT 6/MONTH 9 (±7 DAYS)

At this visit, the following procedures will be conducted:

- Your changes in adverse events and concomitant medications will be documented.
- Your vital signs and weight will be documented.
- Your photos using the VISIA will be taken.
- You will complete your assessments:
  - Subject's Satisfaction with Temple Appearance
  - Subject Self-Perception of Age
- The study doctor will complete the following scales:
  - Temporal Fossa Rating scale
  - Investigator's Satisfaction with Temple Appearance
- You will be scheduled for your next visit.

If you report any unexpected side effects at this visit or at any time after injection, you will be scheduled to come to the office for evaluation.

VISIT 7/MONTH 12/STUDY EXIT (±7 DAYS)

At this visit, the following procedures will be conducted:

- Your changes in adverse events and concomitant medications will be documented.
- Your vital signs and weight will be documented.
- Your photos using the VISIA will be taken.
- You will complete your assessments:
  - Subject's Satisfaction with Temple Appearance
  - Subject Self-Perception of Age
- The study doctor will complete the following scales.
  - Temporal Fossa Rating scale
  - Investigator's Satisfaction with Temple Appearance

- You will exit the study.

What else will happen during this study?

After you receive JUVÉDERM VOLUMA™ XC, the study staff will follow up with a phone call and ask you about your health and any changes in medications. You will be reminded to complete your study diary.

Will I need time to recover after my participation in the study?

For 24 hours after the injections you should avoid heavy exercise, hot showers, steam rooms, facial massage or facials. For 3 days after the injections you should avoid ibuprofen, aspirin, and heavy exercise.

WILL BEING IN THIS STUDY HELP ME?

Participating in this study may help your age-related volume deficit on your facial temporal regions, but there is no guarantee that being in this study will help you. Your age-related volume deficit might not get better or may even get worse while you are in this study. Information from this study might help researchers to better understand the efficacy and safety of JUVÉDERM VOLUMA™ XC for age-related volume deficit on facial temporal regions and help others in the future.

WHAT ARE THE RISKS TO ME IF I AM IN THIS STUDY?

What are the risks of getting JUVÉDERM VOLUMA™ XC dermal fillers for facial temporal regions?

The study doctor or study staff will give you JUVÉDERM VOLUMA™ XC dermal fillers by sticking a needle in your skin. Some problems you might have from this are:

- Redness
- Nodules (small masses under the skin)
- Bruising
- Pain
- Inflammation (pain, swelling, heat, redness)
- Numbness
- Needle marks
- Infection
- Dizziness

Some people who have received JUVÉDERM VOLUMA™ XC dermal fillers have also had the following side effects:

- Itching
- Pain
- Discoloration
- Dryness
- Necrosis (cell death)
- Product migration (movement of the dermal fillers)
- Lumps/Bumps
- Allergic reaction
- Unsatisfactory/unsymmetrical result
- Nausea
- Headache
- Deepening wrinkling
- Blood vessel injury
- Telangiectasia ("spider veins")
- Vision abnormality
- Blindness
- Blanching (skin whitening)
- Dermatitis (inflammation of the skin)

During the injections of the JUVÉDERM VOLUMA™ XC dermal fillers, it is possible (but very unlikely) that the fillers will be injected into your blood vessels. This could cause your blood vessels to become blocked. In addition, this could cause death of tissue or movement of a blood clot through your body.

Please tell the study doctor or study staff right away if you have any side effects. Please tell them if you have any other problems with your health or the way you feel during the study, whether or not you think these problems are related to the study device.

JUVÉDERM VOLUMA™ XC contains lidocaine. People who have received injections of lidocaine have reported the following side effects:

- Allergic reaction
- Numbness lasting up to 2 hours
- Itching
- Redness

Could I have an allergic reaction?

Sometimes people have allergic reactions to JUVÉDERM VOLUMA™ XC dermal fillers or the lidocaine that it contains. If you have a very bad allergic reaction, you could die. Some things that happen during an allergic reaction that could be a sign or symptom of a life-threatening allergic reaction (anaphylaxis) are:

- a rash
- a fast pulse
- sweating
- a feeling of dread
- swelling around the eyes and mouth
- swelling of the throat
- wheezing
- having a hard time breathing
- a sudden drop in blood pressure (making you feel dizzy or lightheaded)
- inability to breathe without assistance

You should get medical help and contact the study doctor or study staff if you have any of these or any other side effects during the study.

If I stop my regular medication(s), what are the risks?

If you stop your regular medication(s) to be in the study, your health might get worse. Please tell the study doctor or study staff right away if you have any problems when you stop or change your regular medication(s).

What are the risks of the study photographs?

There are no expected physical risks if the study doctor or study staff takes photos of your face during the study. It is possible that people who see the study photos will recognize you.

What are the risks of other study procedures?

The most common (temporary) adverse events seen with HA filler injections are:

- Bruising
- Erythema (redness)
- Tenderness
- Lumps
- Bumps
- Swelling

Arterial occlusion (blockage of the artery) can occur if the HA filler is injected into an artery. This can result in:

- Skin discoloration
- Ulceration
- Scarring
- Blindness

If this occurs, the study doctor will discuss options with you. One option may include an enzyme injection known as hyaluronidase, which will dissolve the hyaluronic acid. You will be consented prior to any procedures.

Temple injections have uncommonly been associated with visual disturbances and blindness if the HA dermal filler is injected into one of the ophthalmic arteries or its branches. If this occurs, the study doctor will discuss options with you. One option may include an enzyme injection known as hyaluronidase, which will dissolve the hyaluronic acid. Another option may include eye drops and gentle massage of the eye. You will be escorted immediately to the Bascom Palmer ER for treatment. You will be monitored after the injection procedure so plan to stay in the clinic for at least 15 minutes after the procedure. Visual assessments will be conducted at baseline and at the end of each injection visit using the "Vision Test" application on the iPad or the Snellen Visual Chart.

Possible Adverse Events with Hyaluronidase Injections:

- Loss of filler correction
- Uneven skin surface
- Asymmetry of injected area compared to non-injected area
- Allergic reaction (This may be more common in people with wasp or bee sting allergies. Please let the study doctor know if you are allergic to bee or wasp stings.)
- Anaphylaxis- which is a life threatening allergic reaction
- Development of an allergy (sensitization) to wasp and bee stings
- Pain
- Swelling
- Bruising

Unanticipated Adverse Device Effects (UADE)

If any of these UADE events occur, you will be sent to Bascom Palmer Eye Institute for Evaluation.

- Blindness
- Loss of visual field noted on exam
- Loss of Visual Acuity confirmed by iPad app or Snellen Visual Chart

Filling out the questionnaires and answering the study doctor or study staff's questions could lead you to feel uncomfortable or upset. Please tell the study doctor or study staff if you feel uncomfortable or upset while filling out a questionnaire or answering questions. You have the right to refuse to answer any questions.

There is a risk of loss of confidentiality of your information. You will read more about the protection of your information later in this form. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this study.

What are the risks if I am pregnant or nursing a child during the study?

If you are pregnant or nursing a child while receiving JUVÉDERM VOLUMA™ XC dermal fillers, there may be risks to your unborn baby or nursing child. Some devices and drugs cause premature (early) birth or birth defects. Nobody knows what all of these risks are right now.

If you are a woman who can have children, the study doctor or study staff will talk to you about birth control you must use during the study.

If you think you are pregnant during the study, you must tell the study doctor or study staff immediately. Women who become pregnant during the study will have to leave the study. The study doctor or study staff may ask for information about the pregnancy and the child's health at birth and may share this information with the sponsor.

Please tell the study doctor or study staff right away if you have any side effects. Please tell them if you have any other problems with your health or the way you feel during the study, whether or not you think these problems are related to the study of JUVÉDERM VOLUMA™ XC dermal fillers in the facial temporal regions.

COULD I HAVE ANY OTHER PROBLEMS WITH MY HEALTH IF I AM IN THIS STUDY?

It is possible that you could have problems and side effects after receiving JUVÉDERM VOLUMA™ XC dermal fillers that nobody knows about yet, which include your health getting worse or even death.

Ask the study doctor if you have questions about the signs or symptoms of any side effects that you read about in this consent form.

WILL I RECEIVE ANY NEW INFORMATION DURING THE STUDY?

If the study doctor or study staff learns any new information that might change your mind about continuing in the study, the study doctor or study staff will tell you about it.

WHAT IF I GET HURT OR SICK WHILE I AM IN THIS STUDY?

If you get hurt or sick during this study, the sponsor has no plans to pay the costs of medical treatment. To ask questions about this, talk to the study doctor or study staff.

You do not give up any of your legal rights by signing this form.

Be aware that your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

WILL I RECEIVE PAYMENT?

You will get paid $40 for each study visit you complete for a total of up to $360. If you do not finish the whole study, you will get paid for those visits you completed. The study doctor or study staff can tell you more about when you will get paid.

DO I HAVE TO BE IN THIS STUDY?

Your participation in this study is voluntary. You can decide not to be in the study and you can change your mind about being in the study at any time. There will be no penalty to you, and you won't lose any benefits, except for benefits having to do with the study. If you want to stop being in the study, tell the study doctor or study staff.

The study doctor or study staff or sponsor can remove you from the study at any time, even if you want to stay in the study. This could happen if:

- The study doctor or study staff believes it is best for you to stop being in the study.
- You do not follow directions about the study.
- The sponsor stops the study for any reason.

If you stop being in the study early, the study doctor or study staff may ask you some questions about being in the study. The study doctor or study staff may ask you to participate in some procedures or tests to help you leave the study safely and/or to collect more information for the study.

If a subject withdraws or is discontinued from the study before completion, every effort will be made to complete an exit visit.

If you leave the study, the study doctor and study staff will still be able to use your information that they have already collected.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Your identity will be protected as required by law and according to any policies the study center or sponsor may have. Be aware that your study records (which include your medical records, your signed consent form, and other information) will be shared as needed for the study. For

example, the sponsor, Quorum Review (a group of people who review research studies to protect the rights and welfare of research participants), and the U.S. Food and Drug Administration (FDA) may look at your records.

Please note that the study doctor or study staff may also share personal information about you if required by law (for example, if the study doctor or study staff suspects that you are going to harm someone or yourself). If you have questions about this, please ask the study doctor.

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 CAN I TALK TO ABOUT THIS STUDY?

In the event of an emergency, dial 911 immediately.

If you require emergency care, be sure to tell the emergency care provider about your participation in this study. Contact the study doctor or study staff as soon as possible.

You can ask questions about the study at any time. You can call the study doctor or study staff at any time if you have any concerns or complaints. You should call the study doctor or study staff at the phone number listed on page 1 of this form if you have questions about the study procedures, study payment, or if you get hurt or sick during the study.

Quorum Review reviewed this study. Quorum Review is a group of people who review research studies to protect the rights and welfare of research participants. Review by Quorum Review does not mean that the study is without risks. If you have questions about your rights as a research participant, if you are not able to resolve your concerns with the study doctor or study staff, if you have a complaint, or if you have general questions about what it means to be in a research study, you can call Quorum Review or visit the Quorum Review website at www.quorumreview.com.

> Quorum Review is located in Seattle, Washington.
> Office hours are 8:00 AM to 5:00 PM Pacific Time, Monday through Friday.
> Ask to speak with a Research Participant Liaison at 888-776-9115 (toll free).

HOW WILL MY INFORMATION BE USED AND SHARED FOR THIS STUDY?

This section explains who will use and share your health information if you agree to be in this study. You must authorize this use and sharing of your information by signing this form or you cannot be in the study.

The study doctor and study staff will collect, use, and share health information about you, including any information needed to do the study and other identifying information about you, such as your name, address, and phone number. The information used and shared will include:

- information from your medical records

- information collected about you during the research of JUVÉDERM VOLUMA™ XC dermal fillers in facial temporal regions
- Photographs

Your information may be used and shared with these people for the following purposes:

- The study doctor and study staff to conduct this research.
- The sponsor, Baumann Cosmetic & Research Institute, and people who work with or for the sponsor; and other researchers involved in this study. These people will use your information to review the study, to check the safety and results of the study, and to seek government approval of JUVÉDERM VOLUMA™ XC dermal fillers in facial temporal regions
- Others required by law to review the quality and safety of research, including the FDA, Department of Health and Human Services, Office for Human Research Protections, other government agencies in the United States and other countries, and Quorum Review

After your information is shared with the people and companies listed above, the law may not require them to protect the privacy of your information. To maintain the integrity of this research, you might not have access to any health information developed as part of this study until it is completed. At that point, you generally would have access to your health information.

You can cancel your authorization to use and share your information at any time by writing a letter to the study doctor. If you cancel your authorization, you will not be able to continue in the study.

If you cancel your authorization, the study doctor and study staff will still be able to use and share your information that they have already collected.

This authorization to use and share your information expires in 50 years.

CONSENT

I have read this form, and I have been able to ask questions about this study. The study doctor or study staff has talked with me about this study. They have answered all my questions. I voluntarily agree to be in this study. I agree to allow the collection, use, and sharing of my information as described above.

By signing this form, I do not give up any of my legal rights. I will get a signed copy of this consent form.

Optional Use of Study Photos for Marketing Purposes (check one):

☐ **Yes**, I agree that my study photos can be used for marketing purposes.

☐ **No.** I do not agree that my study photos can be used for marketing purposes. I can still be in the study.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

I attest that the individual providing consent had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participation in this study.

_____
Printed Name of Person Explaining Consent

_____ _____
Signature of Person Explaining Consent Date

I attest that I or my representative discussed this study with the individual providing consent.

_____
Signature of Principal Investigator or Sub-Investigator