Informed Consent Form
NATRELLE® Breast Implant Follow-Up Study (BIFS), 410-Arm

Sponsor / Study Title:	**Allergan – US / "Breast Implant Follow-up Study: A Long-term Observational Study of the Safety of Allergan Silicone Gel-filled Breast Implants as Compared Both to Saline-filled Breast Implants and to National Norms"**
Protocol Number:	**BIFS-001**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

Subject Identification Number: _____

1. Introduction

You are a current subject or have been newly invited to participate in this research study, sponsored by Allergan Sales, LLC (also referred to as "the Sponsor"), for subjects with FDA approved NATRELLE® Style 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants (also referred to as NATRELLE® Style 410 implants). NATRELLE® Style 410 implants are an example of a textured breast implant with the BIOCELL surface texture. On July 24, 2019, Allergan voluntarily recalled all BIOCELL implants and tissue expanders, including NATRELLE® Style 410 implants. Allergan has already contacted physicians and engaged in a public outreach campaign about this product safety alert so you may already be aware of the recall. To obtain comprehensive information about the recall, please visit www.BIOCELLinformation.com.

For new subjects, this consent form describes the study and your role in it. For current subjects, this consent form describes the changes to the BIFS study which are being implemented in 2021. The changes to this study include a decrease in the number of in person clinic visits needed from you, an increase in new subjects in the study, and an increase in the payment you will receive. These changes are described in more detail below.

Your physician has reviewed this study and has agreed to participate as an study doctor. This study is managed on behalf of the Sponsor by a Contract Research Organization (CRO) called Syneos Health. The study doctor or the BIFS Participant Support Call Center will answer any questions you have about this study or this consent form. Please read this form carefully. You have the right to ask any questions you have regarding the information we describe.

2. Purpose of Study

The purpose of this study is to compare Allergan silicone gel-filled breast implants with saline implants or national norms related to:

1) Long-term safety
    - Connective Tissue Diseases (CTD)
    - Rheumatologic and neurologic signs and symptoms
    - Cancer (lung and breast)
    - Suicide or attempted suicide
    - Local complications and the need for reoperations concerning your breast implants
2) Reproduction, pregnancy outcomes, and lactation
    - Pregnancy outcomes
    - Problems related to lactation in subjects who attempt to breastfeed
    - Targeted AEs occurring in offspring
3) Effects on mammography
    - Detection of breast cancer
    - Rate of rupture
4) Subject reported outcomes
    - Satisfaction with breasts

- Psychosocial well-being

5) Silicone subject compliance with MRI recommendations
   - Rupture rate associated with MRI

Approximately 530 subjects with NATRELLE® Style 410 Breast Implants will be enrolled in this study. This includes about 470 subjects enrolled prior to their breast implant surgery (current subjects). An additional 60 subjects will be enrolled after their surgery occurred (New subjects).

3. Duration of Participation

Each subject will be followed for 10 years after receiving their breast implant(s). For example, if your implant surgery date was in February of 2015, you will be followed until February 2025.

4. In order to participate:

New and current subjects must meet all of the following inclusion criteria at the time of their breast implant surgery:

1) Female, age 18 years or older (age 22 or older for breast augmentation patients)
2) Exhibit fluency and literacy in English or Spanish
3) Give your informed consent

New subjects to this study must meet this additional inclusion criteria:

1) Received one or two Style 410 implants between 2015 and 2019.

To participate in this Study, you must also:

- Complete the Baseline Questionnaire described below
- Be willing to complete the questionnaires once a year for the ten years after receiving your breast implant(s)
- Give consent to participate by doing one of the following: 1) sign this consent form and authorization, or 2) provide electronic consent through the secure BIFS website on the Internet (www.bifs.us)

5. You may not participate if:

1) You are transgender
2) The study doctor decides that you are not a suitable candidate for a long-term observational study.

In addition to the reasons listed above, the study doctor will discuss with you other reasons why you may not be eligible to participate in this study.

6. Study Procedures

Current Study Subjects:
You will be asked to complete three different types of questionnaires while in this study. Since you are continuing in this study, you may have already completed several of the questionnaires and will not be asked to do them again. When you will be asked to complete the questionnaires and details on the questionnaires can be found in the table below:

Questionnaire Name	When will I complete it?	What are the Details?
Baseline Questionnaire	Once Before your breast implant surgery	• Questions will ask about your past, current, and ongoing health status, as well as your current contact information. • Complete on a website, telephone, or paper • Takes less than 30 minutes to complete • Must answer all the questions
Annual Questionnaire	Once a year for 10 years after your breast implant surgery	• You will be contacted once a year to collect ongoing information about your health and the status of your implant(s). • Questions will be similar to those from the Baseline Questionnaire • Takes about 30 minutes to complete • Must answer all the questions

Breast Questionnaire	Three times at 1, 4, and 10 years after your breast implant surgery	• Questions will ask about your opinions on your breast implant(s). • Complete on a website, telephone, or paper • Takes less than 30 minutes to complete • Must answer all the questions

You will no longer be required to see your study doctor for a scheduled clinic visit at years 4 and 10 following your breast implant surgery for the purposes of this study. If you have already seen your study doctor for the scheduled visit at year 4 – thank you! You may contact your study doctor at any time for follow-up at your own discretion. You are encouraged to see your study doctor if you experience any complication related to your breast implant(s).

New Study Subjects:

You will be asked to complete three different types of questionnaires while in this study. When you will be asked to complete the questionnaires and details on the questionnaires can be found in the table below:

Questionnaire Name	**When will I complete it?**	**What are the Details?**
Baseline Questionnaire	Once When you enroll in this study	• Questions will ask about your past, current, and ongoing health status, as well as your current contact information. • Complete on a website, telephone, or paper • Takes less than 30 minutes to complete • Must answer all the questions
Annual Questionnaire	Once a year for 10 years after your breast implant surgery	• You will be contacted once a year to collect ongoing information about your health and the status of your implant(s). • Questions will be similar to those from the Baseline Questionnaire • Takes about 30 minutes to complete • Must answer all the questions
Breast Questionnaire	Up to three times at 1, 4, and 10 years after your	• If you enroll in this study after the 1 or 4 year time point after your surgery you

	breast implant surgery depending on when you enroll in the study	will not be required to complete the questionnaire for that year • Questions will ask about your opinions on your breast implant(s). • Complete on a website, telephone, or paper • Takes less than 30 minutes to complete • Must answer all the questions

Since you are being enrolled into the study after your surgery, your study doctor may be associated with Syneos Health rather than a clinic practice. Your implanting surgeon will be contacted to obtain information on your implant surgery.

You may contact your study doctor or your Surgeon at any time for follow-up at the clinic at your own discretion. You are encouraged to see your study doctor or your Surgeon if you experience a complication related to your breast implant(s).

<u>All Subjects</u>
As part of this post approval study, you will be contacted annually by the Sponsor (or designee) during the 10-year period following your breast implantation so that ongoing information regarding your health and the status of your implant(s) can be collected. The information you will be asked to provide will be similar to information collected on the Baseline and Annual Questionnaires.

By signing this consent form, you give the Sponsor (or designee) your permission to contact you via a combination of internet, mail, SMS/text messages, and/or telephone to remind you to provide these annual updates. If you chose to receive SMS/text messages, text and data charges may apply and will not be reimbursed by the Sponsor or designee. Additionally, you may choose at any time throughout the study to opt out of receiving any or all contact methods explained, including SMS/text messages.

If you are enrolled at a study site and move to a new location, you will notify the Sponsor so that arrangements can be made to transfer to a physician in your new area.

If any of your contact information changes, you will update the BIFS Participant Support Call Center. If the Sponsor (or designee) is unable to locate you for a scheduled follow-up questionnaire, you give the Sponsor (or designee) your permission to contact the individuals whose names and contact information you provided on your Baseline Questionnaire for this purpose. The Sponsor (or designee) may commission a reputable locator firm to obtain your contact information.

At any time throughout the 10-year study period, you can report any complications or other items being tracked in this study by contacting the BIFS Participant Support Call Center (866-619-2437) or by logging into the secure BIFS website on the Internet (www.bifs.us). The study doctor will also report any complications related to your breast implant surgery noted on any physical exams that may be conducted as part of an unscheduled study visit.

7. Subject Responsibilities

As a subject, you are responsible for following the study directions and those of your study doctor (or designee). This includes completing and submitting your annual questionnaires, reporting any changes regarding your health and the status of your implant(s), and reporting any changes in how you feel to your study doctor or the BIFS Participant Support Call Center.

If you experience any illness or discomfort during the study, you should notify your Investigator or the BIFS Participant Support Call Center. Your study doctor or designee will then evaluate you to determine if you should continue the study. If you become pregnant during this study, you must immediately notify your investigator or the BIFS Participant Support Call Center.

8. Prohibited Treatments

Surgery to remove one or both of the original NATRELLE® Style 410 Breast Implants and replace it/them with different types of implants will result in you being withdrawn from the study.

9. Reasonably Foreseeable Risks or Discomfort to the subject

This study does not involve experimental drugs, devices, or procedures and there is no risk to participate. Although no physical risk is apparent, there may be a risk as a result of breach in privacy and confidentiality.

10. Medical Benefits

You may not receive any direct medical benefit from participating in this study; however, the Study will provide valuable information regarding the long-term effects of breast implants. As a participant in this study you will have access to various website resources and medical information relevant to your breast implant(s).

11. Alternative Treatments

The purpose of this study is to evaluate the long-term performance and safety of Allergan silicone gel-filled breast implants in study volunteers. Therefore, there are no alternative treatments and your option is to not participate in the study.

12. Confidentiality

A report of the results of this study may be published or sent to the appropriate health authorities in any country in which NATRELLE® 410 Breast Implants may be marketed, but your name will not be disclosed in these documents. The sponsor's monitors, the auditor(s), the Institutional Review Board (IRB)/Independent Ethics Committee (IEC), the regulatory authority(ies) including the United States Food and Drug Administration (FDA) will be granted access to your medical records, as permitted by the applicable laws and regulations, for verification of clinical study procedures and/or clinical study data. Appropriate care will be taken to maintain confidentiality of your medical records and personal health information.

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.

13. Costs

There will be no charge to you for your participation in this study. However, there may be a cost for follow-up care with your surgeon. Your responses to the annual questionnaire may show a need for you to receive more follow up care. All costs for other medical care are contracted between you and your health care provider. In the event that you suffer a research-related injury, your medical expenses will be your responsibility or that of your third-party payer.

14. Compensation

For completing the enrollment process or reconsenting to the study, you will receive $100. For new subjects, you will also receive $275 for answering the baseline questionnaire. You will then receive $275 every year for each completed annual questionnaire. The study site is receiving payment for the conduct of the clinical study.

15. Whom to Contact About This Study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00044865.

If you have any questions concerning this study, you may contact the Sponsor listed below:

Allergan Sales, LLC
Clinical Research Department
2525 Dupont Drive
Irvine, CA 92612

Phone: (866) 619 BIFS (2437)

REGULAR DOCTOR OR SPECIALIST NOTIFICATION OPTION

Please indicate below whether you want your study doctor or the BIFS Participant Support Call Center to notify your regular doctor or specialist of your participation in this study.

☐ Yes, I want my regular doctor/specialist to be informed of my participation in this study:

_____ _____

Name of Doctor Phone

☐ No, I do not want my regular doctor/specialist to be informed of my participation in this study.
☐ I do not have a regular doctor/specialist.
☐ The study doctor is my regular doctor/specialist.

16. Participation

Your participation in this study is entirely voluntary. You may refuse to participate or may withdraw from this study at any time without penalty or loss of any rights or benefits to which you are otherwise entitled.

You may withdraw or take away your permission to use and share your personal health information at any time. You can do this by sending a letter to the study doctor. If you withdraw or take away your permission, you will no longer be able to participate in the study and no new personal health information about you will be gathered. The information that was gathered prior to your withdrawal may still be used and given to others for the purposes described in this consent.

The study doctor or Allergan may also stop your participation in the study at any time. Allergan may stop this study at any time for reasons it determines are appropriate. If you decide to withdraw from the study, you should contact your study doctor immediately.

17. New Information

The study doctor or the BIFS Participant Support Call Center will inform you (or if applicable, your legally authorized representative) of any new information about the study that might develop during the course of this research and might influence your willingness to participate in the study.

If you have breast implants you have a very small, but increased risk of developing breast implant associated anaplastic large cell lymphoma, or BIA-ALCL. BIA-ALCL is not breast cancer—it is a rare type of non-Hodgkin's lymphoma (cancer of the immune system). In most cases, BIA-ALCL is found in the scar tissue and fluid near the implant, but in some cases, it can spread throughout the body. In the cases that have been spread beyond the scar tissue and fluid near the implant, rare cases of death have been reported.

Most patients were diagnosed with BIA-ALCL when they sought medical treatment for implant-related symptoms such as swelling, pain, lumps, or asymmetry that developed after their initial surgical sites were fully healed. In the cases known to FDA to date, BIA-ALCL was diagnosed years after the breast implant was placed. The earliest report was one year after implant placement and the latest was 23 years after the implant surgery. About half the cases occurred within the first 7 years after implant. BIA-ALCL was most often diagnosed in women who had textured implants. The textured implant may have been placed at the most recent surgery or at any other prior breast implant operation.

If you develop swelling or pain around your breast implants, be sure to talk to your health care provider. Your health care provider should consider the possibility of BIA-ALCL if, after you have recovered from your breast implant operation, you later notice changes in the way your breast looks or feels—including swelling or pain around the implant. If your health care provider suspects BIA-ALCL, they will refer you to an appropriate specialist for evaluation which may involve obtaining fluid and some tissue samples from around your breast implant. If a diagnosis of

BIA-ALCL is confirmed, the doctor will develop an individualized treatment plan for you. Because of the small number of cases worldwide and the variety of available treatment options, there is no single defined treatment. However, if you are diagnosed with BIA-ALCL, the National Comprehensive Cancer Network (NCCN) recommends removing the implant and the surrounding tissue.
If you have breast implants you should monitor them and follow your routine medical care. You do not need to take any additional steps. It is not necessary to remove your breast implants if you have no symptoms without a diagnosis of BIA-ALCL.

If you are diagnosed with BIA-ALCL, you can help the FDA understand the disease and effectiveness of treatment. You or your study doctor should report all confirmed cases of BIA-ALCL to the FDA (https://www.fda.gov/Safety/MedWatch/). In some cases, the FDA may contact you for additional information. The FDA will keep the identities of the reporter and the subject confidential.

In addition, if you are diagnosed with BIA-ALCL, talk to you study doctor about reporting it to the PROFILE Registry (https://www.thepsf.org/research/clinical-impact/profile.htm). Every case of BIA-ALCL should be reported to the PROFILE Registry because this helps provide a better understanding of the disease.

If you are considering breast implant surgery, you should discuss the risks and benefits with your health care provider. You may also visit the FDA's Breast Implants website for additional information:
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm064106.htm

For additional information on FDA's analysis and review of BIA-ALCL, please visit:
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm
Do not sign this consent form unless you have had a chance to ask questions and have received answers to all of your questions. If you agree to participate in the study, please sign this document and you will receive a copy to take home with you.

Your signature indicates:

- that you have read and understood the above information

- that you have discussed this study with the person obtaining consent
- that you have had the opportunity to ask any questions you may have
- that all of your questions have been answered to your satisfaction
- that you have decided to take part voluntarily (of your free will) based on the information provided
- that a copy of this form has been given to you.

Your signature also indicates that you authorize the release of your medical records related to this study to the Sponsor, CRO, the IRB/IEC, the FDA, and other regulatory agencies for purposes related to the study or the study drug.

You will be given a signed and dated copy of this consent form for your records prior to participation in the study.

CALIFORNIA ONLY: **You will be required to sign and date the "Bill of Rights for Investigational Subjects" regarding research subjects.**

Authorization (Permission) to Use and Disclose Your Health Information for Research Purposes

A. Purpose of this form

State and federal privacy laws protect the privacy of your health information. Under the law, health information that includes identifiable subject 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 participate in this research study. Your decision not to sign this Authorization will not affect any other treatment, healthcare, enrollment in health plans or eligibility for benefits.

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.

B. What health information will be obtained, used or disclosed?

Health information related to this study may be used 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. For example, it may include but not be limited to your name, mailing/email address, phone number, birthdate, medical record number and social security number. Health information collected in connection with this research study may also be found in the following:

- Medical History
- Physical exam
- Surgical and treatment information
- Mammograms
- MRIs

Allergan recognizes the importance of your privacy and the confidential nature of the information collected as part of this study. To further protect your privacy, a Certificate of Confidentiality has been obtained from the National Institutes of Health. With this Certificate, the study doctor cannot be forced (for example, by a court subpoena) to disclose information that may identify you in any civil, criminal, administrative, legislative, or other proceedings. Identifiable information may be released to federal agencies, however, by request of FDA or the Department of Health and Human Services for auditing or study evaluation purposes or to meet

federal research requirements. Also, the investigators and Allergan may choose to disclose information about you, if that disclosure is otherwise consistent with privacy laws and the terms of this Authorization.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive such information, the researchers may not use the Certificate to withhold that information.

In the event you cannot be located for your annual questionnaire, the Sponsor may disclose your name, social security number and last known address to a reputable locator firm. The Sponsor will not disclose any of your health information to the locator firm or to your designated contacts.

C. 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 Study doctor
- Allergan and any other affiliates, subsidiaries, agents, contractors and related companies of Allergan, as necessary
- Clinical Contract Research Organization
- Study Doctor Research staff

D. Who may receive or use the information?

The parties listed in Section C above may disclose your health information to the following persons and organizations in connection with this research study:

- Sponsor and/or its representatives, including affiliates, agents and contractors (“Allergan”);
- Sponsor’s Development Partner;
- Contract Research Organization;
- Business associates working with the Sponsor on this research study;
- Advarra Institutional Review Board (IRB) who oversee this research study:

- The Office for Human Research Protections in the US Department of Health and Human Services;
- Federal and regulatory authorities (for example United States Food and Drug Administration-FDA, Health Canada) including those outside of the United States.

E. What is the purpose of this research study and 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 check the safety and results of the research study.

Regulatory authorities and the IRB 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.

Your information may also be transferred to other countries which may have different privacy laws.

F. 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 participate 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.

G. 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 (for example information necessary to maintain the integrity or reliability of the research). Any revocation will not be effective to the extent that we have already taken an action in reliance on your authorization. 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 listed on the first page of this form.

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. All information that has already been collected for research study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

Your information may be subject to re-disclosure by the recipients described above. If those recipients are not required by law to protect the privacy of the information, it would thus no longer be protected by this authorization or by law.

H. When will my authorization expire?

This Authorization does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely.

Your authorization for the use and/or disclosure of your health information will end on (insert date for sites in IN, WI and WA) unless you withdraw it in writing before then.

I. 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 (for example, 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

Allergan is required by law to protect your health information. By signing this document, you authorize Allergan 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 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 have received a copy of this form.

By signing below, I acknowledge that:

- I have read all sections of this Informed Consent Form
- I have had my questions answered
- I voluntarily consent to participate in this research study

Printed Name of Participant	
Signature of Participant	Date (dd-MMM-yyyy)

Printed Name of Legally Authorized Representative	
Signature of Legally Authorized Representative	***Date (dd-MMM-yyyy)***

Description of Representative's Authority to Act for Participant

Printed Name of Person Obtaining Authorization	
Signature of Person Obtaining Authorization	***Date (dd-MMM-yyyy)***